APP. J

Department of Toxic Substances Control

Deborah O. Raphael, Director
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Matthew Rodriquez
Secretary for
Environmental Protection

Edmund G. Brown Jr.
Governor

February 15, 2013

Dear All,

As a measure of its commitment to good government and to transparency, the California Department of Toxic Substances Control has launched a comprehensive review of its permit process.

During the past two years, stakeholder feedback and our own internal observations have demonstrated that there is room for improvement in the process of permitting hazardous waste treatment, storage and disposal facilities. Twenty-two businesses are working with outdated permits for various reasons, critics have complained the department does not have clear guidelines for when to deny a permit and businesses complain standards are unevenly applied.

To continue providing a high level of protection, DTSC must review its hazardous waste management guidance and practices as they relate to our permitting program. As a result, we have contracted with California Personnel Services (CPS) to perform an outside review of our permit process. CPS is a self-supporting state agency, created in 1985 to improve the performance of government and non-profit agencies, as well as private companies. Bill Magavern, Senior Policy Advocate for the Coalition for Clean Air, and Tom McHenry, a member of Gibson, Dunn & Crutcher's Environmental Litigation and Mass Tort Practice Group, are serving as advisors to CPS.

A well-crafted and up to date permit provides a level playing field for California businesses and ensures those businesses are using the best available technologies to provide the maximum protection to surrounding communities. The purpose of the review is to provide recommendations for process improvements including standardized processes, clear decision-making criteria and corresponding performance standards. We are committed to following up with the report's findings and making the necessary changes.

Members of the CPS team will work directly with government, community, and industry stakeholders to identify areas for review and recommendations for process improvement. CPS will contact stakeholders, including many members of our External Advisory Group, and conduct feedback sessions in the near future. Recommendations and findings will be made public on the DTSC web site and are expected to be complete by June 30, 2013.

As Director of DTSC, I will value input that the review team collects from our stakeholders, and I am committed to using the team's recommendations and findings to improve the department.

Sincerely,
Deborah O. Raphael
Director, Department of Toxic Substances Control

APP. K

CPS HR CONSULTING

October 2, 2013

Department of Toxic Substances Control

Permitting Process Review and Analysis

Final Report

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About CPS HR Consulting:

CPS HR Consulting is a Sacramento-based non-profit corporation, established as a California joint powers authority in 1985. Headquartered in Sacramento, CPS HR also has offices in Maryland and Texas. It is governed by a Board of Directors representing government agencies throughout the United States. With over 280 team members, CPS serves more than 1,200 public and nonprofit clients throughout the United States and Canada.

CPS helps its clients across a range of issues including classification and pay, organizational reviews, program review, workforce and succession planning, testing, EEO and related investigations, and policy development.

Contents

Executive Summary

The Department of Toxic Substances Control (DTSC) entered into a contract with CPS HR Consulting (CPS HR) on Feb. 1, 2013[1], to conduct a Permitting Process Review and Analysis. The objective was to answer the following questions:

- What is the process of making decisions?
- What factors must go into making a permit determination[2]?
- What must be measured?

CPS HR was asked to review the existing permitting program and develop a recommended standardized process with clear decision criteria and corresponding standards of performance. CPS HR was also asked to document the changes in the permitting process over the past five years based primarily on the record obtained from past internal review, and to obtain perspectives of designated subject matter experts[3] including representatives from the environmentalist, environmental justice, and industry communities. This report provides findings in each defined area.

By way of background, the DTSC Office of Permitting is authorized to issue hazardous waste facilities permits, and to impose conditions specifying the types of hazardous waste that may be accepted for transfer, storage, treatment, or disposal in California. Currently there are 117 permitted Operating Facilities, including 28 Post Closure Facilities (closed and going through final remediation) in the State, that provide for the treatment, storage, or disposal of substances regulated as hazardous waste under federal and state law. A total of 1.82 billion pounds of California toxic waste were disposed of in these facilities in 2012, with 62% treated to the point where it no longer met toxic standards, and 38% placed in landfills. (Table 28, page 100) From a staffing standpoint, currently there are 29 authorized positions allocated to the Office of Permitting, located in Sacramento, Berkeley, and Chatsworth.

There has been significant dissatisfaction with the performance of the Permitting Office, directed at the cost and length of time in completing the permit process and a perception that the Office does not deny or revoke permits as often as it should to address community concerns. The stakeholder interviews conducted as part of this study identified the following major concerns:

1. The need to create clear and objective criteria for making denial/revocation decisions that are based on valid standards of performance and risk;
2. A clear standard for violations that would lead to a denial or revocation;
3. The need for the Department to document and measure a "scorecard" of attributes that would be perceived as a "good result" for the permitting program;

[1] As a Joint Powers Agency originally established by the state, CPS is exempt from competitive bidding requirements under Government Code Sections 6500 and 6502, and as noted in the State Contracting Manual at Section 3.13. All its contracts are subject to review and approval by the Department of General Services.
[2] Based primarily on the directed review of statutory and regulatory mandates, along with the perspectives of subject matter experts, and inputs gathered in Task 5.
[3] See Appendix A for a list of participating subject matter experts.

4. The need to identify and measure appropriate permitting process timelines, and;
5. The need to document, maintain and implement effective financial assurance standards to ensure that facilities can meet their permitted obligations.

The objective of this study was to provide a review of the DTSC Permit Process to develop a standardized process with clear decision criteria and corresponding standards of performance. Its primary conclusions and recommendations follow.

Permitting Actions Not Timely:

The study found that permitting decisions are not made on timely basis, and that lengthy and potentially preventable delays occur due to a lack of standard process and a failure to include all processing requirements in a predictable, standard order that is identified and shared with relevant permitting staff. A lack of sufficient staffing in the unit (Table 29, page 103) also contributes to lengthy processing times, and if current staffing levels are maintained the average processing time can be expected to increase, rather than improve, with an increased number of anticipated permits in the coming years. Currently, permit renewals average 4.3 years from start to finish, with permits issued under Federal Resource Conservation and Recovery Act (RCRA) authority taking 5.0 years and those issued under California Standard permit authority averaging 3.1 years.

This study made contact with three state Hazardous Waste Disposal Offices recommended by the Federal EPA as having "good permitting programs," and learned that two of the three considered a permit renewal period of as little as 180 days to be a typical practice, with up to two years as an infrequent occurrence (see pages 95-96). In addition, the analysis conducted in this study suggests that an average processing time of from 1.5 to 2.2 years should be achievable, and should be a short-term goal of the -California permitting program (see Chapter 8, Pages 96). This is obviously a much shorter period than is now common in California, which currently has an average of 4.3 years per permit.

The study found that the overall average permitting process time, which was 5.0 years prior to FY2003, improved to a 3.2 year average for the period from FY2003 to FY2007, before again increasing to 4.3 years in the most recent time period (from FY2008 through part of FY2013). So while there was an improvement from the oldest period studied to the most recent, the current trend is again towards longer processing time.

Staffing Increase is Necessary:

The recent increase in permit processing time is attributed to at least two major factors. First is a reduction in staffing in the office. Permitting staffing has been reduced significantly from 95.8 personnel years utilized in FY 2007 to just 24.6 personnel years utilized in FY 2009. The initial change was a response to the economic recession in 2009, and its required state budget reductions. However, less than 26.1 personnel years have been utilized in each year since that time (See Table 1, page 26). This study concludes that Department should immediately seek authorization through the budget process to increase its staffing to a total 35 positions (a 20% increase in its current staffing authorization), and should seek to hire and train those positions as quickly as possible. (Chapter 10).

The most positive result identified regarding the Office of Permitting is a steady, long-term increase in the number of operating facilities with "current" permits. This has increased from just 45% in 2007, to 68% in 2009, and to 75% in 2013. However, given increasing permit renewals in future years (Table 33, page 108), it is likely that this steady progress will stop and reverse in the near future with the existing level of staffing. Increased hiring is necessary to avoid an increase in average permit processing time, and to avoid an increase in the number of toxic waste facilities operating without a permit.

Poor Management Practices:

The second primary reason for permitting delays is poor management practices. Between December 2009 and June 2013, the Permitting Program Office did not maintain consistent uniform management, supervisory structure or clear consistent organizational structure. This is demonstrated by the fact that program managers were either re-assigned to other duties or vacant for a majority of the time period from July 2009 through July 2013, while program supervisor positions for all personnel in the unit were either not authorized or vacant for more than half of this period. In other words, there was a four-year period in which direct supervision of personnel lapsed.

The failures to use a standard permit process (detailed in Chapter 5, and explained further below) likely occurred or became worse during that period. Incrementally since that time, the Department has restored a one-to-one relationship between each permitting employee and a supervisor, and as a result, no recommendations regarding restoration of management and supervision were considered necessary. However, this study has concluded that the use of telecommuting in many offices is a contributory factor to less-than-optimal program efficiency and effectiveness. (See Chapter 4, page 32).

It is recommended that DTSC continues to strengthen its organizational structure for permitting staff through a focus on in-person meetings, in-office work, and updated training. Telecommuting should be severely limited or revoked for at least a six-month period while these necessary improvements are put in place. It is recommended that all permit staff duty statements be brought up-to-date along with goals and performance appraisals during this period[4]. Necessary updates to standard templates, work aids, and work processes should be achieved. Work units should also use this time to build solid relationships with their supervisors. Maintaining traditional in-office work groups, with a supervisor at each location is the best method of improving communication and assisting with re-establishment of efficient processes and work production.

Clear Standard Process:

This study concludes that while many aspects of the work process required for a permit renewal are well defined and well known, most of the difficult or complex steps are not clear or well defined. (Chapter 5, pages 33-35). This is one of the most likely reasons for prolonged delays, and for future process improvement.

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[4] An annual update of Duty Statements and current performance standards are a requirement of CalHR, that had also lapsed within the Office of Permitting.

Specific process steps that need to be defined and supported are:

- When and how the CEQA process starts;
- When and how the Disclosure process start;
- When and how the Public Participation staff gets involved in the renewal process;
- Any standard process steps for review of the Part B Application and the associated Technical Review.

Much of the "process" knowledge within the Office of Permitting is in the individual professional knowledge of the DTSC staff which is interpretive and not documented. More importantly, a re-review of the Permit Renewal Team effort of 2007-2009 has not found any structural changes or permanent process changes that have been implemented that could cause significantly improved permit renewals in the future. The "lessons learned" from the Renewal team effort appear to have been misconstrued, and the actions taken after the team experience were damaging to management and supervision in the unit, as noted above.

A standard process is provided as a part of this study (pages 36-39) and it is recommended that it be adopted and used by supervisors as a standard for all permit renewal work in the future. In addition, supervisors and subject matter experts should supplement the process flowchart with instructive notes on the criteria for each decision and the sign-off standards for each process step. This new process must respond to the grey areas identified in this report as follows:

- A defined and coordinated initial process review by DTSC CEQA staff and DTSC Community Involvement staff;
- Initial regular and on-going consultation between enforcement and permitting where necessary;
- A mandatory permit renewal meeting with the appropriate DTSC technical team and the permit applicant;
- A site visit between the appropriate DTSC technical team and the permit applicant early in the Technical Review.

This study also found that the largest share of total permitting time is taken in Technical Review, and that portion of the review comprises 2.7 years by itself -- 63% of the total processing time. This is the greatest potential area for processing time improvement. At the same time, it was learned that no formal process flow or clear instructional materials exist with regard to how to conduct that portion of the review. It is therefore recommended that the Permitting Office develop instructional materials to support the Technical Review process flow. This should include clear and written decision-making criteria associated with each Section, and processing check sheets to match the process steps on the Part B flowchart. In addition, it is recommended that DTSC enter into a cooperative agreement with US EPA to: 1) Access its technical assistance in revision and design of permit processing procedures; 2) Provide materials and training on Technical Review.

Criteria for Denial and Revocation:

As noted already, the stakeholder interviews conducted as a part of this study learned that a principal stakeholder complaint is that there are no clear and objective criteria for making denial/revocation decisions that are based on valid standards of performance and threats. In fact, department officials admit this is true. (Chapter 6 – Page 58.) Two significant and related factors are that there are no clear and objective standards for violations that would support a decision to deny or revoke a permit; and there is no standard for denial or revocation based on three issued Notices of Deficiency.

As a result, this study recommends the Department develop a new system of categorizing violations that reflects whether they present an immediate and direct threat to human health and safety, versus a less urgent threat that can be mitigated or resolved through further actions of the Department. The Department's current definition of "Class 1 violations", although mandated by law, includes both violations that pose immediate and direct threats along with many that are relatively low- or long-term threats. Until the Department has a system of violations that can distinguish between significant threats to human health and safety and lesser threats, it will not be able to provide an objective standard to guide its own staff actions and to inform the public that the significant threats have been mitigated through actions such as permit modification, denial or revocation.

In support of this kind of policy development, this study developed the following factors that might be used to support a decision to continue with permitting, versus those that might be used to support a denial or revocation action:

The following factors argue in favor of continued permitting:

- All aspects of its current operation are in compliance with law;
- Permittee has demonstrated open and prompt communication with DTSC and truthfulness about the operation and its impacts;
- The permittee or the Department on its behalf have communicated promptly and openly with the community around the facility regarding the pending permitting process;
- Any threat to human health or safety, or the environment, (identified through Corrective Action or outstanding violations) is properly identified and mitigated as required by law and regulation;
- There is financial capacity and commitment to complete a closure, or any required remediation, as well as all post-closure costs and adequate financial assurance has been provided.

The following factors argue against continued permitting:

- The existence of any "High Threat" violation which is not resolved in a timely manner;
- DTSC has issued three Notices of Deficiency, and the responses from the facility have been substantially incomplete, substantially unsatisfactory, or deficient;
- The continued operation of the facility poses a significant threat to human health or safety, or the environment, (identified through Corrective Action or outstanding violations) and the facility is not taking active steps to reduce that threat;
- Continuing or consistent delay in a scheduled response which is substantially unsatisfactory, or deficient, and that such unsatisfactory response was willful, or intentional;
- There is inadequate financial capacity and commitment to complete a closure, or any required remediation, and pay all post-closure costs.

It is recognized that such standards will need to be further defined and adopted through administrative law to become effective, and these are offered to the Department as a starting point for such actions.

Permitting Must have Valid Performance Benchmarks:

A series of operational, output, and outcome measures were developed to provide the basis of program performance management. These measures are provided in Chapter 9, pages 97-101. A field audit of a random sample of permit renewal files found that while 85% of these data fields have been entered in EnviroStor, 15% were missing. Additionally, only 43% of the identified critical data fields could be verified against actual records in the available Administrative Record with almost one third of those records containing discrepancies in the reported dates that averaged 45 days duration. While it was concluded that the EnviroStor record was adequate for macro-analysis of program timeliness, it was noted that improvements must be made.

This study recommends that the Department undertake significant improvement in data entry and validation. It recommends supervisory confirmation of all milestone dates input into EnviroStor as a double-check to the current practice of independent project manager entry. This practice will also confirm supervisors are aware of the completion of key permit process milestones, and ensure their intervention when prompt processing is delayed.

1) Objectives and Methodology

Project Objectives

The Department of Toxic Substances Control (DTSC) entered into a contract with CPS HR Consulting (CPS HR) on Feb. 1, 2013[5], to conduct a Permitting Process Review and Analysis. The objective was to answer the following questions:

- What is the process of making decisions?
- What factors must go into making a permit determination[6]?
- What must be measured?

CPS HR was asked to review the existing permitting program and develop a recommended standardized process with clear decision criteria and corresponding standards of performance. CPS HR was also asked to document the changes in the permitting process over the past five years based primarily on the record obtained from 2007 and 2009 internal reviews, and to obtain perspectives of designated subject matter experts[7] including representatives from the environmentalist, environmental justice, and industry communities. CPS HR reviewed and assessed the current timeliness of decisions, and evaluated the adequacy of permit program staffing. CPS HR was asked to assess whether there are any "grey areas" in the permit process, whether there are sufficient staff resources, and whether current resources are being used efficiently. CPS HR was also asked to use the information and analysis obtained to make recommendations for process improvement.

During the course of this study and analysis additional questions were posed, and even though not specifically included in the scope of contract work, every effort was made to provide responses based on information obtained[8]. These included the following:

- Are permits ever denied?
- At what point should a permit be denied?
- What should be the criteria for denying or revoking a permit?
- Is there denial after three notices of deficiency?
- Is the time, cost, and complexity of the process reasonable?
- What should the permitting program accomplish?
- How well is the permitting program meeting those expectations?
- What is working or is not working with the permitting process?

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[5] As a Joint Powers Agency originally established by the state, CPS is exempt from competitive bidding requirements under Government Code Sections 6500 and 6502, and as noted in the State Contracting Manual at Section 3.13. All its contracts are subject to review and approval by the Department of General Services.

[6] Based primarily on the directed review of statutory and regulatory mandates, along with the perspectives of subject matter experts, and inputs gathered in Task 5.

[7] See Appendix A for a list of participating subject matter experts.

[8] Additional questions were raised by Project Advisors and identified stakeholders, both before and during the stakeholder discussions.

- How should the permitting and enforcement programs inter-relate?
- Is financial assurance being adequately addressed?

The scope of work tasked the consultants to work with DTSC management and external advisors to identify a diverse group of stakeholders and members of the public who could provide valuable perspective and recommendations on program performance, to attend the meetings and to obtain a record of comments provided. In order to obtain a high level of independence and objectivity, the contract was amended on April 14 to ask CPS HR to identify and organize the stakeholder meetings, to conduct these meetings and to provide the summary of all results. As noted below, this was done primarily through one-on-one interviews and a supplemental survey.

Project Methodology

The study was commissioned by the DTSC Department Director to provide an objective and independent analysis of the Permitting Process, following the framework of the Government Auditing Standards, 2011 Revision, and the Performance Audit criterion[9]. The Government Auditing Standards "provide a framework for performing high-quality audit work with competence, integrity, objectivity, and independence to provide accountability and to help improve government operations and services[10]."

Two methods were used to ensure the independence of this study. First, CPS as a joint powers agency, is "at a level of government other than the one of which the audited entity is part[11]," and therefore meets one of the primary specified standards for "external review." In addition, the DTSC Director recused herself and members of her staff as primary contract representatives, and asked two members of the Department Advisory Committee to serve as Project Advisors comprised of Thomas McHenry (Gibson Dunn) and Bill Magavern (Coalition for Clean Air).These project advisors met by conference call with the consultant team roughly every two weeks throughout the conduct of the project[12]. The Project Advisors provided suggestions and guidance on: outreach to various stakeholders, current DTSC practices, policy and legal concerns and overall reporting. Jim Marxen, the DTSC Deputy Director of Communications served as the DTSC liaison to Departmental staff and as the primary contract representative. However, Mr. Marxen recused himself from any decisions regarding the project review work and from the approval of any project deliverables.

The General Standards of the Government Auditing Standards documents requirements for independence of review, including "Independence of Mind" and "Independence in Appearance."[13] Part 3.07(a) required auditors to apply the conceptual framework to identify threats to independence

[9] Government Auditing Standards, 2011 Revision, US Government Accountability Office, Comptroller General of the United States, part 2.10.
[10] Ibid, Government Auditing Standards page 5.
[11] Ibid, Government Auditing Standards, part 3.28a.
[12] The resumes/profiles for Mr. McHenry, Mr. Magavern, and CPS HR Project Manager, Mr. Mallory, summarizing their expertise, are included in Appendix A after the list of subject Matter Experts.
[13] Part 3.02 a. and b.

and to "apply safeguards as necessary to eliminate the threats or reduce them to an acceptable level."

In this regard, the CPS HR auditor noted two potential threats to independence. The first is related to the fact that one CPS HR review team member, Denzil Verardo, had served as a Special Assistant to the DTSC Director for performance management implementation, special projects and investigations, from 2006-2011, in Retired Annuitant Status. This potential bias was mitigated in that Verardo's role was as a subject matter advisor to the Project Manager, and he did not develop, nor play a role in developing, any of the final project conclusions nor recommendations. In all, he served for less than 50 hours on the project – less than 6% of all project hours – primarily in an advisory role.

The second threat is based on the fact that CPS HR does perform non-audit services for DTSC, currently including two training projects regarding performance management and 360-degree assessment of the Department management staff. This second threat is mitigated in that the audit project is managed by Richard Mallory, and neither he nor his immediate supervisor, Roger Ganse, is within the CPS HR training group. Neither is subject to any influence or control by the manager and staff providing non-audit services.

That stated, this audit report can make an appropriate assertion of independence of its assessment, and its conclusions.

Since the initial project objectives call for a review of the permit process and its result, key tasks in the work plan were:

1. A review of past DTSC studies and conduct regarding permit processing;
2. The determination of a "primary process flow" for permitting decisions;
3. A field audit of a number of permitting cases;
4. A review of permitting process metrics;
5. Identification of permit tasks and staffing requirements.

All of these efforts, except for the field audit, will be described in subsequent chapters of this report. The field audit is described in the next section of this chapter, however, since its results are fundamental to understanding the accuracy of the EnviroStor[14] data on which much of the subsequent report analysis is based.

A key issue for this report was the legal context of the permitting program. The project plan called for DTSC to provide "relevant statutory and regulatory mandates and procedures." The legal mandate is fundamental in making the determination of whether the program is meeting its requirements. The Department's Office of Legal Affairs provided a foundational White Paper on April 17, entitled "Department of Toxic Substances Control (DTSC) Regulatory Requirements for Permitting." The White Paper is provided in Appendix B.

[14] EnviroStor is the name of the DTSC facility database. It is used as the official operating system of the permitting program, and for release reporting.

One issue raised in the White Paper was whether a permit should be revoked after issuance of three notices of deficiency. The White Paper stated: "If the applicant does not respond adequately to three notices of deficiencies, DTSC is required to initiate proceedings to deny the permit application." However, the White Paper did not define "adequately[15]".

As a result, consultants posed several specific questions to legal and program staff to obtain those fundamental understandings.

The original project work plan called for an initial project meeting and webinar with all permitting staff, primarily to introduce the staff to the work underway, and how it would be conducted as the viewpoint of staff could be very helpful to better understand program results and issues. The "Employee Attitudes" (Chapter 7) were developed based on both the discussion at the meeting with all permitting employees on March 7, along with the results of a structured survey completed by all permitting staff (from April 9th to April 19th).

The additional work regarding the Stakeholder viewpoints is presented in Chapter 6.

This project work was initiated on Feb. 2, 2013, and was completed on Aug. 30, 2013.

[15] This issue is further discussed in Chapter 6, page 59.

Field Audit of Permit Renewals

One of the core analytic reviews conducted by CPS HR was a review of a sample[16] of permit renewals in the DTSC field offices. This was done primarily to validate that the data in EnviroStor was a reliable source for the broader permit program analysis desired for this study. The methodology used was to select a random sample from an alphabetical list of permitted facilities (provided in Appendix C), with the name of the associated field offices supervising each permittee. In this way consultants could go to each of three permitting program unit offices[17], provide the names of the two randomly selected permit renewal files, and pull the Administrative File associated with that renewal. The Administrative File for each of two permit renewals was pulled in each Field Office, and compared to the same EnviroStor record.

The Administrative Record associated with each permit file was almost exclusively a paper file, kept in file rooms maintained by the DTSC Administrative Services, and populated with documents developed by Permitting Office staff. A significant share of the Administrative Record consisted of scanned hard copies, saved as electronic documents within EnviroStor. Almost all of the "hard copy" records reviewed in this audit were paper records, obtained from the Administrative Services file, which were consistently organized in chronological order. In a few cases, records were only found in the scanned format, with no associated paper record.

In five of six field audits, the Administrative files were pulled on-site[18], and were all found to be relatively complete (as noted below), well-organized, neat, and entirely in chronological order. All the file rooms in the unit office locations appeared to be well-run and managed.

In completing the file review, consultants identified nine key data fields that were benchmarks for measuring process timeliness, and that were generally completed by permitting staff[19]. The audit first reviewed the selected EnviroStor record to see if there were dates entered for the nine benchmark fields, and then reviewed the associated Administrative Record to see if documents could

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[16] Since the master list consisted of just 118 records there was no formal selection protocol other than as follows. Files selected were limited to those for which permit renewals were approved, and in the period from 2005-2012. The selections in Cal Center Unit were made from the beginning and middle of alpha order ('A' and 'M'), those from Chatsworth from the middle and end of alpha order ('N' and 'R'), and from Berkeley from the beginning and end of alpha order ('A' and 'S').

[17] Many DTSC employees still refer to the field locations as "Regional Offices," which was their organizational structure prior to a broad department reorganization undertaken in 2008. In fact, there has been no consistent structure or naming for the field office locations since that time, and the term "unit" has been used to be consistent with a new staffing structure adopted by the Department in August, 2013. This structure will provide an on-site supervisor for permitting staff in each field unit.

[18] The two files for the Berkeley Permitting Unit audit were named the night before the associated visit, because of concern that Administrative personnel might not be accessible on the day of the visit. Upon arrival, one of the two Administrative records was provided in a designated work area, and the other was not. The consultant was then able to visit the file room and pulled the file in the same manner as the others.

[19] Consultants conducted a 'beta' audit at Cal-Center Unit, Highway 50 and Watt Avenue, Sacramento, to test and finalize the audit protocol later used in three unit offices.

be found to validate the date entries. A full record of each selected audit is provided in Appendix D. The six renewal actions reviewed included:

- AERC Com, Inc., Hayward, CA
- Aerojet General, Rancho Cordova, CA
- McCormick Selph, Hollister, CA
- Naval Air Station – North Island, Poway, CA
- Rho Chem, Inglewood, CA
- Shell Oil Products – Martinez, Martinez, CA.

One conclusion from the audit is that only 85% of the most critical data fields have been entered in EnviroStor, and 15% are missing. This study did not detect any pattern to the missing data fields – and therefore concluded there was no apparent intent to avoid any specific kind of reporting. However, the analysis found that just 43% of the identified critical data fields could be verified against actual records in the available Administrative Record. In addition, seven of those 23 data fields that could be verified had discrepancies in the reported dates that averaged 45 days duration. Six of the seven discrepancies (excluding the biggest one) averaged just 13 days variance, and it was concluded that the differences reflected imprecise recordation rather than an intent to misrepresent the record. Overall it was concluded is that the EnviroStor record is adequate for macro-analysis of program timeliness. However, it is noted that it is not a complete data record nor is it completely accurate.

> **Recommendation 1-1: The Department must initiate supervisory confirmation of all milestone dates input into EnviroStor as a double-check to the current practice of independent project manager entry, to ensure accurate input that matches the operational record. This practice will also confirm supervisor awareness of the completion of key permit process milestones, and invite their intervention when prompt processing is delayed.**

Other Conclusions:

The close examination of the six permit renewal records as a part of this audit gave greater factual knowledge about the nature of permitting, and possible permit problems. The time for renewal of the audited permits ranged from a minimum of 2 years, 6 months in one instance (Aerojet General, Rancho Cordova), to 13 years, 5 months in another (Rho Chem of Inglewood). Initially, change in staffing was theoretically identified as a principal reason for the length of time for the renewal process. This audit found that was likely not true as the longest renewal was a project managed by the same staff person who works in that office today. Discussion with that responsible staff person and review of the record led to the conclusion that the lengthy time was primarily attributable to a release of toxic substances to groundwater by a previous permittee, and the subsequent successful Department effort to obtain a Court Consent Order for clean-up. That Consent Order was assumed (along with the permit renewal action) by a subsequent owner. Both the court action and the transfer of ownership were prolonged efforts, and the associated "Technical Review" period[20] for this renewal spanned 7 years, 4 months.

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[20] See Chapter 5 of this report, "Standard Process."

Another conclusion only possible through review of the actual Administrative Record (as opposed to the EnviroStor data record) was the lack of consistent process used for permit renewal. This is discussed further in Chapter 5, Standard Process. For example, even though the standard process defined by Permit Program management includes a "Call In Letter" to notify an applicant that a complete permit application is due in 18 months, such a call in letter was found in only one of the six permit records. Discussions with permit staff in the unit offices revealed there was no single department-wide file for standard letter formats, and staff did not have a standardized "call in" letter.

The discussions with unit staff during audit activities, and the examination of Administrative Record files, are cited as additional perspective in other sections of this report, and to supplement the finding provided in Chapter 9, Analysis of Program Metrics.

> **Recommendation 1-2: Develop a network file including templates and samples of best-quality permitting work products.**

2) Background on the Permitting Program

The legal basis of the California Department of Toxic Substances Control, and its Permit Program, is found both in Federal and State law. The primary initiating action was passage of the federal Resource Conservation and Recovery Act (RCRA), enacted in 1976. RCRA is the principal federal law governing the disposal of solid waste and hazardous waste, and standards for the treatment, storage and disposal of hazardous waste in the United States. Interestingly, portions of California's hazardous waste law pre-dated and served as a model for some of RCRA.

The relevant provisions of the RCRA statute are found in Subtitle C, which directs the Environmental Protection Agency (EPA) to establish controls on the management of hazardous wastes from their point of generation through their transportation and treatment, storage and/or disposal. This comprehensive tracking and control is sometimes referred to as life-cycle control, "cradle to grave" regulation. The program imposes stringent recordkeeping and reporting requirements on generators, transporters, and operators of treatment, storage and disposal facilities handling hazardous waste.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as "Superfund," was enacted in 1980 to address the problem of remediating abandoned hazardous waste sites, by imposing retroactive and strict legal liability, as well as by establishing a trust fund (Superfund) to pay for cleanup activities at orphan sites. In general, CERCLA applies to contaminated sites, while RCRA's focus is on managing the ongoing generation and management of particular hazardous waste streams.

The federal RCRA program in California is administered by the DTSC. In 1982, the California Legislature declared that "it is in the best interest of the health and safety of the people of the State of California for the state to obtain and maintain authorization to administer a state hazardous waste program in lieu of the federal program . . .pursuant to the Resource Conservation Recovery Act of 1976." (RCRA, 42 U.S.C. 6926.)[21]

[21] The Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), provides for authorization of State hazardous waste programs under Subtitle C. (42 U.S.C § 6926.) Congress designed RCRA so that the entire Subtitle C program would eventually be administered by the States in lieu of the federal government. Congress did this because States are closer to, and more familiar with, the regulated community and therefore are in a better position to administer the programs and respond to local needs effectively. (Overview of the RCRA Authorization Program, p. 1-1.)

The Legislature further declared that the Department of Toxic Substances Control (DTSC) shall have "those powers necessary to secure and maintain interim and final authorization of the state hazardous waste program" pursuant to RCRA and "to implement such program in lieu of the federal program." (Health & Safety Code, §25101(d).) In adopting standards and regulations, DTSC is required to make standards and regulations conform with corresponding regulations adopted by the US EPA pursuant to RCRA and may adopt standards and regulations that are more stringent or more extensive than federal regulations. (Health & Safety Code, § 25159.5(a).)[22]

In addition to the federal RCRA program, DTSC also administers the state regulatory program for so-called "Non-RCRA" hazardous wastes. The universe of these Non-RCRA hazardous wastes is large and diverse, and extends beyond the Federal RCRA requirements. Hazardous wastes can be liquids, solids, or contained gases. They can be the by-products of manufacturing processes, discarded used materials, or discarded unused commercial products, such as cleaning fluids (solvents) or pesticides. RCRA regulated wastes have one or more of the following characteristics:

1) They are ignitable (at less than 60 degrees Celsius, spontaneously, or under certain conditions);
2) They are corrosive;
3) They are reactive substances (unstable as exhibited by such things as toxic fumes/gases);
4) They are toxic (harmful or fatal when adsorbed or ingested).

In addition to the "characteristic" waste streams, RCRA- also regulates in four categories of "listed" wastes, called the F-list, K-list, P-list, and U-list.

- F-list wastes are called non-specific source wastes and include wastes from many common manufacturing and industrial processes, such as solvents that have been used for cleaning or degreasing.
- K-list wastes are called source-specific wastes and include those from specific industries, such as petroleum refining or pesticide manufacturing, along with designated sludges and wastewaters from treatment and production processes.
- P-list and U-list wastes include discarded commercial chemical products such as industrial chemicals, pesticides, and pharmaceuticals.

California regulates a larger universe of wastes as hazardous. For example, California regulates products with the element mercury such as fluorescent lamps, mercury switches, and the products that house these switches, including mercury-containing novelties. Some "used oil," products are not ignitable, but may contain materials on California's M-list. Other materials regulated in California as toxics include soil generated from a "clean up" and similar materials. These are typically referred to as "Non-RCRA" or "California-only" hazardous wastes.

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[22] On July 23, 1992, California received final authorization from the United States Environmental Protection Agency to implement the RCRA hazardous waste management project, effective August 1, 1992.

After its initial establishment, the California permitting program was re-shaped by the Wright-Polanco-Lambert Hazardous Waste Treatment Permit Reform Act of 1992. That law established a five-tier permitting program to match the statutory and regulatory requirements imposed on each of five categories of hazardous waste facility based on the level of threat posed by them. The five tiers are as follows and the focus of this Report is on the facilities in the top two tiers:

1. Full Permit Tier
2. Standardized Permit Tier
3. Permit by Rule Tier
4. Conditional Authorization Tier
5. Conditional Exception Tier.

This system was explained in an interview with the Chief of the Division of Policy and Program Support, in the DTSC Hazardous Waste Management Office. He said that tiered processing was developed to match permitting requirements to the level of threat posed by activity, with DTSC directly handling the highest two levels (#1 and #2), and local entities providing oversight and control for the remaining three (#3-5). Tiered permitting also creates a comprehensive system of contact and control for hazardous waste generators, and works well in the context of a local, state, and federal waste control system. In California, this is strongly supported at the local level by Certified Unified Program Agencies (CUPAs). There are 83 local government agencies certified by the Secretary of Cal/EPA that maintain a "unified hazardous waste and hazardous materials management" regulatory program, including Hazardous Waste Generator and Onsite Hazardous Waste Treatment (tiered permitting) Programs. CUPAs include city and county land use and environmental health agencies, special planning and regulatory districts, and some special agencies.

These tiers are explained as follows:

- Level 5, or Conditional Exemption, is the lowest level of regulation. This provides for exemption of small-quantity treatment and other low-threat treatment at the facility in which it was generated ("on-site"). Examples would be simple separation of oil from water, container rinsing, and similar activities related to routine business operation. It is left to city and county land use and environmental health agencies (CUPAs) to ensure appropriate use of this exemption.
- Level 4 is next lowest level, and provides for Conditional Authorization. This covers onsite treatment authorization for specific low-hazard water-borne waste streams such as metal-bearing rinse waters, and some neutralization activity. It requires notification and authorization by the relevant local agency (CUPA), but no approval is needed.
- Level 3 is Permit by Rule, and allows some generators to operate according to an agreed-upon treatment plan, certified by a CUPA. It allows authorized on-site treatment of wastes such as concentrated metal-bearing wastes, concentrated acids or alkalis, and similar on-site treatment operations.
- Level 2 is the Standardized Permit Tier, and covers a hazardous waste generator or treatment facility covered under California requirements, or off-site transfer facilities for RCRA wastes including recyclers, oil transfer stations, and precious metal recyclers.
- Level 1 is the Full Permit Tier, and covers RCRA waste treatment, or landfill facilities.

Each entity that generates waste must obtain a unique EPA generator number, issued by DTSC. It must also use a structured manifest system to report each shipment that is generated, using this number for tracking purposes. The manifest must identify the shipment (including content and weight), the transporter, and the destination. Each transporter is similarly registered, as is the facility that receives the waste for treatment, storage or disposal (sometimes referred to "TSD Facilities" or "TSDFs"). Every record of a shipment is reported to the DTSC Generator Information Services Section, and whenever a certified treatment facility receives a shipment, it must report the same information in the same manner. In this way, there is a certified and "closed loop" handling of all hazardous wastes.

The DTSC permitting program pertains to Level 1 and 2 activities, and is intended to ensure safe treatment or disposal of all hazardous wastes.

Permitting Objectives

The objectives of RCRA are found in Section 1003, 42 United States Code 6902, and a partial list of those objectives is provided below (underlined emphasis is added):

- Promoting the protection of health and environment and conserving valuable material and energy resources (1003(a));
- Prohibiting future open dumping on the land and <u>requiring the conversion of existing open dumps to facilities which do not pose a danger to the environment or to health</u> (1003(a)(3));
- <u>Assuring that hazardous waste management practices are conducted</u> in a manner which protects human health and the environment (1003(a)(4);
- Requiring that hazardous waste <u>be properly managed in the first instance</u> thereby reducing the need for corrective action at a future date (1003(a)(5).

RCRA also states that it is "national policy" to reduce or eliminate the generation of hazardous waste "as expeditiously as possible" and that waste which is generated should be treated, stored or disposed "so as to minimize the present and future threat to human health and the environment." (RCRA Section 1003(b).) Thus, RCRA provides the broad objective of reducing hazardous waste generation but recognizes that hazardous waste which is generated must be managed properly to ensure acceptable and safe treatment, storage, and disposal practices.

As the underlined portions of the RCRA objectives above suggests the purpose of RCRA was not simply to eliminate the generation of hazardous wastes, but to establish life-cycle management so that hazardous waste generation is not allowed to threaten human health and the environment.

Indeed, the Congressional Findings provided in Section 1002 of RCRA, 42 USC 6901, note that the "the improvements in the standard of living enjoyed by our population, have required increased industrial production to meet our needs..." and that "continuing technological progress and improvement in methods of manufacture, packaging, and marketing of consumer products has resulted in an ever-mounting increase, and in a change in the characteristics, of the mass material discarded by the purchaser of such products."

A review of California Law indicates that same paramount focus on the protection of public health and the environment. See Cal. Health & Safety Code Section 25101(a) (Legislative Declaration), Section 25135(a)(5)(Safe and responsible management of hazardous waste is critical). And, each permit issued or renewed by the DTSC "shall contain the terms and conditions the department determines necessary to protect human health and the environment." Section 25200(d)(2).

In 1986, the California Legislature passed the "Tanner Act" named after Assemblywoman Sally Tanner that was designed to streamline the procedures for the siting and permitting of new hazardous waste TSD facilities by providing specific application and permit issuance deadlines and an appeal process. (Section 25199.-251999.14.) Section 25199(b) of the Tanner Act, for example, states:

"The Legislature, therefore, declares that there is a critical need to clarify the requirements that must be met, and the basic procedures that must be followed, in connection with the approval of hazardous waste facilities."

Subsection (c) of that Code adds that: "It is the intent of the Legislature, in enacting this article, to establish the means to expedite the approval of needed hazardous waste facilities..." as well as adding new requirements, including but not limited to:

- To ensure that new hazardous waste facilities are not sited unless the facility operator provides financial assurance that the operator can respond adequately to damage claims arising out of the operation of the facility;
- To ensure that the facilities comply with applicable laws and regulations;
- To clarify the procedures to be followed in approving a facility;
- To establish specific means to give the concerned public a voice in decisions relating to the siting and issuance of permits for hazardous waste facilities; and
- To establish a process for appealing local decisions on applications for land use approval for hazardous waste facilities.

By way of summary, the relevant legal provisions support the following general conclusions as related to permitting. First, the protection of public health and the environment is the primary goal of federal and state hazardous waste law. Thus, the cradle-to-grave hazardous waste management program generally and the permitting of RCRA and California-only facilities must be conducted with this objective. Second, RCRA and state law support the reduction and minimization of hazardous waste generation over time, but recognize that there will be a need for treatment and disposal capacity. Third, existing law (Tanner Act) attempts to provide a means for the siting of new hazardous waste facilities with adequate financial assurance. However, as a result of local concerns and other concerns, almost no new capacity has been sited in California since 1986, leaving only the remaining permitted facilities to operate.

As a result of this complex legal framework, a DTSC Division Chief, has explained the position of DTSC in an interview conducted as a part of this review: "We have to maintain [adequate] treatment capacity to handle waste in California in order to protect health and safety." It was stated that the Department has a responsibility "to make compliance easy and economic" such that existing permitted facilities can continue to operate. It was noted that where the cost of compliance gets too high, or when facilities are not easily available, it creates a greater likelihood of illegal disposal of hazardous waste. Failure to have adequate treatment capacity may result in the unlawful and unsafe disposal of hazardous waste (sometimes referred to as "midnight dumping") which would also have an adverse impact on human health and safety.

As is readily apparent, there is a tension between monitoring existing facilities to ensure the protection of public health and the environment and ensuring that these existing facilities continue to operate so as to provide adequate capacity to prevent illegal disposal of hazardous waste. But this does point to a lack of clarity in program purpose, especially where an existing needed facility may also present public health concerns.

Accordingly, this review and analysis posed several specific questions:

- What factors should go into a permit decision?
- Should more permits be denied?
- At what point should a permit be denied?
- Should there be a denial after three notices of deficiency?
- Are the time, cost, and complexity of the process reasonable?

Stakeholder interviews (presented in Chapter 6) indicate criticism of the Department's balancing of this tension.

Specifically, a number of public interest representatives interviewed as part of this project expressed their concern that the Department was more concerned about maintaining treatment or disposal capacity than about public health and the environment. Their comments did recognize the need for "safe management of hazardous wastes in California," but did not recognize an affirmative need for the Department to assist in the accomplishment of that end. In their view, permitting should be viewed as a conditional privilege conferred only on compliant individuals or entities, without regard to the need to consider the maintenance of capacity. In fact, most of the public interest representatives interviewed were opposed to the use of any Department discretion exercised to ensure adequate capacity, and seemed to favor only application of a strict permitting standard. Many of the strongest criticisms offered by that group were about the failure of the Department to consistently identify and use an objective standard, and to act with dispatch to revoke a permit when that standard is not met.

- **Finding:** This study agrees with the observation of the interviewed public interest representatives (see Chapter 6) that there is not sufficient clarity in many critical standards for effective Permit Program operations. For this reason, it is recommended that the Department formally articulate the mission and objectives of permitting program, as a beginning point in a strengthening of its operational standards.

Recommendation 2-1: Formally articulate the objectives and purposes of the Permitting Program based on law, and ensure that these objectives are disseminated and understood by the permitting staff and the broader public. The lack of a clearly stated objectives and purposes is creating an uncertainty in the actions of the Department, and a lack of clarity in public expectations about the Permitting Program. These objectives and purposes should specifically address three policy questions including: What constitutes a timely permitting action; Under what circumstances lengthy permit renewals are in compliance with law, and; When and how the enforcement and required clean-up actions of recorded violations are adequately considered in permit renewal? Once developed, the objectives and purposes should be reviewed and affirmed by Cal-EPA Secretariat, and the relevant Legislative Oversight Committees.

3) Background of Controversy

When this study was initiated, Department Director Debbie Raphael noted that there had been a great deal of expressed public dissatisfaction with the Permitting Program, generally and specific to several permit applications. Her comments posted to the Department web page on March 22 also described a need to "restore public confidence in DTSC", and said that "permitting and enforcement were not as effective as they should have been."

In response, the study team asked both the Director and our project team advisors for a list of the most controversial projects, why they were controversial, and whether any possible causes of the controversy had a direct and/or unique relationship to the subjects we were asked to study. The following is provided as documentation of the issues that were offered as those that have been most controversial, and the causes relevant to the study.

Specific Controversial Permitting Actions

Kettleman City. This is an existing major landfill site, located in the Central San Joaquin Valley, west side, near Coalinga. Pending actions include a Class 3 Permit Modification and renewal. The operator was recently cited for failure to report 72 spills, which the Department considers significant but since each spill was small and entirely contained, without any human health impact. The primary issues pending are in regard to when violations should be actionable, and what action should be taken. Most recently there was also a failure to notify one party or record regarding a proposed action.

Exide. This is a battery recycling facility located in Los Angeles area (City of Vernon). Exide is one of the last "interim" permits (a disposal site in existence prior to the 1982 law that established DTSC and grandfathered pre-existing operators.) It has been controversial both because the South Coast Air Quality district has recently found its air emissions to pose elevated cancer risk in the area, while the Department discovered that the facility was releasing hazardous waste into the soil due to a degraded pipeline. The Department believed Exide was not fully cooperative or responsive.

Phibro-Tech. A treatment facility located in Santa Fe Springs that has requested a new, expanded permit. Advocates say it is being allowed to "function on expired permits," and has done so for 15 years. They believe it is an example of poor enforcement. Advocates argue that it needs to clean up pollution at the site, which has contaminated groundwater.

Chevron Oil. Located in SF Bay Area, at Richmond. Permitted, but advocates believe it is an example of poor enforcement, and should have been sanctioned or fined after a refinery fire in 2012. While DTSC did not levy a fine, the California Division of Occupational Safety & Health (Cal/OSHA) did issue 25 citations against Chevron USA on Jan. 30, with proposed penalties totaling nearly $1 million, for state safety standard violations related to the August 6, 2012 fire at the refinery.

Evergreen. Oil recycling facility in LA Area (City of Carson). It is one of the "big" transfer and treatment concerns. Advocates believe it is an example of poor enforcement, that its permit should be suspended, and that no action has been taken despite "serial leaks over two decades."

These "most controversial" actions were discussed with the project advisors to ensure adequate review of issues within the scope of this review. It was determined that the primary concerns in these matters are similar to what was identified in the previous chapter, with the addition of questions related to:

1. If permit renewal actions are timely;
2. If lengthy permit renewals are in compliance with law;
3. If enforcement and required clean-up actions are adequately considered in permit renewal?[23]

It is noted that the issue regarding the levy of fines is entirely within the realm of enforcement, and outside the scope of this study. This study did include a review of the public participation process, as it is required by law and clearly a part of the permit renewal process.

A further discussion of specific permitting related actions reviewed as a part of this study are provided in the section on Stakeholder feedback, Chapter 6.

[23] Included in Recommendation 2-1, for formulation of a Department response.

4) Organization Structure, Operations and Management

Currently, Permitting is an "Office" within the Hazardous Waste Management Program, with a total of 29 authorized positions in the current fiscal year (FY2013). Of the currently authorized positions, 25 are professional, and largely in Hazardous Substances Engineering classifications, with a few in supervisory-technical classifications. The professional background of most of the Permitting Office professional positions is engineering, chemical science, and geology. The following table shows the staffing level by job classification in the office as determined by the Governor's Wages and Salary Supplement.

Table 1: DTSC – Permitting Division Staffing Levels

CLASSIFICATION	2006-2007*	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013**
Division Chief - Toxic Substances CEA	0.8						
Senior Engineering Geologist	8.8	2.8		0.5	1.0	1.0	1.0
Supervising Hazardous Substances Engineer II	3.0	3.0		0.3	1.0	1.0	1.0
Supervising Hazardous Substances Scientist II	1.0	1.0					
Supervising Hazardous Substances Scientist I	4.0	4.0					
Supervising Engineering Geologist	1.0						
Senior Hazardous Substances Engineer	4.8	4.8	2.6	2.0	2.0	2.5	3.0
Supervising Hazardous Substances Engineer I	6.4	5.0	0.8	--	1.4	1.6	2.0
Senior Hazardous Substances Scientist		1.0	1.0	1.0	1.0	1.0	1.0
Engineering Geologist	11.8	3.0	1.0	--			
Hazardous Substances Engineer	27.5	26.3	13.5	12.3	10.3	13	14
Associate Government Program Analyst	1.0	1.0	2.0	2.0	1.6	1.5	2.0
Hazardous Substances Scientist	19.4	15.3	3.0	3.0	2.7	2.5	3.0
Staff Services Analyst – General	2.6	1.6					
Office Technician – Typing	4.5	4.0	0.7	1.0	1.0	2.0	2.0
TOTAL:	**95.8**	**72.8**	**24.6**	**22.1**	**22.0**	**26.1**	**29.0**

*Permitting and Corrective Action Division
**Authorized Numbers – Actual Personnel Years used not available at the time of study

The 2012-2013 column shows authorized positions for that year, while the columns for fiscal years 2007 through 2012 show the number of authorized positions actually filled. In other words, the columns showing staffing from FY 2007 through FY 2012 subtracts vacant and unfilled positions, even if "authorized" (or included in the budget).

The obvious reduction of staffing from FY 2007 through FY 2009 (from 95.8 to 24.6 positions) is significant, and reflects budget reductions associated with the economic recession and associated state budget reduction in that year. The staffing reductions made in FY2009 have not been reversed, and the Permitting Staff continues to operate with a very low staffing level compared to its recent past. That reduction in overall staffing is a major issue for review, since one of its purposes is to evaluate whether there is a sufficient workforce to complete the work required.

The issue of adequate staffing, timely action, and efficient process have been raised with regard to Permitting since 1997 at least, and a number changes in office name, organizational placement, and management structure have been attempted over the years to respond to these concerns. Ironically, there has been no change in staffing numbers except the roughly 66% reduction in FY09. This section, based on the comments of current and former Department staff, describes the various changes and the perceived impact of those changes on the work.

Changes from 2007-2010

The scope for this contract work called for consultants to document the changes in the permit process over the past five years based primarily on the record obtained from "2007 and 2009 internal reviews", and to obtain perspectives of designated subject matter experts. A list of the designated representatives and subject matter experts is provided as Appendix A, and interviews with each one was conducted, along with a meeting and video conference with all permitting staff statewide (on March 7). However, it was later determined that the record of the "Permitting Team" commissioned in 2007 by the then-DTSC Director, which met consistently until July 1, 2009, was the only internal review that was ever conducted. The relevant record of that team was found in one primary document, the "Permit Renewal Team Closure Report," dated 8/18/2009 (and hereafter called the Closure Report). It is included in Appendix E. Additional interviews conducted throughout this study, including one with the former Director, provided additional information and confirmation of the organizational changes noted below, and while no single source is cited for the following, it presents the consensus views of all these noted sources.

In 2007, the then DTSC Director (who served from Jan. 2006 – March 2009) faced a significant issue in that out of 137 permitted facilities, 76 of these permits had expired and those facilities were continuing to operate as allowed by law on expired permits. The Administration viewed this as a significant problem, with just 45% of all operating facilities holding "current" permits. Her assessment was that the organizational structure was largely at fault, since most program work was done in Regional Field Offices that handled permitting along with a broad range of other Departmental program activities. She argued that permitting actions were not timely because staff needed multiple approvals from various sources in Headquarters program offices in order to proceed with permitting renewal. As she put it in an interview associated with this review: "No single person was in charge of the permitting program" and "responsibility was (split) across multiple people." She said that required decisions "bounced across different work teams." She also noted that the permitting culture was such that, "many employees ...would just ask more questions rather than make decisions[24]."

As a result, part of her response was to eliminate the Regional Field Permitting Offices, eliminating a large number of management positions, and reassigning staff within those offices to combined functional and operational structures within program configurations that had leadership almost entirely in Sacramento.

Within the permitting office all the existing positions were reorganized into two teams, including the Permit Renewal Team and the Operating Facilities Team[25].

The Permit Renewal Team was made up of 15 employees and listed its purpose as "improving the quality and reducing the time required to make final permit determinations; to dedicate resources to issuing permit determinations that are technically sound, legally enforceable, protective of human health and the environment, CEQA compliant and issued in a timely manner.[26]"

The Operating Facilities Team (OFT) was made up of just 13 employees and had a mission of processing all other permitting actions for "current" permit renewals, including operating and post-closure permits, completing clean closures, and handling permit "maintenance" and modifications. This allowed the Permit Renewal Team to focus on its goals of reducing the number of facilities operating without a permit without distraction of these other permitting actions.

It was later noted that the Permit Renewal Team was assigned 11 "project managers" and 15 total employees to process 47 renewal activities, while the Operating Facilities Team was assigned 7 project managers and just 13 total employees to respond to the needs of 130 facilities. This was described as an example of "inequities in the allocation of resources."

Those interviewed as a part of this project described the DTSC organizational changes in terms of upset and confusion, with one person indicating the director "blew up the boxes", and another stating that the reorganization was "controversial." Those interviewed explained that the Director's interest was largely in the Permit Renewal Team, which was established to resolve the critical problem of outstanding permit renewals.

Those interviewed related the impression that the employees perceived as most highly effective were placed on the Permit Renewal Team, while those not selected were assigned to the OFT by default. In addition, because the Permit Renewal Team was charged with rapid results, they were allowed to select the most easily approvable permits of the 67 that were then pending action. Finally, representatives of a number of other program offices were assigned as adjunct staff to the Permit Renewal Team, to emphasize the need for action.

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[24] Interview conducted with the then DTSC Director, May 15, 2013

[25] This information was provided by current Permitting Office Chief, and from the historical record.

[26] Closure Report, attached in Appendix E

The current Permits Office Chief recalled that the projects selected for this rapid review action were the least controversial, with the most cooperative operators, and the least complex issues. As a result, he believes there is limited learning possible from this experience as these "easier" facilities present fewer permitting challenges. However, he feels that one valid lesson is that the assignment of technical specialists to the review team assisted in timely action. He noted that especially in the area of obtaining CEQA review, having a person trained in writing environment documentation was critical. Such an activity comprised additional staffing time for Permitting.

The Permit Renewal Team was "closed" on July 1, 2009[27] and reported that it had issued 38 of the 47 permit decisions it had committed to complete upon its formation, 29 months earlier. Another Department report indicated that in December of 2009 there were 89 facilities operating with permits and just 42 without – a 68% "current" rate. It reported that the time to complete a permit declined to 1.7 years (20.4 months) in 2008 and 1.9 years (22.8 months) in 2009.

The current Supervising Environmental Planner in the CEQA Unit of the DTSC Office of Legal Affairs, was the legal counsel assigned to the Permit Renewal team in 2007. She was part of a review team of 9 other employees from other Divisions that were asked to provide direct support to permitting. In an interview conducted on Aug. 1 she observed that the apparent success of the team was primarily the result of defined limits in its work assignments and its generous staffing. She also noted that the team was given a favored status, including new laptops, and permission to travel and to attend conferences.

Some of the assessments given for the Permit Renewal team success have argued that Permit Staff was given authority to "make decisions" regarding other programs' sign off on permit decisions. However, the current Supervising Environmental Planner says that with regard to CEQA approvals, "the process we had internally (then) is the same that we have now," and that there was no change in the processing rules during the Process Renewal Team. In further discussion with consultants she agreed that the inclusion of a CEQA specialist on the team was probably successful because key issues were discussed amicably early in the permit processing, rather than languishing unsolved until later stages of review. This observation is addressed in the recommendations below.

Permit Team's Conclusions Regarding Success

The Department issued the June 2009 report ('Closure Report') to summarize its lessons learned. While a number of conclusions were offered for the perceived Permit Renewal Team success, the one that stands out most clearly is that the use of "dedicated resources" and team members who were allowed to "align their workload" resulted in meeting project goals: In other words, a **realistic workload assigned to available staff**. Clearly this practice has not been maintained or replicated in the current timeframe, as the staff assigned to Permitting and its two teams dropped to historically low levels in 2009 and afterwards (see Table 1), as the overall state budget crisis worsened. This

[27] Based on Department report, "Permit Renewal Team Closure Meeting," dated July 1-2, 2009

misallocation has not been altered even today, and is likely to significantly impact the future success of this unit.

The study also echoed the original theory offered by the then Director, that making permitting staff accountable for results, and that **reducing the number and levels of approvals necessary**, particularly through elimination of the Regional Office structure, was very helpful. While no empirical evidence is available, this study concurs that it was likely a significant factor, because the process of obtaining approvals across organizational boundaries is often problematic, since the time imperative binding the requesting unit is not necessarily binding on the approving unit. At the same time, the desire to obtain full technical compliance that is highly motivating to the approving unit is often not fully embraced by the initiating unit. However, this study does not agree that the abandonment of supervisory structure was helpful, as we will discuss in the next section.

This study agrees with another practice cited in the final report, that each project manager **develop and post a project plan for each renewal** based on the unique need and circumstances of their assigned renewal action. This practice is consistent with good project management, and it must be noted that it has been largely abandoned (except perhaps in the Chatsworth permitting staff unit) in the intervening years.

The **use of model permits and consistent permit structure** (or process), was also endorsed in the closure report, and it was noted that these models should be supported by "reference checklists". This study agrees that this was also likely a significant factor in the earlier team success, and is another practice that has been abandoned since team closure, as noted in the following chapter.

The use of teams for permitting actions is also endorsed by the closure report, and this is a recommendation with which the present study disagrees. This is the case because the only attribute of having "teams" that directly relates to permit processing is that of completing "tasks at hand" based on specialized knowledge, and of obtaining required approvals in a "flatter" organization. The issue of "teams" implies that always having a large work group assigned to every permit renewal is an aid, while it seems apparent that teams would only be necessary on larger or more complex renewals. The use of teams also implies that having associated program review staff on the team, for example to include member from CEQA or Human Health Risk Assessment units, would always make the work quicker. However, as noted in the earlier interview with the current Supervising Environmental Planner in the CEQA unit, there was no program change in that period of time (2007-2009), and "the process we had internally (then) is the same that we have now." This means that the positive result achieved was not the result of the permitting project manager commanding the associated program experts to produce positive results, but rather, of shared goals and good communication early in the process.

As a result, the actual best practice is an extension of the earlier recommendation to develop and post a project plan for each renewal – but with a focus on development of a project team and project management techniques appropriate to the action at hand. This would normally be done through **development of a project charter** associated with each renewal action. Such a project plan would require the project manager to anticipate the project team members that would be required for the proposed action, and to negotiate their participation, and a communications plan to achieve mutual goals. The use of these basic project management practices will encourage task, timeline and resource planning that should smooth the workflow.

Relevant Structural Issues

Between December 2009 and the present (August, 2013), the Permitting Program Office has not maintained uniform management, supervisory structure or a clear and consistent organizational structure. This is documented both through the statements of individuals interviewed, by HR Division records, and by a review of basic organizational documents such as duty statements and organizational charts.

Permitting staff interviewed as part of this project indicated that after the two teams were disbanded in 2009, that three new teams were established according to the type of permitting action, including Landfills; RCRA Storage and Treatment; and Oils and Standardized Permitting. The Landfills Team reviewed all permitting work of that type, and its actions were reviewed by a Senior Engineering Geologist. The RCRA Storage and Treatment Team was headed by a Senior Hazardous Substances Engineer (HSE). The Oils and Standardized Permitting Team was headed by a Senior Hazardous Substances Engineer (HSE). However, while the <u>work</u> was reviewed by these three specialists, there was no system of direct supervision of each employee in the Permitting Office until April of this year. In other words, there was a four-year period in which work outputs were reviewed, but direct supervision of personnel lapsed.

Management of the Permitting Program had also lapsed. In 2009, the Chief of Permitting was also assigned as Acting Deputy Director of the Department. Permitting personnel expressed that because of her other duties, this caused a vacuum of leadership at a time during which Permitting was already being challenged. Not only was there a lapse in Supervision, as noted, but the available staffing was reduced by almost 70% between FY09 and FY10. A new Permitting Chief was appointed to serve on March 2, 2012, but retired on Dec. 25 of that same year. Then another lapse in management occurred until the current Chief was appointed in February, 2013.

The concern with these significant lapses in management and direct supervision of all personnel is that attendance, performance, coaching, and training of employees did not come under consistent and regular review by a designated staff person, and a consistent system of responsibility and accountability lapsed. The lapses in use of a standard permit process (detailed in Chapter 5) likely occurred or became worse during that period. One documented observation was that "the work product and quality of work severely declined" during this period, and "accountability was lost."[28]

Incrementally since that time the Department has restored a one-to-one relationship between each permitting employee and a supervisor, and appointed a Supervising HSE I on 2/14/11, to supervise

[28] Assessment of Denzil Verardo, who served as a Special Assistant to the DTSC Director for performance management implementation, special projects and investigations, from 2006-2011.

the permitting employees stationed in Berkeley, and another on 5/9/2012 to supervise the permitting employees stationed in Sacramento. A third HSE I was selected on July 18, 2013 to supervise the employees stationed in Chatsworth.

Based on comments of employees, and direct observations of consultants during field visits, it has been concluded that the use of telecommuting in many offices is extensive and unplanned by management, and that this is a contributory factor to less-than-optimal program efficiency and effectiveness.

Analysis of this history leads to a conclusion that appropriate management, work unit cohesiveness, and effective work organization has suffered for an extended period of time, and that focused efforts are needed to restore best practices in permitting.

Recommendation 4-1: DTSC should establish a clear and predictable organizational structure for permitting that is focused on in-person meetings, in-office work, and updated training. Telecommuting should be severely limited or revoked for at least a six-month period while these necessary improvements take place and the objectives and purposes in Recommendation 2-1 are implemented. All permit staff duty statements should be brought up-to-date along with goals and performance appraisals during this period. Necessary updates to standard templates, work aids, and work processes should be achieved. Work units should use this time to build solid relationships with their supervisors. Maintaining traditional in-office work groups, with a supervisor at each location, will improve communication and assist with re-establishment of efficient processes and work production.

5) Standard Process

The documentation of a standardized process for permitting was a primary purpose of this study, and it was asked there are "grey areas" in the current process. The study was asked to develop a recommended process with clear decision criteria and corresponding standards of performance. It was asked to answer the question, "What factors must go into making a permit determination?"

Attempts to Define the Standard Process

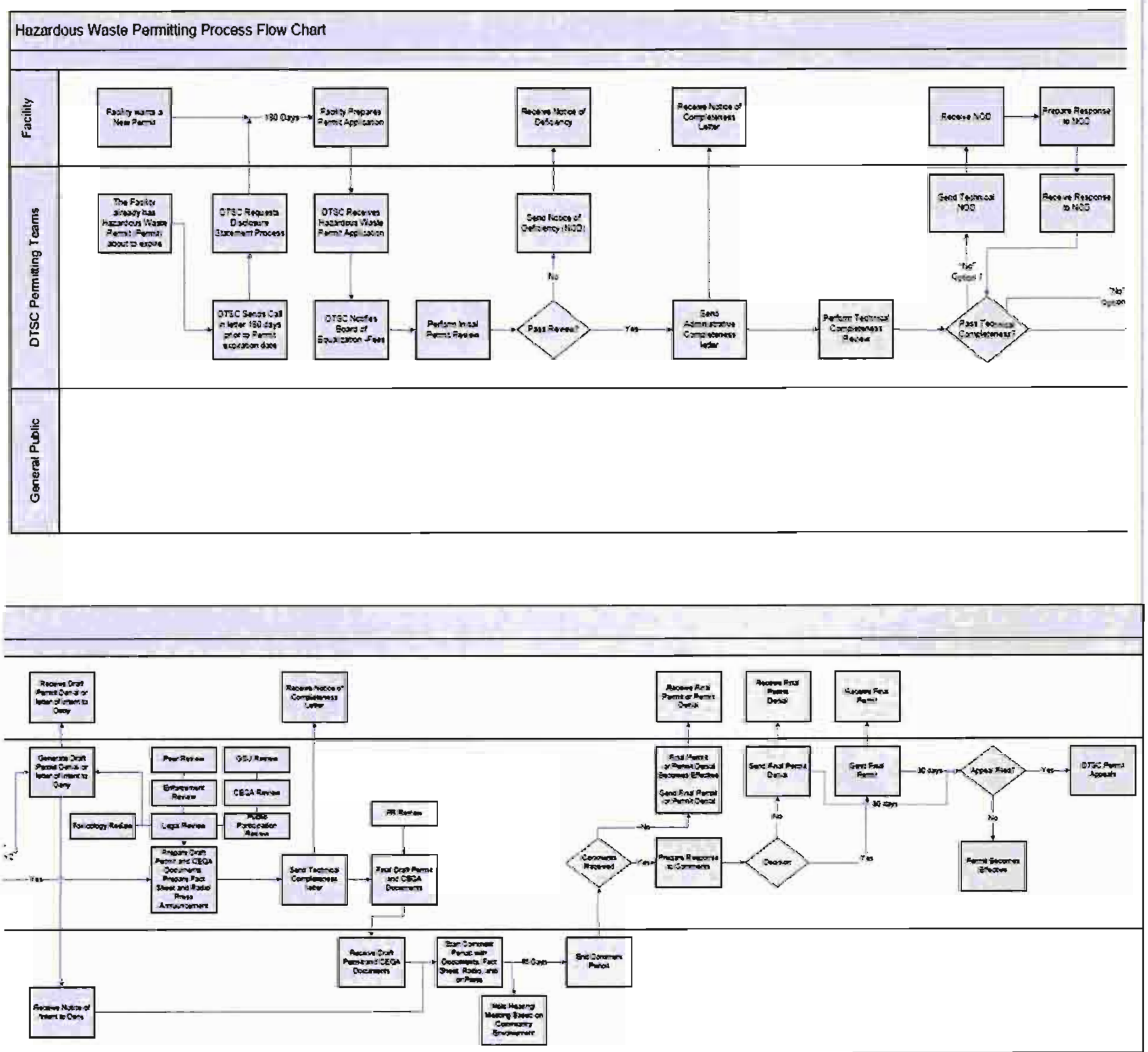
When this study was initiated, Office of Permitting project sponsors were asked if a standard process flowchart existed. The chart represented in Figure 1 on the following page was provided. A complete copy of this flowchart was printed, and major segments were illustrated in a PowerPoint presentation at a meeting and video conference with all permitting staff on March 7.

Permitting staff first expressed surprise regarding the process flowchart, and asked where it had come from? When told that it was provided by Permitting Program management, and that it was saved on the Office' SharePoint site, participants said that the workflow is not realistic and does not capture how things are really done. For example, they noted that the draft permit is always reviewed by legal prior to technical completeness letter being sent.

Other significant process-related comments made by the employee group was that the Permit Processing Handbook was last updated in 2001 and is not useful for staff to learn how to process a permit, and that there are no guides or instructions available regarding the Technical Review of a Part B application. Permit staff also said there is a 'grey area' to consider in permitting actions due to enforcement actions[29].

[29] This was a comment made at the all permitting staff meeting held on March 7. No further detail on the meaning of the comment was provided, but it was believed to mean that there is uncertainty regarding further permit processing in instances where the facility has outstanding violations.

Figure 1: Existing Standard Permitting Process Flow Chart



Following the all-employee meeting on March 7, a revised process flow document was created, and an April 9 meeting was scheduled with the Permitting Chief, and all supervisors and "team leads," so that a revised standard process flowchart could be created. This initial review group included the current DTSC Permitting Chief, the Supervising HSE I's from the Berkeley and Sacramento Offices, the Senior HSE's who headed the RCRA Storage and Treatment Team and Oils and Standardized Permitting Team, and a Senior Engineering Geologist. Surprisingly, there was significant disagreement among this group about key process steps. For example, there was debate about when the "call in" letter was supposed to be sent to each permittee, initiating the permit renewal cycle. It was finally agreed that it <u>should</u> go out "18 months prior to existing permit expiration", rather than the 6 months shown on the previously existing process flow chart. In addition, it was observed that when the Department finds the initial Part A and Part B application to be incomplete, it sends an Administrative Incomplete letter and not a "Notice of Deficiency." It was agreed that a Notice of Deficiency (NOD) is only sent during review of the Part B application and operating plan[30], and that it is reserved for use during the more contentious Technical Review period.

A revised proposed standard process flow document was created and resubmitted for approval four more times, and produced proposed standard process documents on April 17, May 22, June 12 and July 12. No agreement on standard steps was ever reached even though it was decided to narrow the review group to just the current DTSC Permitting Chief and the Senior Engineering Geologist[31].

Specific areas on which agreement could not be reached include:

- When and how the CEQA process starts
- When and how the Disclosure process start
- When and how the Public Participation staff gets involved in the renewal process
- <u>Any</u> standard process steps for review of the Part B Application and the associated Technical Review

Because of this failure to agree, this study reviewed what was actually done during the random audits of permit renewal actions. Additional interviews were also scheduled with the Legal Office, the CEQA Unit, Federal EPA, Public Participation supervisors, and with Financial Assurance staff to review perceived roles, and best practices for DTSC Permitting.

Recommended Standard Permit Process

The following pages depict the recommended process flow chart, based on information obtained from all sources. The specific recommendations associated with its adoption follows. A task list aligned with the process flowchart is provided in Appendix F.

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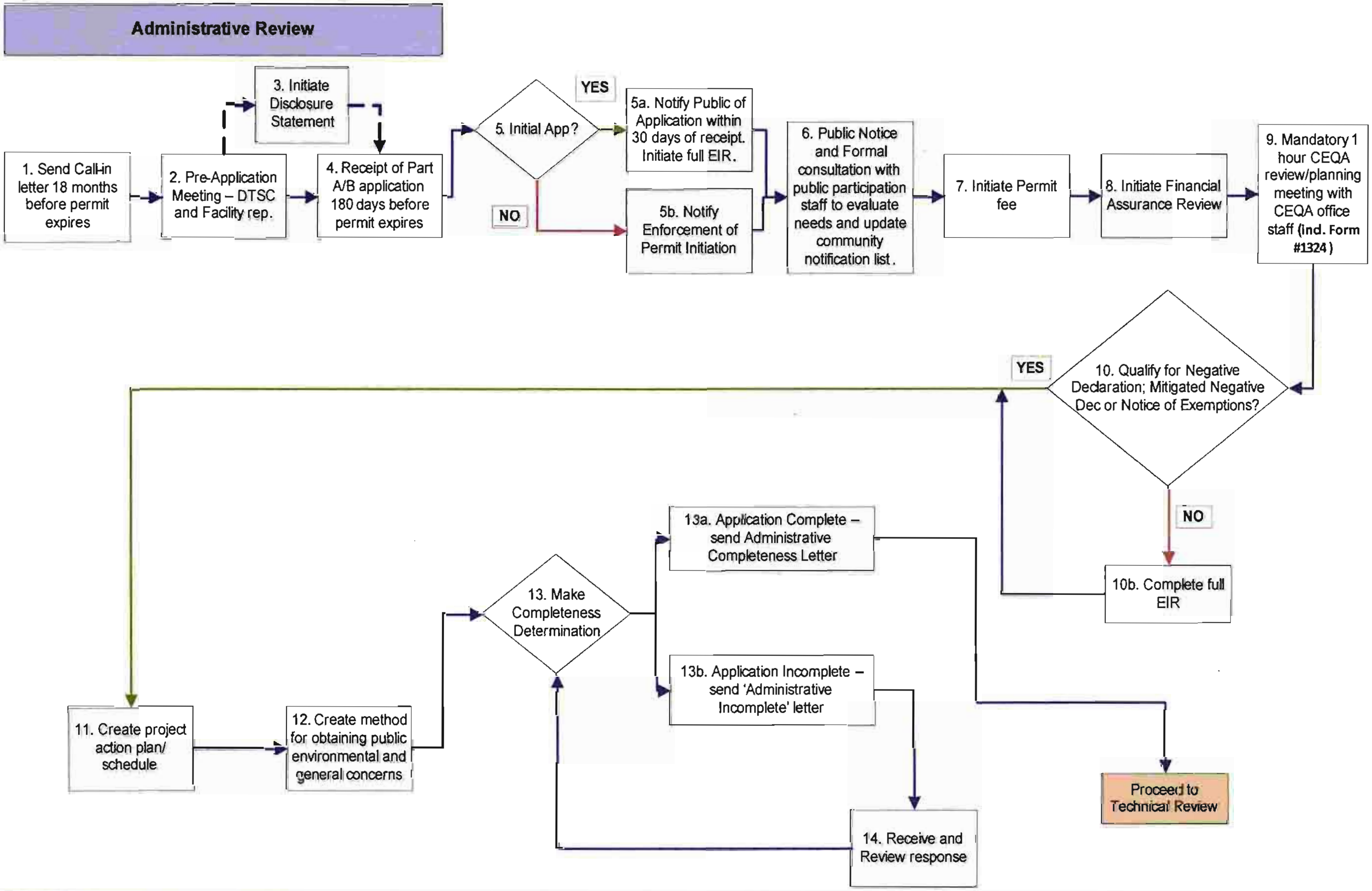
[30] Despite this agreement reached among permit staff on appropriate terminology, the Health and Safety Code makes reference to issuance of a notice of deficiency during administrative review, indicating that the law may not be consistent and clear.

[31] These reviewers were seeking approval of a broader group in acceptance of "standard" process steps.

Figure 2: Recommended Permitting Process Flow Chart



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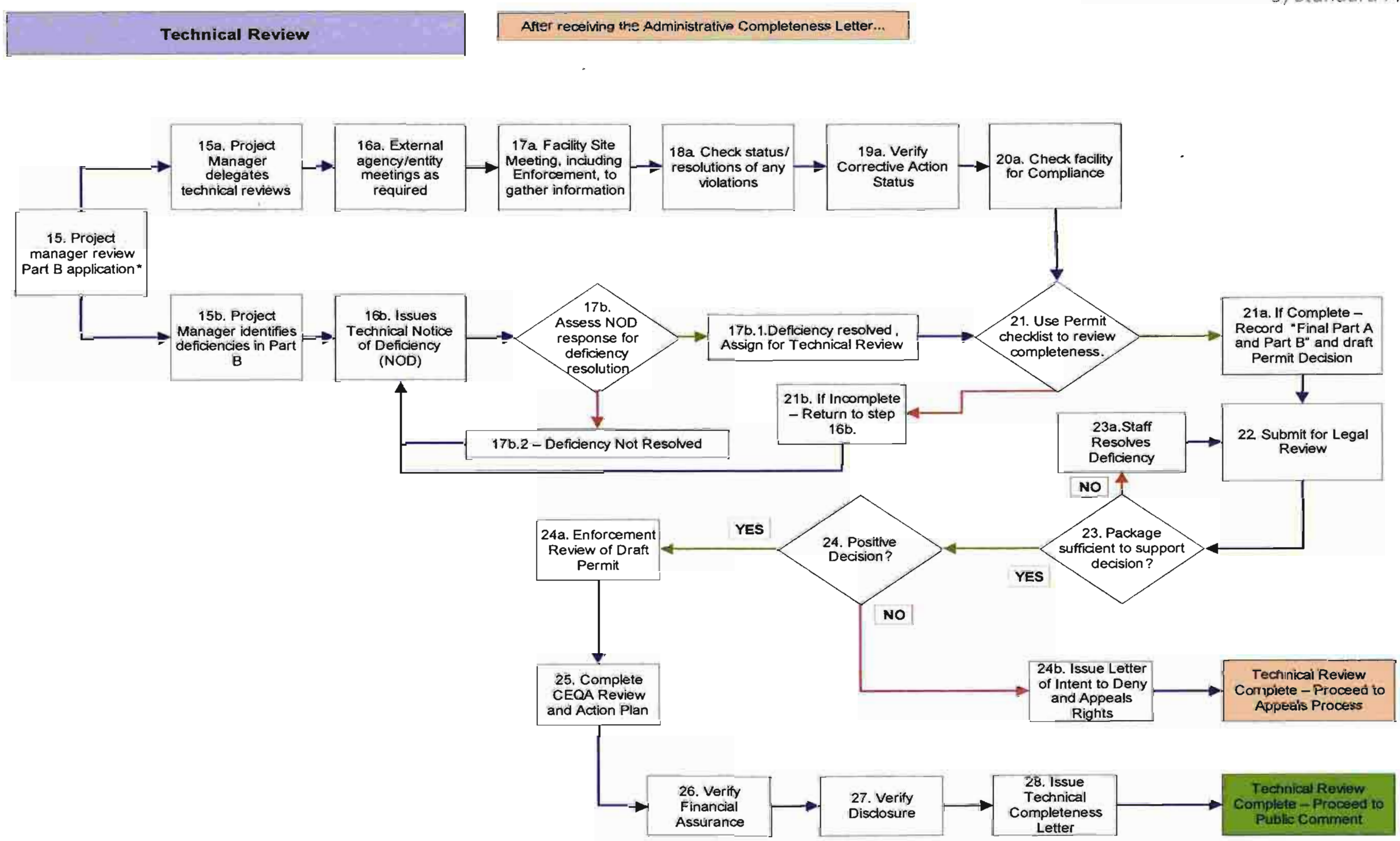
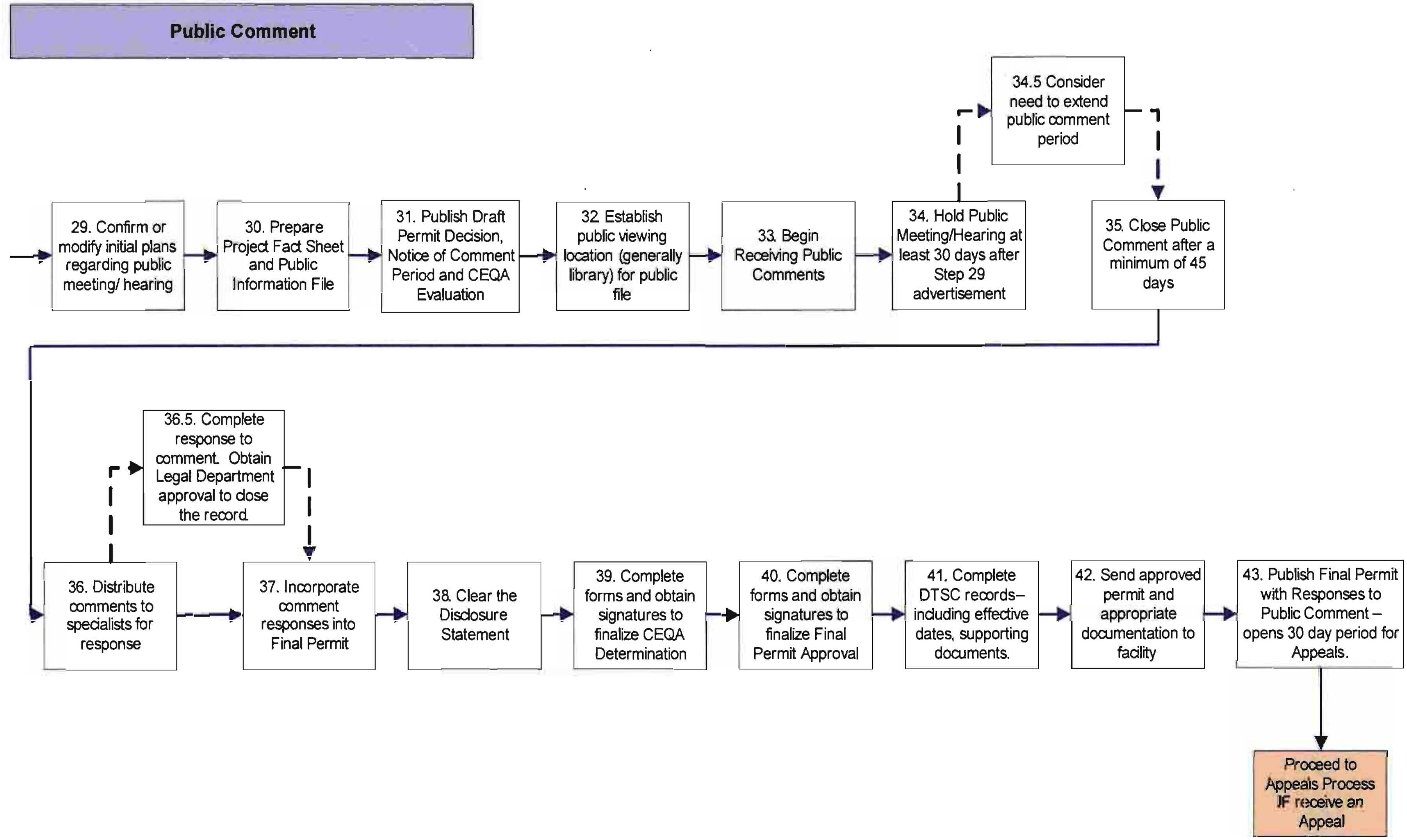
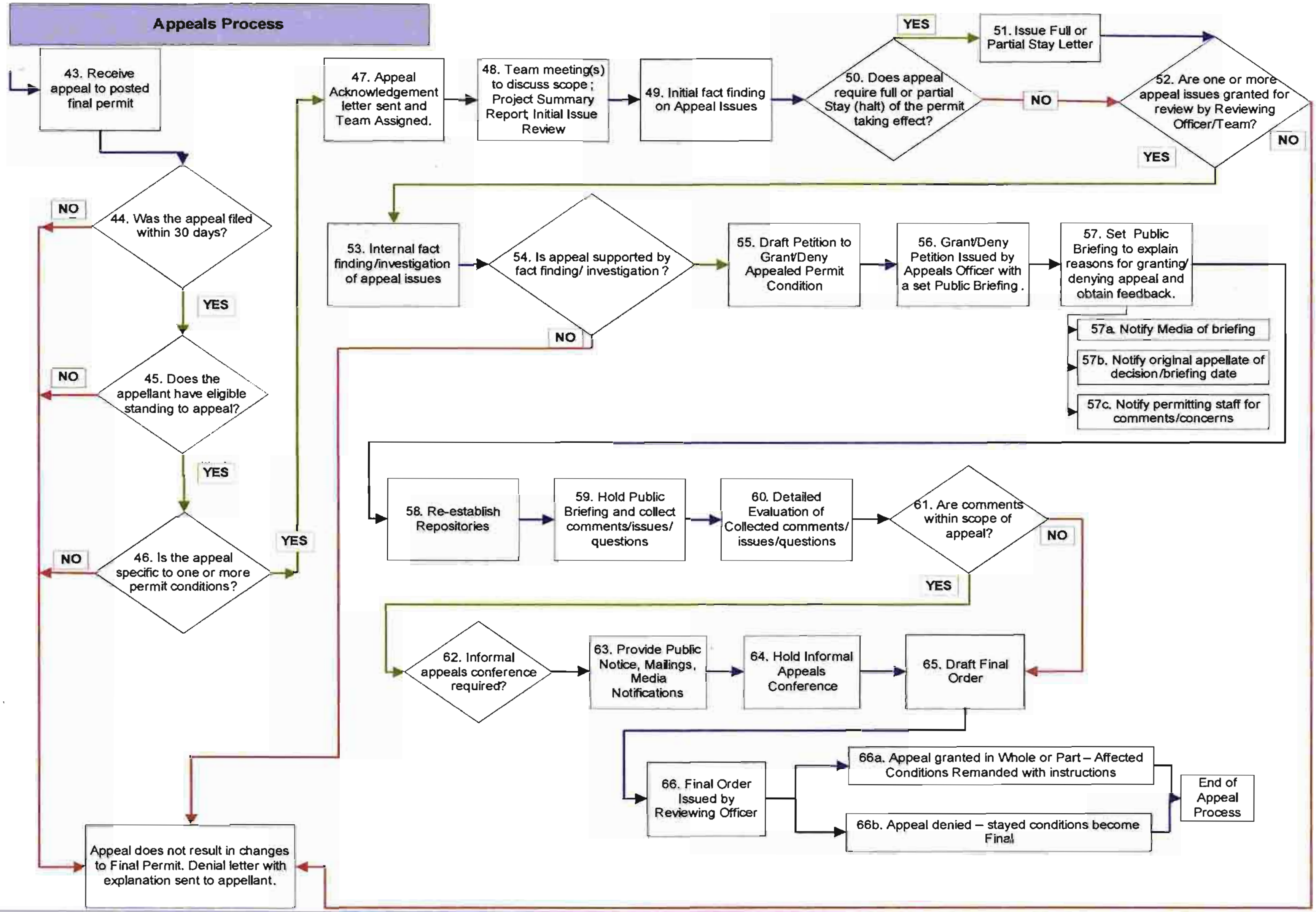


* See Flow Chart for Part B Application for more detail


Public Comment
29. Confirm or modify initial plans regarding public meeting/ hearing
30. Prepare Project Fact Sheet and Public Information File
31. Publish Draft Permit Decision, Notice of Comment Period and CEQA Evaluation
32. Establish public viewing location (generally library) for public file
33. Begin Receiving Public Comments
34. Hold Public Meeting/Hearing at least 30 days after Step 29 advertisement
34.5 Consider need to extend public comment period
35. Close Public Comment after a minimum of 45 days
36. Distribute comments to specialists for response
36.5. Complete response to comment. Obtain Legal Department approval to close the record.
37. Incorporate comment responses into Final Permit
38. Clear the Disclosure Statement
39. Complete forms and obtain signatures to finalize CEQA Determination
40. Complete forms and obtain signatures to finalize Final Permit Approval
41. Complete DTSC records– including effective dates, supporting documents.
42. Send approved permit and appropriate documentation to facility
43. Publish Final Permit with Responses to Public Comment – opens 30 day period for Appeals.
Proceed to Appeals Process IF receive an Appeal


Appeals Process
43. Receive appeal to posted final permit
44. Was the appeal filed within 30 days?
45. Does the appellant have eligible standing to appeal?
46. Is the appeal specific to one or more permit conditions?
YES
NO
47. Appeal Acknowledgement letter sent and Team Assigned.
48. Team meeting(s) to discuss scope; Project Summary Report, Initial Issue Review
49. Initial fact finding on Appeal Issues
50. Does appeal require full or partial Stay (halt) of the permit taking effect?
51. Issue Full or Partial Stay Letter
52. Are one or more appeal issues granted for review by Reviewing Officer/Team?
53. Internal fact finding/investigation of appeal issues
54. Is appeal supported by fact finding/ investigation?
55. Draft Petition to Grant/Deny Appealed Permit Condition
56. Grant/Deny Petition Issued by Appeals Officer with a set Public Briefing.
57. Set Public Briefing to explain reasons for granting/ denying appeal and obtain feedback.
57a. Notify Media of briefing
57b. Notify original appellate of decision/briefing date
57c. Notify permitting staff for comments/concerns
58. Re-establish Repositories
59. Hold Public Briefing and collect comments/issues/ questions
60. Detailed Evaluation of Collected comments/ issues/questions
61. Are comments within scope of appeal?
62. Informal appeals conference required?
63. Provide Public Notice, Mailings, Media Notifications
64. Hold Informal Appeals Conference
65. Draft Final Order
66. Final Order Issued by Reviewing Officer
66a. Appeal granted in Whole or Part – Affected Conditions Remanded with instructions
66b. Appeal denied – stayed conditions become Final
End of Appeal Process
Appeal does not result in changes to Final Permit. Denial letter with explanation sent to appellant.

The earlier noted failure of Permitting staff to agree on the applicability and accuracy of the existing process flowchart, followed by the failure of supervisors and team leads to be able to define a clear permit process after five attempts is evidence that there is no agreement on the standard permitting process at the present time. The result is that there is no standard best practice is being followed, no standard for training, and no standard for tracking. It is therefore recommended that this be corrected.

> **Recommendation 5-1: Adopt the revised process flow for permitting proposed in this report, or a similar standard process flow. Require notes on the criteria for each decision and the sign-off standards for each process (or project) step. Specify a clear logic for any alterations in dates or tasks. Such a process must respond to the grey areas identified earlier as follows:**
>
> - **A defined and coordinate initial process review by DTSC CEQA staff and DTSC Community Involvement staff;**
> - **Initial and regular/as needed consultation between enforcement and permitting;**
> - **A mandatory permit renewal meeting with the appropriate DTSC technical team and the permit applicant;**
> - **A site visit between the appropriate DTSC technical team and the permit applicant early in the Technical Review.**

The additional steps recommended above were based on additional interviews and research that is summarized here.

The defined initial process review by the DTSC CEQA Unit is based on an Aug. 1 interview with the Supervising Environmental Planner in the CEQA Unit and former Unit Director. Both noted that this step is now bypassed in most cases, and that the CEQA staff is typically involved only in the final permit approval action, when the Unit is asked to approve any "Notice of Determination" of negative impact. The current Supervising Environmental Planner in the CEQA Unit said this practice is "unfair" and leads to unnecessary delay and additional work in many instances. It can also lead to Departmental rework where there was poor initial decision-making. Since appropriate CEQA decision making is based on the appropriate completion of a CEQA Initial Study Checklist (DTSC Form #1324), it will require at least an initial consultation between the Permit project manager and the CEQA to ensure appropriate information is provided.

The recommendation for a defined initial process review by DTSC Community Involvement staff is based on information obtained at an Aug 13 interview with the Public Participation and Community Relations Branch Manager and her three unit supervisors. This group stated that like the CEQA staff, the Permit Renewal Project manager rarely brings them into projects "within an appropriate time to meet community outreach needs" and they are never included in initial scoping meetings to determine a community outreach strategy, or to update a community contact list or determine outreach needs. As stated before regarding CEQA liaison, this practice can be expected to contribute to unnecessary delay, error, or rework where there was poor initial decision-making.

The recommendations regarding an initial meeting between enforcement and permitting has already been recognized as a need within DTSC, and is in the process of being implemented.

The recommendation for an initial permit renewal meeting with the appropriate DTSC technical team and the permit applicant was observed to occur in several of the permit renewal actions reviewed in the field, and that such a meeting replaced a number of process steps that were otherwise done incrementally, and sometimes apparently missed. Since this change reflects the combination of necessary tasks it is believed to be a best practice and a process simplification that will also promote uniform practice.

The recommendation for a site visit between the appropriate DTSC technical team and the permit applicant early in the Technical Review process is generally acknowledged as a best practice within the Permit Office. In addition, a site visit at the time of the initial permit renewal meeting would be advised in complex renewals, where significant changes in the operation or the community had occurred in recent years, or where the project manager had never been to the site before.

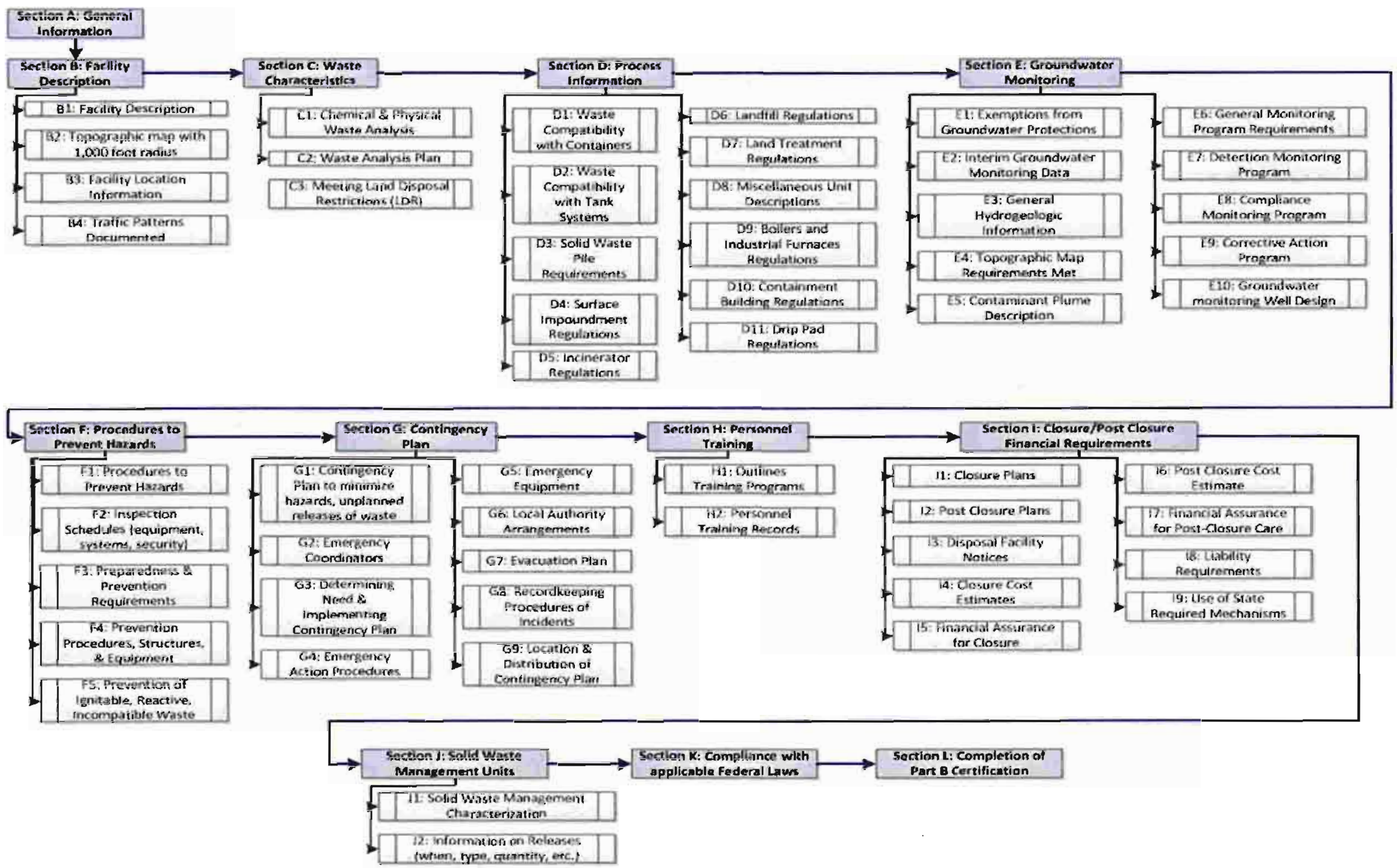
Part B – Technical Review Process

The preceding flowchart shows only a "high level" process relative to the processing of the Part B Application – that portion of renewal referred to as Technical Review. Permit Office leads and supervisors were unable to provide any formal, step-by-step guide, checklist, or other work aid to assist in Technical Review. The basic EPA issues "Permit Completeness Checklist – Part B" was continually cited as the primary source. However, that document is approximately 150 pages long, and its decision flow is very difficult to follow. Indeed, this source document is well known to DTSC permitting staff that had initially cited difficulty in performing the reviews.

A review of past training materials uncovered a document: "SESSION 11, RCRA Permit Training, Reviewing the Permit Application," published by US EPA, that provided a very extensive step-by-step guide to the Technical Review, and that should be much more widely known and used within DTSC.

The entire "Permit Completeness Checklist – Part B" was flowcharted as part of this study, to aid in understanding the steps and actions, so that permit writers can clearly follow them. An abbreviated version of this flow chart is presented in Figure 3 on the next page, with the full flow chart in Appendix G.

Figure 3: Abbreviated Part B Application Review Flow Chart



Recommendation 5-2: The Permitting Office should develop instructional and guidance materials to support the Technical Review process flow. This should include clear and written decision-making criteria associated with each Section, and processing check sheets to match the process steps on the Part B flowchart. The U.S. EPA materials should be used as a reference.

In an additional project interview, the Manager of RCRA Facilities Management Office for the Federal EPA, said that: "CA DTSC has been somewhat of a loner in the past, and has ignored help available through the Region. For example there is a strong network of RCRA permit writers in other states that holds regular information sharing teleconferences, but CA has not been involved." He believes that collaboration within the Region and with other states would help establish consistency and thoroughness by the California office. At the very least, the California Permitting Office is not fully accessing training possible through the Federal EPA, Region IX office.

Recommendation 5-3: DTSC should enter into a cooperative agreement with EPA to: 1) Access its technical assistance in revision and design of permit processing procedures; 2) Provide materials and training on Technical Review; 3) Participate in regional permitting discussions and training.

The Manager of the RCRA Facilities Management Office for the Federal EPA also gave his viewpoint that frequent changes in management and structure, noted in Chapter 4, have been a significant detriment to the efficiency and effectiveness of the DTSC permitting program. "California has gone through a pretty tumultuous past, including internal leadership, consistency, and quality of actions. That has not been the case with Arizona and Nevada. The California organization has been pretty fractured (but) ... things are starting to change... Historically California has had a lot of 'acting' personnel... (the Past Director) removed middle managers, and that stripped a lot of leadership and knowledge."

The lapse of sufficient program management has been a significant problem for permitting, which has only recently been corrected. As a result, this study has come to the conclusion that future additional changes in management at the civil sèrvice level should be discouraged, to allow time for the recommendations of this report to be implemented and for leadership to be held accountable for those changes.

Recommendation 5-4: Future changes in management at the civil service level should be discouraged, to allow time for the recommendations of this report to be implemented and for leadership to be held accountable for those changes.

A summary of the remainder of Shaffer's interview is provided in Table 2, with the entirety of the interview notes provided in Appendix H.

Table 2: Summary of Interview with Manager of RCRA Facilities Management Office for the Federal EPA

	Key Points/Observations
General Background	• Current Manager of RCRA Facilities Management Office has been in the position for 3 years, and before that was doing data side for EPA • Under the Toxic Substances Control Act, EPA maintains sole responsibility for permitting PCB storage/disposal sites; clean-up of PCB contaminated sites • EPA administers grant fund to CA for RCRA activity and sets goals for DTSC in accordance with GPRA – concern that this goal will not be met this year. • EPA maintains general oversight regarding maintenance delegations, reviewing state programs approximately every 10 years and taking back/returning delegations as needed. • EPA Regional office is able to assist states with more difficult facility permitting and with technical assistance.
California's status	• CA has gone through tumultuous past, including internal leadership, consistency, and quality of actions; NV and AZ have appointed new directors, but not had the frequent changes in senior management as CA • Specific issues include a fractured program compared to other states, scattered employees state wide often with no direct supervisory oversight; delayed or missed communications on project status or organizational decisions • The elimination of middle management resulted in lost leadership and knowledge and lower quality permits • CA permit quality could improve by providing permit requirements on the permit, as NV and AZ already do, rather than expecting and relying on facility to interpret and apply regulations to their site. • AL and FL are good programs with strong reputations, while CA is considered a strong program and environmental leader, but program management is not a considered strength. • CA asked EPA for advice on improving program 6 months ago and was provided 12 recommendations, but does not actively engage in collaboration with strong network of RCRA permit writers in other states with regular calls
Outcomes/ Metrics	• Goal is set for number of permit decisions per year, negotiated through grant work plan process; failure to meet goals results in discussion of grant dollars but EPA won't immediately withdraw the money • EPA tracks permitting actions, reviews list of facilities with expired permits and forecasted renewals with DTSC at least every two months • CA data quality is a big issue – DTSC needs to own and maintain accurate data to provide comprehensive understanding of regulated universe
Risk Standards	• EPA has extensive risk assessment protocol and sees it as their role to provide assistance to states at various times • CA has not adopted Federal Standards, not required to do so. • EPA assisted in part of Kettleman assessment, offered but was declined to assist in Exide • Part B Application is federally mandated – Caleb provide 15 page training module on Part B; EPA has done training, audited permit decisions – but stopped doing that about 10 years ago – may be needed again

Process and Project Management

Both Process Management and Project Management are disciplines that provide a framework for planning and control of permitting work. Typically the Process Management framework is used for work activities that best meet the definition of process: A set of defined incremental activities that transform an input to a valuable output for an end-user or customer. The Project Management framework is best used to plan and control work that best fits within its definition: A temporary endeavor undertaken to create a unique product, service, or result.

This study observed that while Permit Renewal largely conforms better to the definition of process, it also conforms in some important ways to the definition of project. The project aspects that are particularly relevant are the unique attributes of each facility, its site, and its operational plan. Indeed, many of the comments made by Permitting staff during the course of this review were related to the unique attributes of each facility and its renewal.

Process Management applies to Permit Renewal in that the legal and procedural steps required for evaluation of an application, and the order of primary actions is applied repetitively.

Overall, there is a useful purpose for the application of both process management and project management practice in permit renewal. The background and logic for using several relevant project management techniques are provided in Chapter 4, starting on page 29, under the heading "Permit Team's Conclusions Regarding Success."

The specific project management techniques recommended include the use of a charter[32] and a project plan for each permit renewal.

> **Recommendation 5-5: Each project manager should initiate a project "charter" at the time of the 'call-in letter', and should complete that charter by the time a complete permit renewal application is received. A project charter structure will direct the project manager to consider and plan for all project variables, and should address:**
> - **the significant objectives to be addressed;**
> - **what is "in scope" and "out of scope" for the action;**
> - **the specific deliverables that will be produced;**
> - **the estimated effort, cost and duration of the effort;**
> - **the required project team and what roles they will have;**
> - **the communications plan for the project team;**
> - **the stakeholders and any role they will have;**
> - **the renewal project assumptions, constraints, threats and necessary approvals.**
>
> **The charter will help in structuring the project team and in development of the project plan.**

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[32] A Project Charter is a document issued by the project initiator or sponsor that formally authorizes the existence of a project and provides the project manager with the authority to apply organizational resources to project activities. It often includes scope, deliverables, a timeline, stakeholders and other relevant project information.

Recommendation 5-6: Immediately after completion of a charter, the project manager should develop and post a project plan for each renewal. The project plan should show all major tasks, and a timeline for completion of each. This project plan should be reviewed and approved by a supervisor and a team lead for that type of renewal.

Implementation of the following additional process management best practices will also assist:

Recommendation 5-7: Develop a standard lexicon of terms regarding permit renewal actions, so terms such as Notice of Deficiency are not used during Administrative Review, and so that a common, standard process is consistently described in all departmental communication.

6) Stakeholder Attitudes

Introduction

As a part of the assessment of the existing DTSC Permitting Process, stakeholder attitudes were assessed through structured interviews (individual and small group interviews) and a survey. There was an intended overlap between the two, and the survey was primarily intended to obtain feedback from those who did not or were unable to participate in interviews.

Since this study was commissioned to answer several specific questions it was decided that questions should begin with the principal areas of investigation, although several questions outside the scope of the primary investigation (such as financial assurance) were added. The questions were viewed as a means of developing the reasonable expectations for permitting, to see whether shared expectations exist within various interest groups, and to evaluate the additional areas. The following questions were developed by CPS HR consultants and project advisors to achieve that purpose:

- What should the permitting program accomplish?
- How well is the permitting program meeting those expectations?
- What is working or is not working with the permitting process?
- Provide specific examples of what is working or is not working.
- What should be the criteria for denying or revoking a permit?
- How should the permitting and enforcement programs inter-relate?
- Is financial assurance being adequately addressed?

The DTSC Office of Communications provided public contact lists as a starting point, and Advisory Committee members helped consultants to identify the stakeholders to be invited to reflect a balance of different program interests. In all, 41 persons were identified in three broad categories (A full list is provided in Appendix I). A total of 21 persons were identified as representatives of community involvement and environmental organization. This group is referred to as "Public Interest/ Advocates" in this report. A total of 10 persons were identified as representatives of permittees or the waste disposal industry, and lobbyists or attorneys were included in this group. This group is referred to as "Industry/ Lobbyist". A total of 10 additional persons were identified who represented "General/ Government" including past DTSC officials (including two previous Department Directors) Federal EPA, two Certified Unified Program Agencies (CUPA), and several former legislative staff persons familiar with the issues.

The project team (CPS HR consultants working with the two Advisory Committee members) first attempted to schedule the interviews in five separate focus groups by interest group and in regional areas, and invitations were sent to all participants. Originally this was planned to include an Industry and Lobbyist focus group in Sacramento on June 3; a Public Interest/ Advocate group in Los Angeles on June 5; another Public Interest/ Advocate group in the Bay Area on June 10; and a "legislative and regulatory" group in Sacramento on June 3. Due to low response rates, CPS HR canceled the focus groups and instead invited stakeholders to participate in individual or small group interviews, most of which were conducted by telephone conference call. All identified stakeholders were contacted via email using an email template to standardize communications. Follow-up emails were sent or phone calls made to those stakeholders that did not respond to requests for participation.

Ultimately, 22 of the 41 invited responded, including nine from the Public Interest/Advocate group, seven from the Industry/Lobbyist group, and six from the General/Government group. With the exception of one focus group held at the CPS HR Offices in Sacramento on June 3, which involved four Industry/Lobbyist representatives (three in-person and one by phone), and separately three individual in-person interviews, the remaining stakeholders participated in individual or small group telephone interviews. The three in-person interviews were conducted with the former Department Director on May 15; the former Acting Department Director on May 21; and with a Consumer Advocate, on June 5. The full list of participants is provided in Table 3.

Table 3: Stakeholder Interview Participants

Stakeholder Category	Stakeholder Name	Interview Date
Public Interest/ Advocates	Luis Olmedo	6/3/2013
	Liza Tucker	6/5/2013
	Ingrid Brostrom	6/11/2013
	Bradley Angel	6/17/2013
	Maricela Mares-Alatorre	6/17/2013
	Denise Duffield	6/26/2013
	Martha Dina Aguello	6/26/2013
	Daniel Hirsch	6/26/2013
	Andres Soto	6/27/2013
Industry/ Lobbyist	Bob Hoffman	6/3/2013
	Chuck White	6/3/2013
	Peter Weiner	6/3/2013
	Bob Lucas	6/3/2013
	Phillip Retallik	6/20/2013
	David Nielson	6/20/2013
	Bob Brown	7/2/2013
General/ Government	Maureen Gorsen	5/15/2013
	Maziar Movassaghi	5/21/2013
	Gale Filter	5/28/2013
	Mohsen Nazemi	6/7/2013
	Ed Lowry	6/7/2013
	Caleb Shaffer	7/19/2013

Interview Responses and Analysis

The interview responses, separated by stakeholder group, are summarized herein.

Section 1: Summary of Input from the Public Interest/Advocate Group

According to the activists group, DTSC's permitting program should accomplish safe management of hazardous waste in California. They expressed that DTSC should exercise its authority in order ensure protection of public health, safe disposal and equitable management of hazardous waste.

Related to how well the permitting program is meeting those expectations, the consensus was "not well." Points to support this view include a perceived strong bias towards industry at the expense of public health, facilities operating without permits or in interim status, a perceived lack of adherence to law, failure to consider cumulative impacts and a lack of transparency and poor communication with the public. Multiple stakeholders in this group expressed the view that DTSC does not fully leverage the authority they are granted and that the industry holds the strongest position of power in the process[33].

When asked what is working well with the permitting process, most of these stakeholders did not have any input, although it was mentioned that it is better to have facilities permitted than not, even if the process is flawed. Regarding what is not working well, their comments focused on: the ties that current or former DTSC employees have to industry; a public process that is ineffective; health concerns in burdened communities; perceived incompetence of DTSC staff, and; subpar data systems (e.g., EnviroStor). Their recommendations included implementing timelines for permits, changing the fee structure for permits, and adjusting the ebbs and flow of the work cycle by staggering the length of permits based on set standards.

Multiple examples were given of what is not working in the permitting process, including the following:

- *Santa Susana Field Laboratory (SSFL).* Discussion revolved around the influence of Boeing (owner of SSFL) on DTSC. Examples that were given included a workgroup (that included agencies and community members) that was dissembled by DTSC and replaced by a group with Boeing representatives taking the place of community members. Discussion included past illegal behavior on the site allowed to occur by a perceived lack of enforcement, resulting in an explosion and worker deaths. Additionally, previously agreed upon clean-up agreements for contamination at the site were changed; advocates felt this occurred based on Boeing's influence over DTSC[34].

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[33] Issues relative to the function or authority of the Department as a whole are beyond the scope of this report, except to note the unanimity of opinion on this issue, from the Public Interest/ Advocate Group.

[34] DTSC officials explained that this site was a former rocket and nuclear energy experimentation facility operated by the US Department of Energy and Boeing's predecessor, Rocketdyne, and that it had hazardous waste storage and surface impoundment units under a permit at one point in time. They stated that surface impoundments have been closed and are now under a post closure permit. One of the permitted storage areas was in DOE's operational area and has yet to go through the "closure" process. All of these regulated activities are currently being wrapped together into the Cleanup

- *Kettleman Hill Landfill.* Discussion revolved around the opinion that DTSC does not put enough consideration into the cumulative impact on the vulnerable community of Kettleman City during the permitting process. An example was given of an insufficient Environmental Impact Report (EIR) conducted by the county during the CEQA process that DTSC accepted instead of developing a new EIR.
- *Exide Technologies – Vernon Plant.* The facility was given a corrective action in 2002 that was never put in place.
- *Phibro-Tech.* The facility has operated for 16 years on an expired permit, did not follow corrective actions required by DTSC, and fought financial assurance requirements.
- *Western Environmental, Inc. – Mecca Facility.* The facility operated without a valid RCRA hazardous waste permit without DTSC's knowledge; activists felt this demonstrated a clear lack of communication within the department.
- *Casmalia Resources Hazardous Waste Management Facility.* The facility was closed after community protests. Inadequate financial assurance led to tax dollars paying for a large part of the closure.

When asked about the criteria for denying or revoking permits, the activists were in agreement that minor permit violations (e.g., issues with paperwork) should not lead to serious consequences but serial violators should have their permits denied or revoked (e.g., 2-3 serious violations that have potential to impact public health). Suggestions included putting more emphasis on cumulative impacts, past compliance issues and financial liability. Activists discussed strict fines for violators and a consistent, quantifiable formula for DTSC to follow when deciding whether to deny or revoke permits; they felt it should not be left up to the discretion of individuals and should follow the law.

Regarding the inter-relation of the permitting and enforcement programs at DTSC, activists felt efficiency could be increased by improving communication between the programs. A specific suggestion inferred if permit operating conditions could be made very clear and adjusted to fit the patterns of behavior, it could improve coordination between the permit writer and the enforcer. Additional discussion on the topic focused around the poor job many felt both programs were doing (i.e., weak, polluter-friendly, and lax).

Discussion on financial assurance focused on ensuring that publicly funded money is not used for clean-up if or when DTSC fails to require adequate financial assurance from facilities. Suggestions included adjusting financial assurance for inflation each year, considering the enforcement history of a facility when determining appropriate amount of financial assurance, always requiring financial assurance when a corrective action order is in place, and not adjusting clean-up costs or fines for a facility based on their financial situation.

Program's site investigation and cleanup processes, and as part of their process they intend to complete the administrative requirements of closure or post closure along with the cleanup certification.

Section 2: Summary of Input from Industry/ Lobbyist Group

According to the industry/lobbyist group, the permitting program should allow for the ability to get a permit within a reasonable period of time if the company is meeting the law and other standards. Additionally, the program should ensure there are sufficient permitted facilities to handle California's hazardous waste and manage the permitting process with specific timelines for actions. Group representatives believe that the imposition of specifications beyond what is required by law should not be arbitrarily imposed, and should be justified by the need to protect human health and environment.

It was expressed that the permitting program is not meeting these expectations and that something in the process is fundamentally flawed. Facilities should no longer be operating under interim status and DTSC is not anticipating workload well based on permit renewal dates.
No timelines exist that hold employees accountable for making timely decisions.

When asked about what is working well, it was mentioned that some permit writers put forth great effort and that the process for smaller or less controversial facilities is adequate (though it still has room for improvement). Some, but not all, in the industry/lobbyist group did feel that the new reorganization of DTSC is a step in the right direction and is designed for accountability and consistency. Regarding what is not working well, the discussion focused on DTSC allowing unreasonable opposition to permits that is not based in science or law, political issues (e.g., Director being a political appointee), a lack of consistency between permitting process for different facilities, personnel issues (i.e., permit writers not suited for the job and not being rewarded for success - only punished for failure), and a lack of support from other programs or offices within DTSC (e.g., legal). A steering committee was recommended to track progress and help lower level employees like permit writers or technical experts clear obstacles and make decisions. Other recommendations included focusing on statute and regulations only, contracting out the permitting program, and implementing the Federal program and switching all states to a "permit by rule" system (requires facilities to have plans on file for inspection rather than approved beforehand).

Examples were given of permits tied up in legal processes for years without "justifiable" reasons. Other examples of what is not working well included:

- *Kettleman Hills Landfill.* EPA has stated that there is no harm to human health and the environment at the facility yet the permitting process is delayed based on concern expressed by the public.
- *Exide Technologies – Vernon Plant.* The facility serves as an example of when a permit should be revoked; it is on an interim status permit and has numerous air quality, solid waste and hazardous waste issues.

When asked about the criteria for denying or revoking permits, the permittees and representatives expressed that this should occur when permit holders do not abide by the state required criteria. Other suggestions for denying or revoking include if the permit applicant does not meet administrative completeness, previous compliance issues exist, or if financial unpinning falls apart. It was recommended that criteria are laid out clearly and decisions be based on science and law instead of emotion.

Regarding how the permitting and enforcement programs should inter-relate, two points of view were discussed. On one hand, they feel it is important for the two programs to be able to speak the same language for efficiency's sake; it was also expressed that not contaminating each process is important.

Discussion around financial assurance focused on the fact that despite past issues, financial assurance is required currently and is evaluated annually. Examples were given of facilities that closed with costs even less than what was posted via financial assurance. A suggestion was made that DTSC contract out the financial assurance function of the permitting program to an entity that possesses the appropriate knowledge on the topic.

Section 3: Summary of Input from General/ Government Group

When asked what the permitting program should accomplish, the general/ government group representatives stated that it should identify lawful behavior and give very clear guidance about lawful operating conditions and what is required of the permitted facilities. Other expectations include coordination with other permitting and regulatory agencies and suggestions for timelines that other agencies follow were given. Regarding how well the permitting program is meeting these expectations, the answer was "not well"; though many public agency representatives did not feel comfortable answering this question because they think they are too far removed from the current process.

No comments were provided about what is working well within the permitting program. Related to what is not working, public agency representatives mentioned unclear language in permits, lack of incentives for facilities to obtain current permits, a lack of clarity about roles of various regulating agencies, and inconsistencies in databases across agencies. Multiple issues around institutional design were presented with the point made that the current design does not lend itself to swift decision making. Discussion centered on internal power struggles within DTSC, a lack of accountability and responsibility for outcomes and limited career ladders that lead to too many employees in management (i.e., promotions are made to retain employees because there are only two levels of scientist positions).

Multiple examples of what is not working with the permitting program were provided, including:

- A property had contamination when a new owner bought the land for storage of equipment and was told he would not be culpable for the clean-up; 15 years later he received a bill for $800,000 from DTSC. The culpable person was no longer alive and able to fund the clean-up. The amount of money that had accrued was only from DTSC reviewing the information, no active steps or physical work to clean up the site had occurred.
- A consultant developed a scientifically sound plan to remediate the contamination for a strip mall project, spending $30,000 to build the plan. Following, DTSC spent 18 months reviewing the plan. Fifty hours a week for 18 months was charged by DTSC to review the 30 page document, resulting in a total fee of $180,000 for the review. Thirty three DTSC employees reviewed the same document.

- Examples were given of how different regulating agencies within California do not know what the other agencies are doing and of DTSC holding facilities to different standards than other permitting or regulatory agencies in CA.

When asked about the criteria for denying or revoking permits, public agency representatives suggested categories of standards that would lead to denial or revocation (e.g., one imminent endangerment to environment or community, three serious violations, or numerous violations that are not serious). The difference between the two concepts was also discussed. It was suggested that denial of a permit should be dependent on a holistic analysis around protection of the public from exposure or releases and revocation of a permit should be the result of a history of not being able to comply with important permit conditions.

It was expressed that permits should be written to be clear and enforceable but there were differing opinions regarding how the permitting and enforcement programs should inter-relate. Discussion included the idea that one program should be handling both functions as well as that permitting and enforcement should be completely separate from one another to allow due process.

Regarding financial assurance, public agency representatives commented that DTSC has not always pursued financial assurance fully, that assumptions do not always appropriately take into account catastrophic events and many smaller companies would not have the resources to cover clean-up.

Survey Responses

In order to capture the largest amount of stakeholder input within time and resource restraints, the entire group that was invited to participate in focus groups or interviews was offered the opportunity to complete an attitude survey regarding the permitting program, and offer open-ended comments as a part of that feedback. The survey questions were developed by the CPS HR consultant and designed to assess overall stakeholder attitudes on the current permit processes, and issues relevant to this study.

A five point Likert scale was used to assess the scaled response section, which included the first eight statements of the survey:

- 1 = Strongly Disagree
- 2 = Disagree
- 3 = Neither Agree or Disagree
- 4 = Agree
- 5 = Strongly Agree.

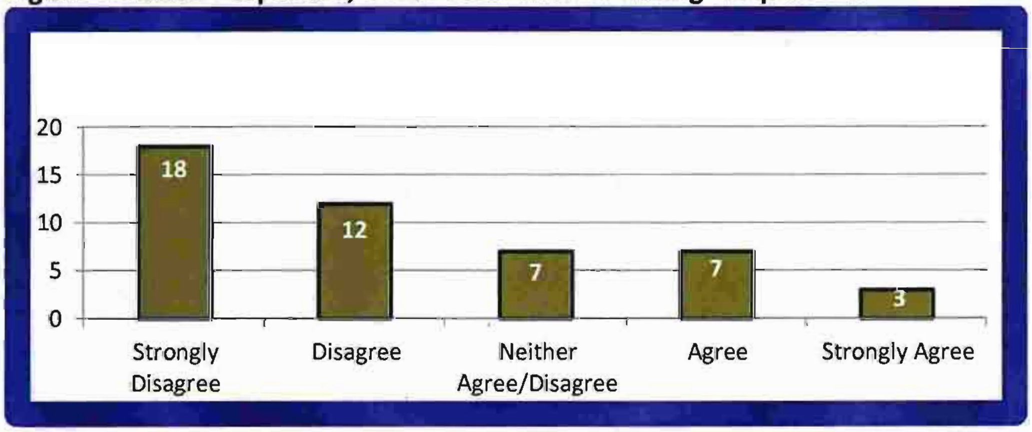
CPS HR utilized an online software tool, Qualtrics, to develop and administer the survey. Qualtrics allowed respondents to access the survey through a web link, sent via e-mail. The survey invitations were sent following the interview sessions with each participant. Respondents were given a due date of June 15, 2013. The full online survey is located in Appendix J.

Results

At the conclusion of the data collection period, of the 41 stakeholders who were invited to complete the survey, two in the Industry/Lobbyist group and two the Public Interest/ Advocate group had completed the survey in addition to two partial completions by uncategorized stakeholders. The data was analyzed and results are reported as an aggregated summary to ensure confidentiality.

Despite the small size of the respondent group, the results seemed to conform to the tone and content of the focus groups, and the formal scale for response added an objective satisfaction measure to amplify the meaning, and to give the Department a formal basis to track any future changes that may occur. Primarily for these reasons, the results (even though based on a very limited sample size) are provided below. As can be seen in Figure 4, the survey respondents largely disagreed with the statements, indicating overall dissatisfaction with the current permitting process.

Figure 4: Scaled Responses, Overall Stakeholder Rating Frequencies



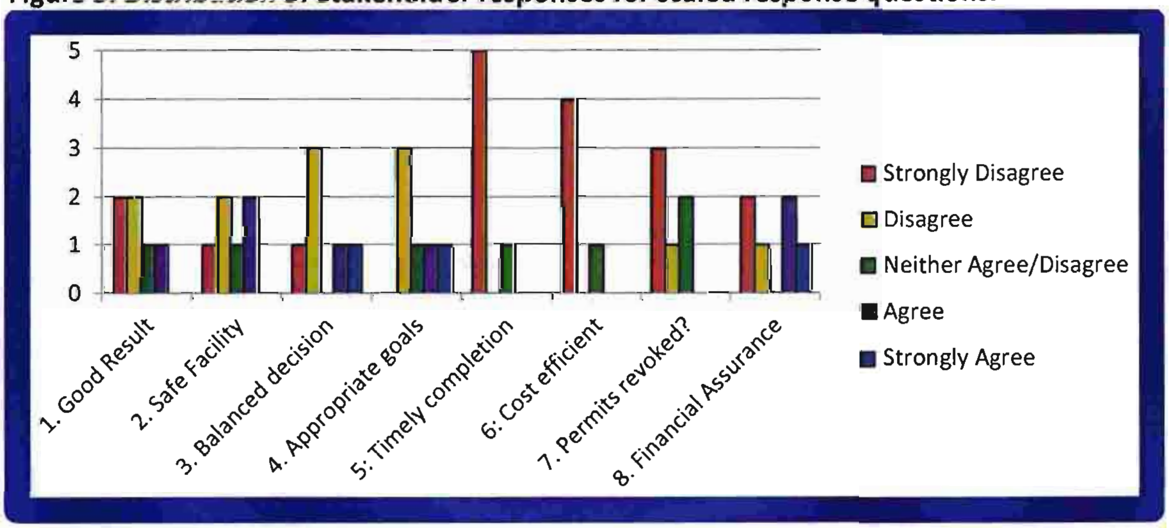
As demonstrated in the distribution of responses for each of the questions, documented in Table 4 and Figure 5 below, the stakeholders were most dissatisfied with the cost and length of time it took to complete the permit process. Additionally, they did not feel that permits were revoked as needed or that the overall process ended with a good result.

The failure to obtain what is perceived as a "good result" may be the most concerning, since a fundamental statutory role of the Department is to protect the health and safety of the public, and to protect the environment, but there are no objective measures to show success in these areas. As a result, the quality of the permitting work depends on the positive perception of those attributes by stakeholders, which does not now exist.

Table 4: Distribution of responses by Question

Survey Question	Strongly Disagree (1)	Disagree (2)	Neither Agree or Disagree (3)	Agree (4)	Strongly Agree (5)	Average (SD)
1) Most times the permitting process produces a good result.	2	2	1	1	0	**2.17** (1.17)
2) Most times the end result of the permitting process is a safe facility with an enforceable permit.	1	2	1	2	0	**2.67** (1.21)
3) Permit decisions show an appropriate balance between community needs and regulatory requirements.	1	3	0	1	1	**2.67** (1.51)
4) I think the DTSC permit program has appropriate goals.	0	3	1	1	1	**3.00** (1.26)
5) The permitting process is almost always completed in a reasonable period of time.	5	0	1	0	0	**1.33** (0.82)
6) The permitting process is almost always completed at a reasonable cost.	4	0	1	0	0	**1.40** (0.89)
7) Permits are revoked when necessary.	3	1	2	0	0	**1.83** (0.98)
8) Financial assurance is being adequately addressed.	2	1	0	2	1	**2.83** (1.72)

Figure 5: Distribution of Stakeholder responses for scaled response questions.



Analysis of All Stakeholder Comments

Despite a diversity of opinions gathered in this process, an unanimity of opinion exists in several key areas. All three groups reported similar ideas that permit revocation or denial should be based **only** on 1) the presence of a clear, documented threat to public safety, human health, or environmental preservation OR 2) failure to meet a pre-determined set of clearly defined and measurable criteria after a holistic analysis of the facility. Many respondents endorsed the idea that permit revocation or denial should be based on the total number of violations, abidance with laws/regulations, compliance with corrective actions (current and historical), and availability of financial assurance in the event of closure. Just as importantly, none argued against these ideas.

Ironically, both the Industry/Lobbyist group and the Public Interest/Advocate group felt that the Department's decisions are unduly influenced by the other, and that they do not get what they perceive is fair and equitable treatment.

Other suggestions endorsed by many stakeholders were to:

1. Create clear, objective, and measurable criteria for making denial/revocation decisions so they are based on facts of science and law and not on emotion or individual discretion. For example, have three class 2 violations equal a class 1 and three class 1 violations result in immediate revocation of the permit.
2. Identify appropriate process timelines and enforce them.

In addition to these two general areas of improvement, the Public Interest/Advocate group representatives also made the following suggestions:

- Add specific measurable environmental parameters for air, soil, and water conditions to the permit process and make that information available and understandable to the facilities and to the public utilizing a system that is easier to use than Envirostor.
- On the Administrative side, change the fee structure for permits and stagger the permit lengths to adjust and balance the ebbs and flows of the work cycle.
- Personnel procedure suggestions included reducing the amount of Management staff by offering incentives other than promotion to retain staff, cross training permitting staff and enforcement inspectors and providing better permitting training overall, and eliminating the ability for lobbyists/lawyers to go above regulators heads to upper management to complain about permit conditions/stipulations.

The Industry and Lobbyist group representatives identified the following additional suggestions:

- Re-emphasize to DTSC permitting staff that the goal is to ensure enough authorized facilities to handle California hazardous waste, not trying to prove fault with a facility. The permitting process is a collaboration with the Hazardous Waste facilities – the facility should not be treated as the opposition.
- Focus on ensuring that facilities understand and follow statutes and regulations without imposing extra requirements unless they are clearly linked to the preservation of human health, public safety, or the environment.

- Create a steering committee to track permit progress and help permit writers/technical experts clear obstacles and make decisions to avoid unnecessary holdups in the process.
- Contract out permitting or implement a Federal program to switch to a "permit by rule" system.
- Analyze the reasons for requirements imposed on some facilities that are beyond statutes and regulations and if there is no concrete, objective reason related to the preservation of public safety, human health, or the environment – eliminate the excess requirements. Additional requirements beyond statutes/regulations should not be assigned by independent discretion.

Overall, the three groups presented similar ideas of permitting goals, current deficiencies, and future improvements with each group being focused on a slightly different viewpoint[35]. The Public Interest/ Advocate Group focused on the result of the permit process and provided multiple examples of permit processes with negative repercussions to the community, public, or environment. The Industry/Lobbyist Group was more focused on the process, length of time of the permitting process, and the road blocks within the process rather than what occurred after the permit was received. The General/Government Group focused on a combination of the two addressing some specific negative repercussions but mainly focusing on obtaining the most efficient process.

Many of the specific suggestions provided do not have any associated logic or analysis to support their believed benefit. For example, the opinion of the public interest/ advocate group that "reducing the amount of management staff" would have a beneficial effect is contrary to the analysis of this study, and without its own justification. Likewise, the results of this study indicate an unlikely benefit for the suggestion of some industry/ lobbyist group representatives to "create a steering committee to track permit progress and help permit writers/technical experts clear obstacles and make decisions."

The most meaningful shared stakeholder concerns include:

1. The need to create clear and objective criteria for making denial/revocation decisions that are based on valid standards of performance and threat;
2. A standard for violations that would lead to a denial or revocation;
3. The need for the department to document and measure a scorecard of attributes that would be perceived as a "good result" for the permitting program;
4. The need to identify and measure appropriate process timelines, and;
5. The need to document, maintain and implement effective financial assurance standards.

Findings and Recommendations

This section provides further analysis of several areas of common belief discovered (as noted above) during the stakeholder analysis. This further analysis was undertaken at the request of the project advisors, as a means of providing further direction to the Department in Permitting Program

[35] A table summarizing and comparing the responses from the three groups is available in Appendix K, with the entirety of the Raw Comments in Appendix L.

improvement. This analysis was based on additional interviews with Department officials and document review.

- **Finding:** The Department does not have clear and objective criteria for making denial/revocation decisions that are based on valid standards of operational performance and threat. Two significant and related factors are that there are no clear and objective standards for violations that would support a decision to deny or revoke a permit; and there is no standard for denial or revocation based on three issued Notices of Deficiency. These problems should be resolved.

  Recommendation 6-1: The Department should develop a new system of categorizing violations that reflects whether they present an immediate and direct threat to human health and safety, versus a less urgent threat that can be mitigated or resolved through further actions of the Department. The Department's current definition of "Class 1 violations", although mandated by law, includes both violations that pose immediate and direct threats along with many that are relatively low- or long-term threats. Until the Department has a system of violations that can distinguish between significant threats to human health and safety and lesser threats, it will not be able to provide an objective standard to guide its own staff actions and to inform the public that the significant threats have been mitigated through actions such as permit modification, denial or revocation.

Discussion: The current legal definition of Class 1 violations is contained in HSC 25110.8.5 (a), and includes language that defines significant and imminent threat (in sub-paragraph 1), along with language that better defines relatively low threats (in sub-paragraph 2). Sub-paragraph (2) includes any "deviation (that is) significant enough that it <u>could</u> result in (a significant threat)."[36] This overly-broad definition has inhibited the public perception of high-threat violations that need appropriate action by the Department. This deficiency could be addressed in a number of ways. Perhaps most directly, the Department could work collaboratively with the California State Legislature to revise the definition in law. But the Department should probably first have a firm definition of its preferred language, and that could be developed through creation of its own advisory standards as a first step. Such advisory standards may need to define both a threat standard and an operational behavior standard that reflects the most significant threats, and to distinguish those from events that might only represent a single indicator or operational deficiency, or an event that needs short-term correction to mitigate a possible threat. Three other states – Arizona, Alabama, and Florida - as recommended by EPA, were briefly reviewed as a comparative reference to California's processing. One of the discoveries was a detailed violation matrix from Arizona, which has been partially replicated in Appendix N as a potential starting point for discussions and the creation of defined violation categories. Additional information on these three states is available in Chapter 8, pages 95-96.

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[36] The current Violation Regulations definitions are provided in full in Appendix M.

A closely related issue is in regard to a mistaken public understanding regarding a legal requirement that a permit be cancelled or revoked after issuance of three Notices of Deficiency during a permit renewal cycle.

- **Finding:** There is currently no defined requirement that the Department "initiate proceedings to deny the permit application" unless the applicant either: 1) "does not respond" in a timely manner, or: 2) Responds with substantially incomplete or substantially unsatisfactory information on three or more occasions." In other words, it is commonly misunderstood that the Department should or must act to deny a permit after three Notices of Deficiency.

  Recommendation 6-2: The Department should distinguish between Notices of Deficiency that are prejudicial from those that are not, with grounds for prejudice being defined by the language in HSC 25200.8, including "substantially incomplete or substantially unsatisfactory information", or an untimely response. This change should be pursued as a change to Administrative Law. (The definition of "prejudicial" in the context of this recommendation is that an action to revoke a permit or renewal action would be <u>required</u> after a maximum of three such actions.)

Discussion: The Notice of Deficiency is a notice used during technical review of a permit application, to clearly instruct the applicant regarding deficiencies in their proposed Part B application and/or Operational Plan. A broad misunderstanding of the significance of issuance of three or more of such Notices has created unnecessary controversy and concern, affecting the belief and actions of DTSC workers and the interested public. The Department should clarify those instances where responses to such letters are accepted with prejudice, to communicate both to the applicant and to the public that a breach of good faith has taken place.

During discussion of both of these issues with the Deputy Director for Hazardous Waste Management and the Chief of Enforcement, there was agreement that the lack of an adopted threat standard for permitting actions is also a significant inhibitor of one of the primary stakeholder criteria for the denial or revocation of a permit: "the presence of a clear, documented threat to public safety, human health, or environmental preservation." The current Chief of Permitting also agreed that this is a significant program constraint.

The Federal EPA representative stated that EPA does have a risk standard that could be used by DTSC. Project Advisor Bill Magavern agreed that DTSC should articulate a standard for the presence of a clear, documented threat to public safety, human health, or the environment, and supported the use of USEPA's one-in-one-million cancer death risk standard. But he also advised that the Public Interest/Advocate group would not support over-reliance on risk assessments, because they can be manipulated to justify a predetermined result.

Recommendation 6-3: DTSC should develop and adopt a risk standard for permitting, consistent with stakeholder input that the program must have a standard to demonstrate a clear, documented threat to public safety, human health, or environmental preservation, as a primary driver of appropriate permitting action.

It is noted that many stakeholders support imposing a limit on the length of time and the conditions under which a facility can operate on an interim permit, to eliminate situations where facilities continue for many years on expired permits – even though it is legal to do so as long as the permittee has submitted a timely and complete application within 30 days or more prior to the expiration date of the previous permit[37]. Most persons who advocate such a standard agree that it should not be imposed when permittees are operating in good faith and encounter unanticipated delay, but only where there is a lack of good faith or an unresolved threat to public health and safety. The adoption of Recommendations 6-1, 6-2, and 6-3 will reduce the possibility that such "bad faith" and high risk facilities will be allowed to operate for many years on expired permits. Study Advisor Thomas McHenry notes that there is nothing inherently bad about an expired permit associated with a permit renewal – and that often such extensions of time are allowed only with additional limitations on the facility that are viewed as necessary to protect the public.

Financial assurance was a subject of strong interest among both the Public Interest/ Advocacy group and the General/ Government Group. The Industry/ Lobbyist group was not opposed to the maintenance of appropriate financial assurance, but felt that an appropriate standard now exists. The shared hope is that permitted facilities set aside and maintain sufficient financial capacity to ensure publicly funded money is not used for clean-up and closure.

To best document current practice, consultants scheduled an Aug. 1 interview with the Division Chief for Policy Implementation and Support, and the Financial Responsibility Unit Manager. They stated that the Financial Responsibility Unit is charged with securing an appropriate financial mechanism for each permittee, and ensuring that it is enforceable by the Department. However, they are not involved with the cost estimate, and rely on the Permitting Project Manager to provide the correct amount.

The Financial Responsibility Unit Manager stated the Financial Responsibility Unit conducts a Financial Assurance Review regarding any permit action only on the request of the Permitting Project manager, and will make sure that the required financial commitment is available, and matches the cost estimate plus inflation.

The current Permitting Chief stated that it is Department policy to obtain and review the sufficiency of Financial Assurance at the time of permit or permit renewal, with allowance for annual cost adjustments to reflect future inflation. He stated that Permitting requires each applicant to provide a clean-up estimate prepared by a third party, and that should be reviewed and accepted by the Project Manager. However, he acknowledged there is no specialized staff to perform this function in Permitting, and that not all cost estimates are reviewed at this time due to insufficient staff to perform required tasks[38]. He also acknowledged that Department policy of updating Financial Assurance cost estimates every five years for existing permittees is also not achieved due to a lack of staff.

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[37] CA Code of Regulations, Title 22, Section 66270.51.

[38] Comments provided in an Aug. 21 telephone interview with R.Mallory, CPS HR Consulting.

As a result, it is a finding of this report that Department policy with regard to financial assurance is not being achieved, and that action should be taken to do so.

> **Recommendation 6-4: Expand the specialized staffing of the Financial Responsibility Unit to allow for its independent review of clean-up costs and financial assurance obligations, and require sign-off prior to permit renewal. Require compliance with Department policy to update financial assurance every five years. As an interim measure, DTSC should contract out the financial assurance function of the permitting program to an entity that possesses the appropriate knowledge on the topic.**

It is noted that all participants agreed that the Permitting Office should establish reasonable timelines for each stage of the permit process and hold staff accountable for meeting these deadlines. While this recommendation seems to have merit, it is not based on a finding that there is either sufficient staffing to accomplish this work, nor a "best practice" process to follow to achieve any reasonable timelines imposed. Given the likelihood that systemic barriers may inhibit the accomplishment of these goals, and the elimination of systemic barriers is the job of management, it does not make sense to impose consequences for failure ("accountability") on the hazardous waste engineers who serve as the primary staff persons responsible for permitting actions.

7) Employee Attitudes

Introduction

As a part of the assessment of the existing DTSC Permitting Process, a survey was created to obtain an overall perception of the current processes from current employees. The survey was designed to obtain information in three segment areas of inquiry. The first area assessed the overall timeliness, effectiveness, and clarity of the existing permitting process. The second area focused on more specific aspects of the permitting process and work environment. This included assessment of the workload and staffing levels, Permitting organization and management, work environment, worker commitment, and overall quality of the permit. The third area provided respondents an opportunity to provide general feedback, identify existing barriers, identify ways to assist project managers, and identify ways to make their job easier through 4 open-ended questions.

The first two areas, encompassing questions 1 to 64, utilized a five point Likert-type scale using the following scale anchors:

- 1 = Strongly Disagree
- 2 = Disagree
- 3 = Neither Agree or Disagree
- 4 = Agree
- 5 = Strongly Agree.

In the event that the respondent felt that the statement did not apply to the permitting processes at DTSC, a sixth rating scale option, "Not Applicable", was also provided.

While the interpretation of favorable versus unfavorable scores on surveys of this type is subject to professional judgment, we have accepted that scores of 2.8 and lower identify areas that have a strong need for attention. Scores of 2.81 to 3.2 are regarded as mediocre but not necessarily actionable. Scores from 3.21 to 3.8 are regarded as good. Scores of 3.81 and above are considered excellent, and composite scores of 4.51 to 5.0 are almost never seen, since most participants will always see room for improvement.

In addition to the 64 statements and open-ended questions, the participants were asked to identify their location from the following: Sacramento – Cal Center; Sacramento – Headquarters; Chatsworth; Berkeley; or Decline to State; and to indicate whether they were in a supervisor/manager position or not. This reported distinction between the two classification levels will be referred to as supervisorial and non-supervisorial.

CPS HR used the online software tool, Qualtrics, to develop and administer the survey. Qualtrics allowed respondents to access the survey through a web link, sent via e-mail. The surveys were sent on April 9, 2013 to 25 DTSC employees, requesting their participation and response by April 19, 2013. The full survey is presented in Appendix O.

At the conclusion of the data collection period, 20 of the 25 invited respondents had completed the survey. A total of five of all respondents identified themselves as supervisory/managerial positions, representing 25% of the total. The data was analyzed and results are reported as an aggregated summary to ensure individual response confidentiality.

Process Segment Analysis

The first area, encompassing questions 1 to 24, asked the same six questions about each of the four permit process segments, as defined below and depicted in the flowcharts presented on pages 36 to 39.

- **Administrative Review:** This process segment begins with initiation of a permit request, through submission of the Part A and Part B Applications, up to the Notice of Administrative Completeness.
- **Technical Review:** This process segment begins after Notice of Administrative Completeness and covers the review process up to sending a Technical Completeness letter, and completion of the "final" draft permit and CEQA documents.
- **Public Comment:** This process segment begins with the public notice of decision through any public hearing and a final Permit Decision.
- **Appeals Process:** This process segment begins with a Permit Decision to Completion of Permit Appeals Process.

One of the primary design elements of the survey was to obtain a structured and objective feedback from all Permit Office employees regarding the timeliness, effectiveness, and clarity of the existing permitting process overall and within each process segment. This was done using the Likert-type scale with the same six questions for each segment. The average rating for each of the questions by process segment is presented in Table 5.

Table 5: Average employee perceptions of Permitting Process

	Administrative Review	Technical Review	Public Comment	Appeals Process	Overall
1. DTSC follows a clear, standard process.	3.55	3.2	3.8	3.33	**3.47**
2. There are clear decision criteria.	3.4	3.2	3.55	3.00	**3.29**
3. This process segment is almost always completed in a reasonable period of time.	3.55	2.45	3.55	2.78	**3.08**
4. There are no "grey areas" in processing.	2.8	2.45	3.3	2.33	**2.72**
5. Most times this process segment runs well.	3.6	3.05	3.5	3.11	**3.32**
6. Most times this process segment produces a good result	3.55	3.3	3.45	3.44	**3.44**
Segment Average	**3.41**	**2.94**	**3.53**	**3.00**	**3.22**

While the overall score of all attributes of all process segments was 3.22 – at the bottom of the range that is considered "good" – there are several areas that ranked at 2.8 and below and are therefore targets for immediate action. The lowest ranked process segment was Technical Review, with a 2.94 "mediocre" overall score. Two areas of technical review received the lowest scores, with an average rank of 2.45 indicating a strong need for attention, and those were:

- "This process segment is almost always completed in a reasonable period of time"
- "There are no grey areas in processing."

While permitting employees believe there is a "clear standard process," and ranked that at 3.47, respondents still felt that there are grey areas in all segments, and ranked that overall at a negative and actionable at 2.72.

> **Findings:** Employees clearly feel there are grey areas in all process segments, and that these are worst in Technical Review. Permitting employees believe that "Technical Review" is the most problematic process segment. The 2.72 scoring of "grey areas" in all process segments supports a finding that the permitting process is not predictable, and needs improvement. It is reasonable to believe that the existence of grey areas directly contributes to delays and delays in processing.

Permitting Mechanisms and Work Environment

The second area of inquiry, encompassing questions 25 to 64, examined specific components of the permitting process and environment. This area had three sub-areas to break the questions into related items, as follows:

- Time, Resources, and Management Actions – encompassing questions 25 to 34.
- Permit Staff Workplace and Appreciation – encompassing questions 35 to 59.
- Permit Best Practices(Permit Quality) – encompassing questions 60 to 64.

Most actionable areas in the survey are revealed by looking at the lowest rated questions, and the following table shows the 15 lowest scores, overall, excluding the process segment responses shown above. The Time, Resources, and Management and the Permit Staff Workplace and Appreciation sub-areas had seven statements each in the bottom 15, with only one low rated statement from the Permit Best Practices.

Table 6: Lowest Rated Statements in Permitting Mechanisms or Work Environment

Question	Mean
43. Tools and guidance available for the permitting process are current.	2.05
25. Staffing resource levels are adequate for the job we are asked to do.	2.16
32. Permit actions do not suffer from inconsistent direction.	2.26
30. Project managers usually do not experience unnecessary delays due to the decision process within the Department.	2.42
27. Project managers are able to get subject matter expert review in a timely manner.	2.47
54. For most of the permit renewals I have worked on over the past two years, community representatives have assisted in making the process run smoothly.	2.56
42. Project managers are given sufficient training.	2.58
47. Management does a good job setting clear program goals and priorities.	2.63
33. Envirostor is making permit work harder.*	2.74
57. For most of the permit renewals I have worked on over the past two years community representatives have contributed to intelligent, appropriate decision making.	2.78
26. Project managers have sufficient time to give continuing focused attention to required permit activities.	2.79
29. Project managers are able to get analyst and clerical support services in a timely manner.	2.79
38. It is a rare exception when we are asked to do work that we feel is a waste of our time.	2.79
61. The required statutory and/or regulatory authorities used in permits are clearly understood by all.	2.79
45. Tools and guidance are adequate in order to enable me to do my job efficiently and effectively.	2.84

*Responses were recoded so lower numbers reflected more disagreement with the statement.

Findings:

- **Employees do not feel the "tools and guidance" are current (question 43) or "adequate ... to enable me to do my job efficiently and effectively (question 45)." It is observed that this is a likely contributory cause for the "grey areas" in process cited above. This finding is supportive of recommendations 1-2, 5-1, 5-2, 5-3, 5-7.**
- **Employees feel strongly that there is insufficient staffing to support the workload (question 25); and that they do not "have sufficient time to give continuing focused attention to required permit activities" (question 26). They do not feel that project managers can get necessary "analyst and clerical support services in a timely manner." The staffing levels are further analyzed in Chapter 10 and supports reported perceptions of insufficient staff levels.**

- **Employees do not feel "the required statutory and/or regulatory authorities used in permits are clearly understood by all" (question 61). This finding is supportive of recommendations 6-1, 6-2 and 6-3.**
- **Employees feel that current management could better promote workflow with more clear and consistent direction and guidance.. (Reference to questions 30, 32, 38, and 47). This is supportive of recommendations 5-1, 5-2, 5-3 and 5-4.**
- **Employees do not feel that Project Managers are provided with sufficient training or internal resources for technical SME review to obtain efficient permitting processes. (question 27 and 42) or . This finding is supportive of recommendation 5-3.**

The top 6 statements (due to a 2 way tie for statements 5 and 6) are displayed in Table 7, with the results being split between the Permit Staff Workplace and Appreciation and Permit Best Practices sub-areas.

Table 7: Highest Rated Statements in Permitting Mechanisms or Work Environment

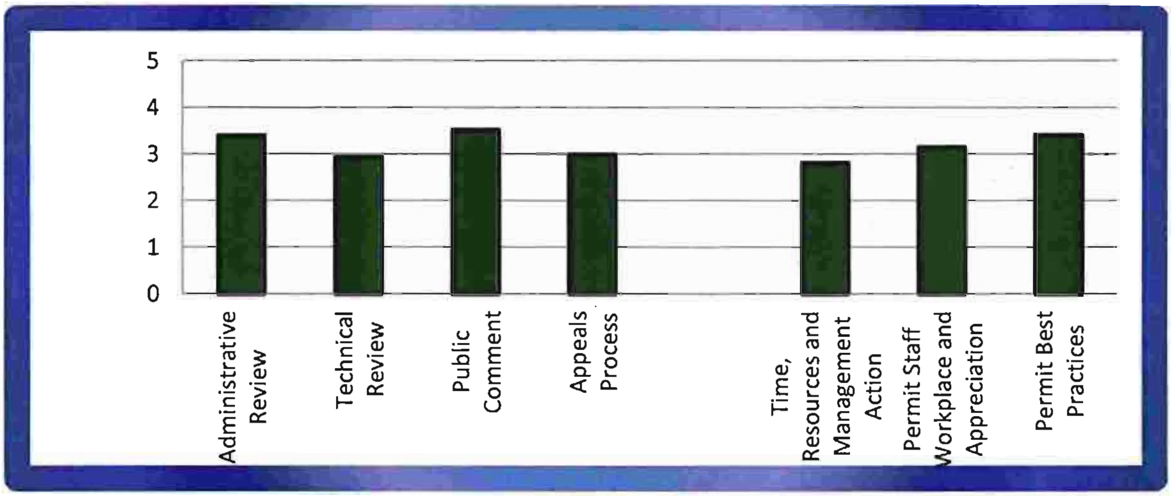
Question	Mean
40. I am personally committed to helping my work unit meet its goals.	4.29
41. My work makes a positive difference in the communities located near my facilities.	4.00
60. Permit requirements are clearly cited in the permit.	3.84
51. Most times the end result of the permitting process is a safe facility with an enforceable permit.	3.79
39. I am satisfied with the level of commitment to work shown by my co-workers in this work unit.	3.68
63. The permit is reviewed to ensure the most recent standards (e.g., laws, regulations, plans, policies) are being used.	3.68

Based on the least and most favorably rated statements, staff acknowledged that the presence of gray areas, the desire for more clear guidelines, but they are also committed to what they do and feel it does create a positive impact on the community. This is an indicator that staff may not only be open to changes but also be willing to help with the implementation of any changes that make the process more efficient and consistent.

Overall Scoring Responses

The overall scores provided for the primary survey segments are shown in Figure 6, and supports the findings that both the Technical Review phase, and the Time, Resources, and Management issues, described in the findings above, are the most negatively rated by employees.

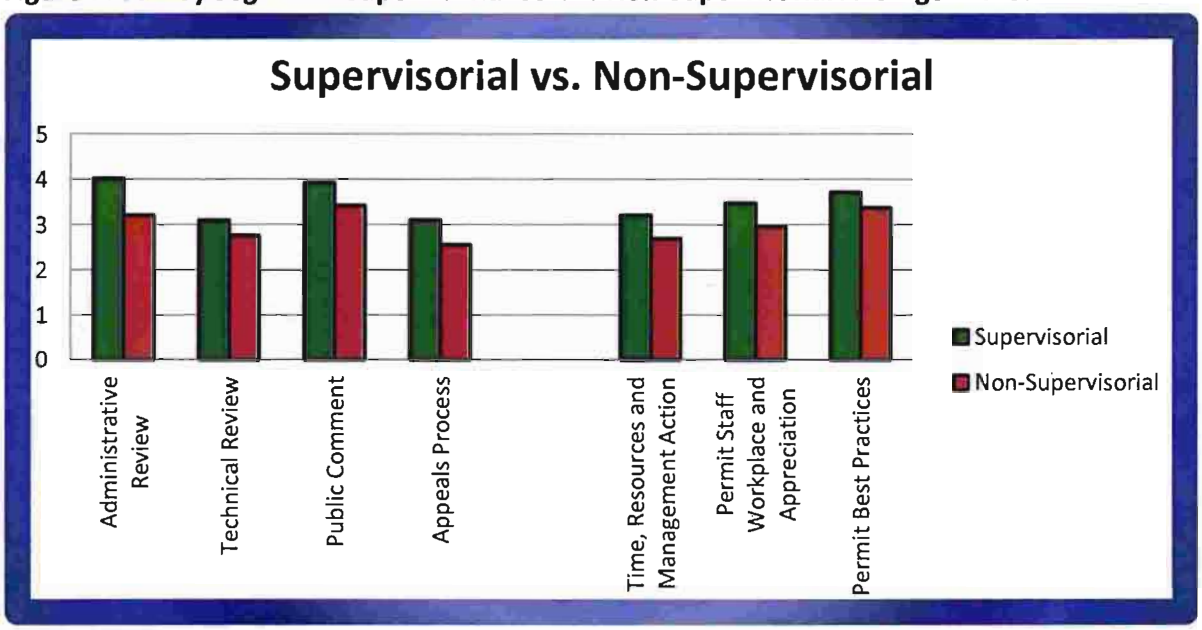
Figure 6: Survey Segments Overall Average Scores



Supervisorial/Managerial versus Non-Supervisorial/Managerial

In verification of key issues it is often helpful to see if the Supervisors and Managers share the same points of view as the employees, or if there is any contradiction. In order to do so, this analysis segregated supervisory and non-supervisory responses. The average response of the supervisorial and non-supervisorial respondents across the segments is presented in Figure 7. The full breakdown of average responses by individual statement for the Supervisory, Non-Supervisory, and Overall combined responses, along with the percentage of respondents who indicated each statement was applicable to their job, is presented in Appendix P.

Figure 7: Survey Segments Supervisorial versus Non-Supervisorial Average Scores

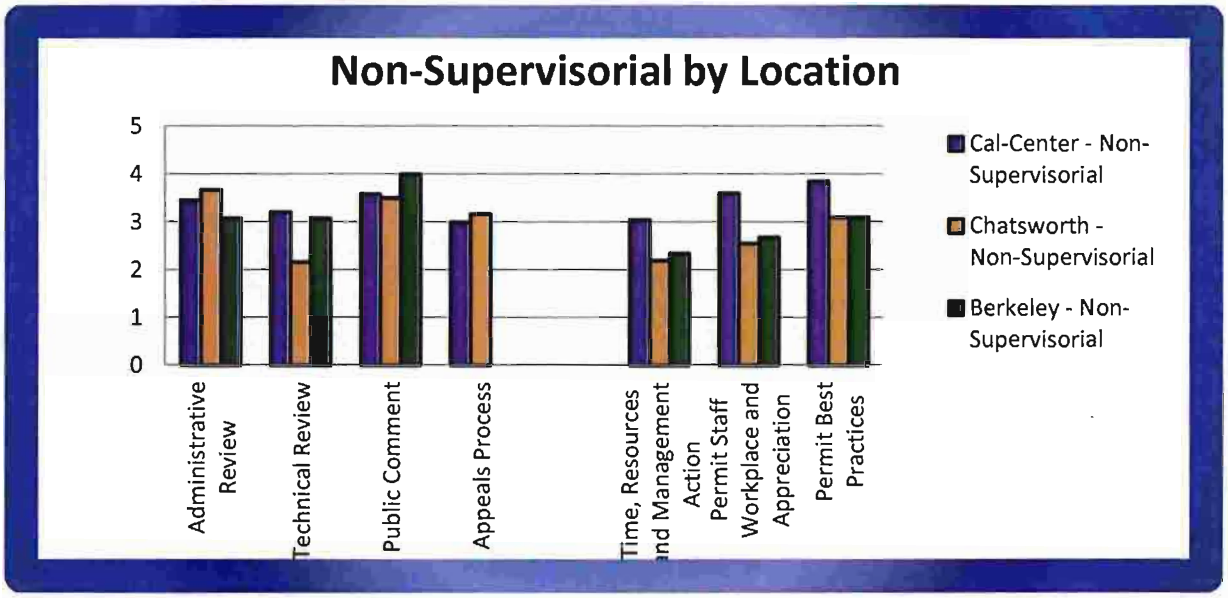


The results showed that the supervisorial employees see management structures and workplace issues in a more positive light than do those who work in front-line service delivery. So for example, while supervisors scored the Time and Resources issues at about 3.2 (mediocre but acceptable), the front-line staff ranked them at about 2.7 (serious and needing action). Overall, the views of both the supervisory and non-supervisory staff conformed in relative ranking, and after accounting the positive bias of supervisors, in scoring as well.

Cal-Center, Chatsworth, and Berkeley Non-Supervisorial

The supervisorial respondents were all located in the Sacramento Cal-Center, but the non-supervisorial were spread between the Sacramento Cal-Center, Chatsworth, and Berkeley. Figure 8 shows the average non-supervisorial responses by location.

Figure 8: Survey Segments Non-supervisorial by Location Average Scores



While no strong single themes came from this analysis, Chatsworth supplied the lowest rating for five of the seven categories, while Cal Center supplied the highest rating for four of the seven. For example, while Cal-Center scored the Technical Review period at 3.21 (good), the employees at Chatsworth scored them at 2.1 (serious and needing action). Similarly, the scores on Time, Resources, and Management statements averaged to 3.05 (mediocre) for employees at Cal-Center, but only 2.2 (serious and needing action) for employees at Chatsworth. Berkeley had more mixed results with the highest average score in the Public Comment (4.0 – excellent), but the lowest on the Administrative Review (3.08 – mediocre) while scoring in between Cal-Center and Chatsworth on the Time, Resources, and Management; Permitting Staff commitment and work environment, and Permit Best practices.

The lower scores in Chatsworth office potentially align with the fact that there has been no supervisor assigned to that office for many years, and the higher scores in the Cal Center Office potentially conform to the fact that most of the Permitting Office supervisors and team leads are in that office.

It is typical of organizational studies of this type that "face time" with leadership has the ability to improve understanding of the program and mission, on-going feedback on work performed, and morale.

The full breakdown of average responses by individual statement for the Non-Supervisory responses from the Cal Center, Chatsworth, and Berkeley locations, along with the percentage of respondents who indicated each statement was applicable to their job, is presented in Appendix Q.

Open Ended Question Analysis

The third and final section of the survey consisted of four open-ended questions to gather additional information on current processes, barriers to these processes, and potential suggestions to improve any issues. The overall themes from the open ended questions are explored here, but the full responses to the following four questions can be found in Appendix R. The list of questions and response rate is provided in Table 8.

Table 8: Employee Survey Open Ended Questions

Survey Question	Number of Responses
1. General feedback on ways to address current permitting process issues.	16 of 20 responded
2. What are currently the biggest barriers to a more effective permitting process?	16 of 20 responded
3. Do you have any suggestions about what could be done to help new project managers learn more thoroughly and quickly so they can start doing work sooner?	20 of 20 responded
4. What actions would help you to do your job even better? Which one action is the most important?	18 of 20 responded

Review of the responses to these questions revealed that many ideas showed up in the responses to all the questions. Given this overlap, the overall themes for these questions are summarized in the following key points:

- Staff has more work than time, being given non-permit related work to complete, with work being distributed based on facilities rather than employee availability/current workload.
- Technical Subject Matter Expert review takes a long time as SMEs are pulled to non-permitting actions, or review is being conducted by non-licensed engineers/scientists
- The level of review needed should be based on complexity of the permit (ranging from peer review, supervisor review, Technical SME review)
- Decisions need to be made based on consistent, clear guidelines that need to be established and defined.
- There needs to be a method of identifying, discussing, and resolving issues through more open communication where everyone has a voice and decisions are clearly shared and explained for future reference.

- Current permit process guidelines are outdated, unclear, or vague – need to be updated, standardized, and enhanced for clarity to ensure consistent process/procedures are followed – removing some of the guesswork in processing.
- Historical information/decisions/communication are not easily accessible, resulting in staff having to re-research facility facts, re-discuss decisions; There is a need to convert paper files to electronic files stored in a more organized tracking software for easy reference/research.
- Regulations need to be clarified with how it applies to the permitting process in layman's terms.
- Need a central, organized location (online) for resources such as templates and examples of forms, letters, memos and other tools for easy access/reference
- Need staff members whose sole responsibility is to monitor, update, and maintain procedure, regulation, decisions made, and facility files
- Emphasis is placed on meeting unrealistic schedules/turnaround times, rather than meeting quality standards which results in more work down the line when problems have to be fixed
- Staff morale is low, culture negative as staff does not feel appreciated, has no incentive
- Perceived lack of appreciation/incentives, favoritism, and the need to justify why they "fail" to meet arbitrary schedules results in a negative culture and low staff morale.
- Everyone involved in the permit process needs to be held accountable to the same achievement goals as motivation toward permit review deadlines – currently not everyone is accountable to timelines.
- Management needs to have more of a presence, clearly identifying long term goals/plans, and participating more in providing guidance to project managers, holding staff accountable for actions, and sharing in decision making.
- Need to improve communication between all those involved with the process, including having supervisors and support staff in the same location as those working on the permits
- There is a lack of formal training, more of a "learn as you go" mentality – but training is needed for support staff, permit writers, and project managers– especially on the Part B application (which could use simplification).
- Project Managers are provided with very little training before hitting the floor – suggestions to improve this process are the focus of question 3.

Question 3 focused on methods to help new project managers learn more thoroughly and more quickly so they can start doing work sooner. The responses emphasized the need for more interactive, thorough, and overall better training compared to current perception that they are given a procedure manual with instructions to read it and then hit the floor. The responses included some very specific ideas, summarized below.

- Early training should focus on how to navigate laws and regulations, and how it pertains to permit writing processes
- Provide standardized training manual, any past department communications, decision documentations, and historical permit information (hopefully digitalized at some point) to gain an understanding of the history and types of permit issues that can come up.

- Visit and work with facilities to assist in understanding entire process and encourage consistency
- Pair new Project Manager with either a peer or supervisor, after initial training, reconvene after they work through a couple of cases for any follow up questions
- There was some differences in opinion here in whether it should be a peer that knows the processes first hand but is already overbooked or a supervisor who may have more time for questions, but does not do the work on a daily basis.
- Once on the floor, start with basic/simple projects and increase complexity, utilizing supervisor/peer partner for clarifications or questions.
- Create video training modules for initial training and periodic review by current staff
- Provide annual or bi-annual refresher courses to ensure consistency of permitting process (this could apply to ALL employees)

Conclusions/Recommendations:

Since open-ended comments can easily reflect the opinion of only one respondent, they are best used to confirm and explain observations and findings that are confirmed in other review sections. Where interesting and apparently relevant suggestions are made, they are noted for further study and evaluation. With this in mind, results note confirmation with:

- A perception of a lack of resources
- A need to improve the process and update support materials
- A need for supervisors to assist with resolving work flow problems, to provide feedback, and to assist in work flow management
- A need for better communication and training.

It is recognized that making improvements in an environment of work backlog, inadequate program performance, and insufficient resources is the highest level of challenge in organizations. It is often expressed as the facetious situation of "building an airplane while flying it[39]." This is due to the fact that there is very little discretionary time, and that arbitrary reassignments will force some goals or tasks to be abandoned to accomplish others.

Several improvement strategies are possible though, and first among those is to find tasks that are costing more time than saving, and to focus on those with the highest net yields first. These are sometimes described as "pay now or pay later" tasks such as training, that should save time long-term even though they will definitely cost time short-term.

During this study, it was discovered that the last comprehensive program training in Permitting was conducted in early 2012, and that a basic set of training materials were developed at that time. It is therefore recommended that this training be updated and offered incrementally to all permitting employees, both to refresh training and to further identify process areas that need attention.

[39] An amusing video on the subject is available at: http://www.youtube.com/watch?v=L2zqTYgcpfg

Recommendation 7-1: As soon as Recommendations 5-1 and 5-2 are substantially addressed, Permitting should re-offer its 2012 training materials with appropriate updates. This training should be provided to all employees in 90-minute segments, in person and by video conference, on a regular twice-a-month schedule. This should be used as an opportunity to refresh training and to further identify process areas that need attention.

Another best case area for improvements is to find "improvement" tasks that individuals have to complete based on current work priorities, but that could provide additional value for others. So for example, if a worker performing a complicated Technical Review could document decision points at the same time they performed the work, they might be able to provide a first draft of a work template for the program. Closely related is asking for someone with a special interest in an area, and in which they would be willing to make an "extra effort" to improve the program on a volunteer basis. This approach would be ideally suited to implementation of Recommendation 1-2, that calls for development of a network file with templates and samples.

Recommendation 7-2: The Permit Office Manager and Supervisors should develop a list of tasks and actions called for as a part of the improvements recommended by this study, in priority and chronological order, and periodically review it with all staff, possibly at the twice-a-month training meetings. Volunteer assistance should be solicited to develop all materials, and draft products reviewed and approved by designated groups of two or three subject matter experts.

During the all-staff meeting conducted at the initiation of this study a number of permit program employees mentioned that the Permit Application Handbook was last updated in January, 2001, and was out-of-date and no longer of assistance. IF management decides that such an update is a high priority, then the approach stated in Recommendation 7-2 could be used to do so. This study found no reason to believe that such a comprehensive handbook would be more helpful, however, than the development of a process flowchart with decision criteria and sign-off standards as recommended in 5-1 and 5-2.

As a last observation, it is noted that the acquisition of temporary resources to bring a program back to a current and effective operational status is sometimes helpful. So for example, Recommendation 6-4 for "catching up" the Financial Assurance Reviews might be best served doing so with contract help. Such a contractor could perhaps write program guidelines as well as catching up past work.

8) Macro-Analysis of the Permitting Process

Historical Comparison

This Chapter provides a comprehensive analysis of the time required for the Permitting Process and its specific segments, including Administrative Review, Technical Review, Public Comment, and Appeals. This study reviewed permitting data from January 1985 to May 2013, with a focus on permit processes completed in or after FY2007-2008. The focus on those completed in the most recent six years[40] was decided on so that current processing steps, technology, and resources were reflected.

A database of permit processing activity in this period was created for the analysis using records from the Department's records database, Envirostor. When possible, the most recent complete permit process for each of the facilities was used. The creation of this database was hindered by various missing dates for key activities and the appearance that multiple permit processes were occurring simultaneously with no clear distinction between the processes[41]. Where attribution of data to the renewal process was not possible, some records were discarded, and these facilities only provided pieces of the process (e.g. Time in Technical Review was identified, but time in Administrative Review was not discernible and therefore not used.) Overall, a total of 115 facilities were used in the database, each contributing data for at least one segment of the permitting process. Table 9 provides the number of facilities that contributed to the analysis of each segment of the process individually and overall (required start of the Administrative *and* End of Public Review to calculate the overall time).

Table 9: Frequency of Contributing Facilities

Permit Process Segment	Number of Contributing Facilities
Administrative Review	63
Technical Review	72
Public Review	105
Overall Process	101

In addition to documenting dates of key permitting activities, the database documented basic demographic information about each facility including permit authority, facility type, size, and status.

[40] The recent time period includes the last 5 complete fiscal years and any information that was available for FY12-13 at the time of the study (not a complete years' worth of data) resulting in 5 to 6 years' data.
[41] It is believed that the multiple entries were the result of permit modifications, partial closures and similar activities that were processed in parallel during a permit renewal.

Historic Trends in Permit Processing Time

The first component of the macro-analysis reviewed whether permit processing time has been decreasing, increasing, or has been consistent over time. This was assessed by breaking the permit records from approximately the last 30 years into three groups, as depicted in Table 10.

Table 10: Historical Time Period Cut-offs

	Time Period	Age of Permits	Number of Contributing Facilities
1	Permits completed in or before FY 2002	Completed more than 10 years ago	17
2	Permits completed between FY's 2003 and 2007	Completed 6 to 10 years ago	41
3	Permits completed between FY's 2008 and most of 2013	Completed in last 5 to 6 years	54

The boundary of years for these analytic periods was somewhat arbitrary, but was selected to depict the first years of DTSC operation, the period up to the Permit Process Team effort (2007-2009), and the period since the Permit Process Team effort. It was assumed that through this method it could be objectively determined whether the Permit Process Team effort had resulted in any permanent change in permit processing, and if so, how much.

It must also be noted that since all desired benchmark dates were not available in EnviroStor, that some variation in the start and stop for each major process segment was required. Because of the need to have a uniform analytic method to account for missing benchmark dates, the process segment start- and stop-points were defined using the following rules.

- The start of the permit process and Administrative review period was the earlier date of either the receipt of the Part B application **or** the expiration of the prior permit.
- The end of the Administrative Review and start of Technical Review was the earlier date of either the submission of the Administrative Completion letter, or issuance of the first Notice of Deficiency.
- The end of the Technical Review and start of Public Review was the earlier date of either the documentation of Final Part A/B or submission of the Technical Completion letter.
- The end of the Public Review period and permit process was the earlier date of either the documented permit completion or the effective date of the new permit.

The average number of days spent processing permits from start to finish, as well as within the Administrative, Technical, and Public Review periods individually was calculated for the permits completed within each time period. The results are presented Table 11, showing improvement across all review periods between the first and second time periods, but only in the Administrative and Public Review periods moving from the second to the most current time period. The Technical review, and correspondingly the Overall permitting process, increased significantly between the second and current time period.

Table 11: Overall Average Permit Processing Time (in days)

	Administrative Review	Technical Review	Public Review	Overall Permit Process	Overall Permit Process Range	Days in Administrative Extension	Percent of Permits over 5 years
1. Completed in or before FY 01/02	723 days	839 days	538 days	1,806 days (5 years)	383 to 3,747 days	1,222 days	5 of 12 (42%)
2. Completed between FY 02-03 and 06-07	285 days	568 days	356 days	1,151 days (3.2 years)	188 to 3,607 days	879 days	6 of 37 (16%)
3. Completed between FY 07-08 and most of 12/13	176 days	990 days	195 days	1,564 days (4.3 years)	294 to 5,866 days	1,294 days	16 of 52 (31%)

Please note that the reported days in the "Overall Permit Process" average reported above are not the total of the average of each preceding segment in that group (row). This is the result of the fact that whenever reviewed process segments did not include a defined begin and end point in the data record, the entire segment was disregarded, even in cases where the total elapsed time from the beginning to the ending point for the **entire process** was retained. So there is variation in the number of segments used to compute the average time in each column. This is explained further in relation to introduction of Table 12, on page 77.

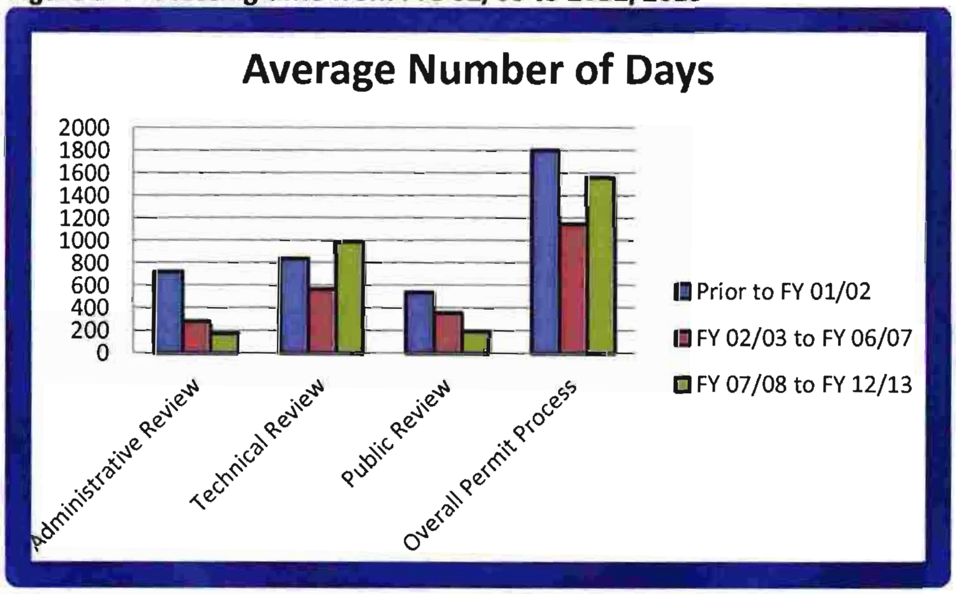
In addition to overall processing time, the length of time in administrative extension (time between the existing permit expiring and the new permit taking effect) and the number of completed permits that took longer than 5 years to process was examined. As can be seen in the last two columns, there was improvement between the first and second time periods, and a decline in performance in the third time period.

- **Findings:** There has been progressive improvement in the Administrative and Public review periods, but returns to longer processing times in the Technical review period, and correspondingly in the overall permit processing time, after initial improvements during the second time period. Similarly, there was improvement followed by a decline in performance for time spent in Administrative Extension and in the number of permits taking longer than 5 years to process. Although the most recent period shows an average processing time of 4.3 years per permit, which is an improvement over the 5.0 years for those completed prior to

FY2003, it is also a step back from the average processing time of 3.2 years in the period from FY2003 to FY2007. While a specific cause and effect relationship was not established, this study believes the strongest correlating factors for the negative changes from the second to the third period is the dramatic reduction in staffing in FY2009, combined with the abandonment of a clear, predictable and traditional organizational structure for permitting in FY2008. These two factors are also believed to be the most likely root causes for the current lack of support for Technical Review, and the resultant measured 74% increase in Technical Review period from the second to the third (current) time period.

Figure 9 shows the reduction in processing time across the three time periods, with smaller changes in each individual review period, and a more noticeable change within the overall processing time.

Figure 9: Processing time from Pre 02/03 to 2012/2013



Analysis of Current Segment Processing Time

The next portion of this study analyzed the permit process segment processing time in the most recent period. With the historical time period-based analysis depicting an increase in processing time, the macro-analysis turned to a more in-depth evaluation of the most recent period. A subset of the database utilizing 54 facility permit processes completed in FY 2008 or later was created for the remainder of the macro-analyses. This database was created with the assumption that the records are representative of the current permit process with the aforementioned limitations. A demographic summary of the types of facilities in this subset is summarized in Appendix S.

The time spent in the administrative, technical, and public review periods, and the overall processing time was examined overall, as well as by permitting authority and facility type, using the same definitions of the review periods as above. The average number of days to process permits overall and within each respective review period for the most current time period is presented in Table 12. It must be observed that the total of the averages of the process segments in each line do not add to the total average processing time. This is the result of the fact that whenever defined process segments did not have a defined begin and end point, the entire segment was disregarded. So for example in the RCRA permit analysis, there were 33 permit renewal records ("N=33") that were complete and able to be used to determine the length of processing from beginning to end, while only 24 had recorded milestones that allowed computation of the Administrative Review period (i.e. 9 had the Administrative start date, but not the Administrative end date).[42]

Table 12: Average Permit Processing times in days for 2007-2013

	Administrative Review	Technical Review	Public Review	Overall Permit Process	
Overall	176 *(N = 40)*	990 *(N = 49)*	195 *(N = 53)*	1,564 *(N = 52)*	4.3 years
RCRA	242 *(N = 24)*	1,046 *(N = 29)*	135 *(N = 33)*	1,811 *(N = 33)*	5.0 years
Standard	78 *(N = 16)*	905 *(N = 19)*	301 *(N = 19)*	1,134 *(N = 19)*	3.1 years
Treatment Facility	150 *(N = 14)*	1,149 *(N = 14)*	177 *(N = 16)*	2,177 *(N = 16)*	6.0 years
Storage/Transfer Facility	236 *(N = 15)*	757 *(N = 18)*	295 *(N = 18)*	1,208 *(N = 19)*	3.3 years
Land Disposal	N/A	N/A	N/A	N/A	N/A
Post Closure	138 *(N = 10)*	1,182 *(N = 14)*	112 *(N = 16)*	1,490 *(N = 15)*	4.1 years
Land Disposal	N/A	N/A	N/A	N/A	N/A
Large Post Closure	44 *(N = 7)*	1,292 *(N = 11)*	102 *(N = 12)*	1,646 *(N = 11)*	4.5 years
Large Storage	450 *(N = 2)*	289 *(N = 1)*	102 *(N = 2)*	2,669 *(N = 2)*	7.3 years
Large Treatment	129 *(N = 6)*	1,077 *(N = 6)*	171 *(N = 7)*	2,375 *(N = 7)*	6.5 years
Medium Post-closure	90 *(N = 2)*	486 *(N = 2)*	132 *(N = 3)*	604 *(N = 3)*	1.7 years
Mini Storage	113 *(N = 1)*	272 *(N = 1)*	91 *(N = 1)*	476 *(N = 1)*	1.3 years
Small Post Closure	447 *(N = 2)*	937 *(N = 2)*	178 *(N = 2)*	1,562 *(N = 2)*	4.3 years
Small Storage	595 *(N = 4)*	662 *(N = 5)*	163 *(N = 5)*	1,612 *(N = 5)*	4.4 years
Small Treatment	131 *(N = 2)*	1,375 *(N = 3)*	152 *(N = 3)*	2,171 *(N = 3)*	5.9 years
Standardized Series A	68 *(N = 4)*	1,137 *(N = 4)*	131 *(N = 4)*	1,336 *(N = 4)*	3.7 years
Standardized Series B	133 *(N = 6)*	1,040 *(N = 7)*	604 *(N = 7)*	1,473 *(N = 7)*	4.0 years
Standardized Series C	40 *(N = 3)*	704 *(N = 5)*	118 *(N = 5)*	720 *(N = 5)*	2.0 years
Standardized Series Small Quantity Series C	53 *(N = 1)*	678 *(N = 1)*	99 *(N = 1)*	830 *(N = 1)*	2.3 years

Note: Total N in subgroups does not always equal Overall N due to 3 facilities missing demographics

[42] No "latent period" is identified in this analysis (as noted on pages 84- 85 because the Public Review was identified to begin at completion of the Technical Review, and so this measure is lost in this analytic approach.

Separating permits by authority type, the RCRA permits took three times as long during the Administrative review, slightly longer in the Technical review, but notably less time during the Public Review periods compared to the Standard permits. The RCRA permits took on average, 2 years longer to process than the Standard permits.

Separating permits by facility type revealed inconsistent patterns with the Storage/Transfer facilities taking the longest in the Administrative and Public Review periods, but the shortest amount of time in the Technical and overall periods. The Post Closure facilities revealed the opposite pattern with the longest average time in the Technical Review, but the shortest in the Administrative and Public Review periods. The Treatment facilities, which had average Administrative, Technical, and Public Review durations in between the Storage/Transfer and Post Closure facilities durations, ended up with the longest overall permitting process times.

There were no permits completed in this time frame for Land Disposal facilities.

Separating permits by facility size, the Small Post Closure, and both Large and Small Storage facilities took notably longer than the other size distinctions in the Administrative Review. The Technical Review Period was the longest period for all except for the Large Storage facility, with the Small Treatment and Large Post Closure taking the longest time to process on average. The Public Review Period was fairly consistent, with the exception of the Standardized Series B facilities, which took approximately 4 to 5 times as long as the other billing sizes.

Overall, the permitting process took approximately 4.3 years from start to finish, ranging from 1.3 (Mini-Storage) to 7.3 (Large Storage) years once broken down into different facility billing sizes. Table 13 presents average permit completion time from largest to smallest, broken down by permit authority, facility type, and facility billing size.

- **Finding:** The largest share of total permitting time is taken in Technical Review, and that portion of the review comprises 2.7 years by itself, and 63% of the total processing time. This is the greatest potential area for processing time improvement.

Table 13: Average Permit Completion Times

Facility	Average Permit Completion Time
Overall	4.3 years (1,564 days)
By Authority	
RCRA Authority	5.0 years (1,811 days)
Standard Authority	3.1 years (1,134 days)
By Facility Type:	
Treatment Facility	6.0 years (2,177 days)
Post Closure	4.1 years (1,490 days)
Storage/Transfer Facility	3.3 years (1,208 days)
By Facility Billing Size:	
Large Storage Facility	7.3 years (2,669 days)
Large Treatment Facility	6.5 years (2,375 days)
Small Treatment Facility	5.9 years (2,171 days)
Large Post Closure Facility	4.5 years (1,646 days)
Small Storage Facility	4.4 years (1,612 days)
Small Post Closure Facility	4.3 years (1,562 days)
Standardized Series B	4.0 years (1,473 days)
Standardized Series A	3.7 years (1,336 days)
Standardized Series Small Quantity C	2.3 years (830 days)
Standardized Series C	2.0 years (720 days)
Medium Post Closure	1.7 years (604 days)
Mini-Storage	1.3 years (476 days)

* Insufficient data to include Land Disposals in Facility Type or Billing Size

The total average permit processing time was examined to determine if the averages above were consistent across the years within this time period. Table 14 shows the number of permits completed each year, along with the average duration in years it took to process these permits from the start of the administrative review until the end of the permit process, as defined above.

Table 14: Average Time to Process Permits Completed in 2007 to 2012.

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Average Time in Years to Complete	3.6	3.5	2.6	9.8	6.0	4.4
Number Permits Completed	14	16	10	5	6	3

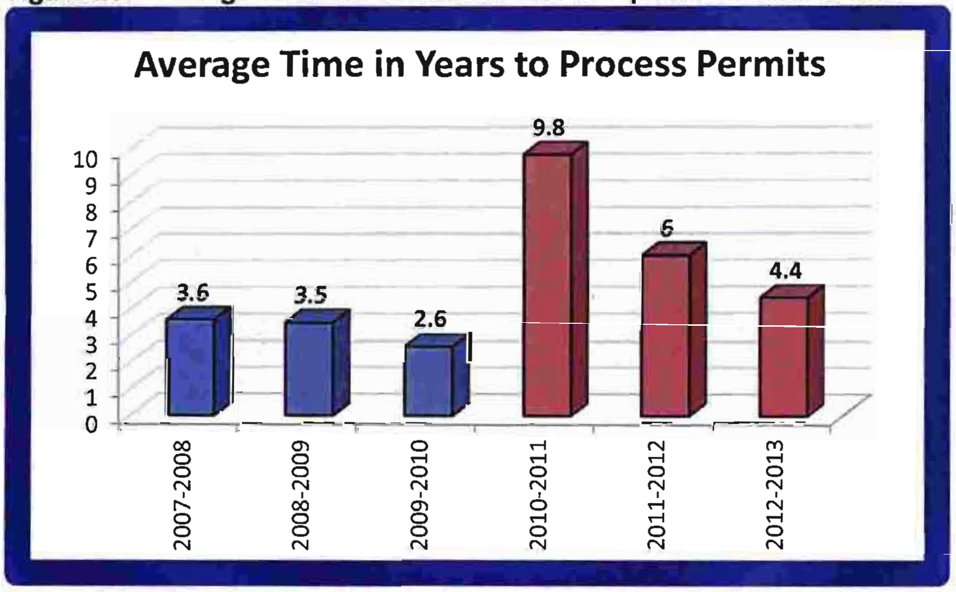
The table below shows the time to process data reflected by calendar year rather than by Fiscal Year as noted above. These results were found to be comparable to previous Department reports regarding time to process permits, and were validated in this manner.

Table 15: Average Time to Process Permits by Calendar Year

	2007	2008	2009	2010	2011	2012
Average Time in Years to Complete	3.1	4.1	2.5	5.1	7.1	6.3
Number Permits Completed	14	13	12	8	6	5

- **Findings:** As can be seen in Table 14 and Figure 10, the average time to process permits completed from 2008 through 2010 fluctuated between 2 and 4 years, with the lowest average processing time of 2.6 years occurring in fiscal year 2010. While a specific cause and effect relationship was not established, this study believes that the drop in average time to process permits dropped from 2007 through 2010 as a result of the implementation of the permit processing team. This team focused only on the permits it judged as easiest to process quickly[43], in order to quickly reduce the number of facilities operating under expired permits. The permits completed in 2010 through 2012 took noticeably longer jumping as high as 9.8 years as well as fewer permits being completed per year. It is believed that the large increase afterwards was the result of returning to the remaining more difficult pending permit actions.

Figure 10: Average Time to Process Permits Completed in 2007 to 2012



Permit Process – Segment Review and Overall Analysis

In efforts to further understand the permit process and identify any potential trouble areas, each review period defined above, as well as the permitting process from start to finish, was more thoroughly studied using the subset of data focusing on the permits completed in FY's 2008 through parts of FY 2013. The dates provided by the Department (Envirostor) were used to create numeric measurements to objectively assess the overall functioning of the permitting process. Each of the measurements was assessed for outliers, or extreme values, that would disproportionally influence the averages and portray an unrealistic assessment of that part of the process. A full list of the key

43 Three Department subject matter experts offered the point of view that the Team was allowed to pick those permits that were believed easiest and quickest to process.

dates[44] and measurements, formulas to obtain these measurements, and any removed outliers from the calculated measurements is available in Appendix T.

The following sections analyze the time required for each permit process segment, including the Administrative Review, Technical Review, Public Review and Comment, and Appeals process. Differences in processing time are calculated for the permit type (RCRA or Standard) and by the Facility Type. It was impractical to break the information by Facility Size at this level as the information would be potentially misrepresented because the groups would be too small and more reflective of individual facilities than general facility sizes.

Overall this analysis discovered that the following average times for processing:

- Administrative Review – 176 days
- Technical Review – 990 days
- Public Review Period – 195 days

Differences and variances as noted above are explained below. In addition, where possible, data on the performance or timeliness of important sub-components is provided.

Administrative Review Period:

The first direct action taken in a permit renewal process is the issuance of the Call-in letter to remind facilities that their permit is up for renewal. This step is more preliminary and not measured as part of the Administrative Review timeframe, but it is necessary that this step be completed in a timely manner so it is assessed within this section. The three timeframes analyzed within the Administrative Review are presented in Table 16, with the range and average processing time overall and for each of the sub-groupings. The three timeframes are as follows.

1. *When was the Call-in Letter sent* – measured the amount of time before (or after) the existing permit expiration that the call-in letter was sent.
2. *When was Part B Application received* – measured the amount of time before (or after) the existing permit expiration that the Part B Application was received.
3. *Length of Administrative Review* – measured the amount of time from the Start of the Administrative review (either receipt of Part B or expiration of prior permit) to the Finish (completion of the Administrative Completion Letter or issuance of first NOD if letter was not available).

[44] Overall, approximately 85% of key activity dates were documented (after removing the appeal and NOD dates as they do not apply to all facilities), with the Final Part A/B, permit completion date, public comment open and close dates, and the new permit effective and expiration dates being documented 94% of the time or greater while the dates for the Technical Completion Letter and when the Public Hearing was held being documented only 70% and 50% of the time, respectively.

Table 16: Administrative Review Summary by Permit Type

		When was Call-in Letter sent in relation to permit expiration date?	When was Part B Application received in relation to permit expiration date?	Length of Administrative Review
OVERALL		*M* = 422 days prior (684 days prior to 24 days after expiration)	*M* = 227 days prior (378 days prior to 26 days after expiration)	*M* = 176 days (*SD = 278)* (3 to 957 days)
Permit Authority	RCRA	*M* = 328 days prior (684 days prior to 24 days after expiration	*M* = 188 days prior (40 – 312 days prior to expiration)	*M* = 242 days (*SD = 321)* (7 to 957 days)
Permit Authority	Standard	*M* = 510 days prior (414 - 539 days prior to expiration	*M* = 278 days prior (378 days prior to 26 days after expiration)	*M* = 78 days (*SD = 164)* (3 to 675 days)
Facility Type	Treatment Facility	*M* = 417 days prior (553 days prior to 24 days after expiration	*M* = 260 days prior (93 – 378 days prior to expiration)	*M* = 150 days (*SD = 220)* (3 to 808 days)
Facility Type	Storage/ Transfer Facility	*M* = 437 days prior (182 - 520 days prior to expiration	*M* = 220 days prior (365 days prior to 26 days after expiration)	*M* = 236 days (*SD = 343)* (6 to 957 days)
Facility Type	Land Disposal	N/A	N/A	N/A
Facility Type	Post Closure	*M* = 382 days prior (211 - 684 days prior to expiration	*M* = 179 days prior (145 – 219 days prior to expiration)	*M* = 138 days (*SD = 268)* (7 to 887 days)

In order to encourage timely completion of the permit process, it is regulated that the call-in letter should be sent to the facility no later than 18 months (540 days) prior to the expiration of the current permit. The provided records showed that the call in letter was sent as early as 684 days prior to current permit expiration (1.9 years) to as late as 24 days after the permit expired, averaging out at 422 days prior to the permit expiration – 78% of the time required by policy. This allows slightly more than a year for the facility to submit the application and the permitting staff to complete the entire permit process.

The facility is then responsible for submitting the Part B application at least 30 days before the existing permit expires. Records indicate that the Part B application was received as early as 378 days before the permit expires (approximately 1 year) to 26 days after the permit expires; averaging out at 227 days before the permit expires. This shows that most permittees are very early in submitting the required application and allow slightly more than 7.5 months for the permit process to be completed before the permit expires. Industry standards suggest the Part B application to be submitted at least 180 days prior to the permit expiration, which would allow up to an additional 5 months for the permitting staff to process the application. Looking at the permits that were completed in or after FY 2008, two-thirds (67%) of the permittees submitted their application earlier than 180 days prior to permit expiration, and with the exception of the one facility that submitted it after the permit expiration date, the remainder (30%) submitted their application between 30 and 180 days prior to the permit expiration. Looking at the average submission time, all of the facility subtypes submitted the Part B application before the technical due date.

The expectation is that the Administrative Completion letter should be submitted within 60 days of the receipt of the Part B application, therefore the average processing time should be around that 60 day mark. The time spent on the call-in letters and waiting for Part B application to arrive impacts completion of the permit process before the existing permit expires, but does not factor into the Administrative Review segment. Records indicate that the Administrative Completion letter was submitted as early as 3 days and as long as 957 days after receiving the application (2.6 years), averaging out at 176 days (approximately 6 months after receiving the application – three times the expected timeframe). Since this analysis presented performance below the expectations, further examination between subtypes was done. As can be seen in Table 16, the RCRA facilities took notably longer (almost 8 months) while the Standard authority facilities took just slightly longer than the expectations (2.6 months). However, looking at facility types, the averages are larger ranging from 2 to 4 times the expected timeframe, indicative of the influence of the RCRA permits within each group.

The Administrative Review could potentially be improved by implementing the following:

1) Ensure that call-in letters are uniformly sent at least 18 months prior to the current permit's expiration. This is currently included in the proposed process flowchart, referenced at recommendation 5-1.
2) Seek a change in requirements making the Part B Application due 180 days prior to the expiration of the existing permit. Given that the current guidelines mandate that Permitting issues its Completion of the Administrative Review Letter within 60 days after receipt of a complete Part B Application, there is insufficient time for initial processing prior to most permit renewals. This almost guarantees that the permit process will not be completed before the existing permit expires. Based on current records, this would not inconvenience the facilities as most of them already submit their application prior to the 180 day deadline.

Recommendation 8-1: The Department should research whether and how to change its requirements to make the Part B Application due 180 days prior to the expiration of the existing permit. This objective and purpose should be reviewed and affirmed by Cal EPA Secretariat, and if agreed to, recommended to the appropriate Legislative Committees for statutory revision.

Technical Review:

The Technical Review period begins where the Administrative Review period ends. Although, this is the period where a majority of the time is spent, there were only two timeframes assessed. These two timeframes are presented in Table 17, with the range and average processing time overall and for each of the subgroupings. The two timeframes assessed were as follows.

1. *How long did the Technical review segment take from Start to Finish* – measured how long the process took from the end of the Administrative Review to the earliest date between completion of the Final Part A/B or the Technical Review completion letter.
2. *Was there a latent period between the Technical and Public Review* – measured how much, if any, time was lapsing between Technical Completion and Public Comment (Begin).

Table 17: Technical Review Period by Permit Type

		How long did the Technical Review segment take from Start to Finish?	Was there a latent period between the Technical and Public Review?
OVERALL		*M* = 990 days (*SD = 803)* (272 to 3,423 days)	*M* = 37 days (*SD = 74)* (0 to 348 days)
Permit Authority	RCRA	*M* = 1,046 days (*SD = 850)* (272 to 3,423 days)	*M* = 40 days (*SD = 68)* (0 to 266 days)
	Standard	*M* = 905 days (*SD = 764)* (476 to 3,298 days)	*M* = 35 days (*SD = 88)* (0 to 348 days)
Facility Type	Treatment Facility	*M* = 1,149 days (*SD = 791)* (526 to 2,750 days)	*M* = 73 days (*SD = 114)* (1 to 348 days)
	Storage/ Transfer Facility	*M* = 757 days (*SD = 677)* (272 to 3,298 days)	*M* = 34 days (*SD = 56)* (1 to 219 days)
	Land Disposal	N/A	N/A
	Post Closure	*M* = 1,182 days (*SD = 999)* (272 to 3,423 days)	*M* = 10 days (*SD = 10)* (0 to 39 days)

The Technical Review period was identified as housing many of the issues during the Employee and Stakeholder Attitude assessments in terms of unclear or inconsistent guidelines and recordkeeping. There were no identified guidelines for how long the Technical Review should take, but the provided records identified the process as taking anywhere from 272 days to 9.4 years (3,423 days), averaging out to approximately 2.7 years. Breaking the facilities into the subtypes, the RCRA authorized facilities took approximately 4.5 months longer than the Standard authorized and the Post Closure and Treatment facilities (3.2 years each) took longer than the Storage/Transfer facilities (2.1 years), which is opposite of what was seen in the Administrative Review period.

It is a conclusion of this study that the complexity and uncertainty regarding technical review should be directly addressed through adoption of recommendations 5-1, 5-2, 5-5, 5-6 and 5-7.

Once the Technical Review is complete, the permit decision should be drafted and the project fact sheet should be completed within about two weeks, or less. While it is possible that very short delays are entirely explained by the necessary preparation of a project "fact sheet" and related materials, many project managers have noted that even these activities are typically complete prior to final submission of the Technical Review package for legal review. So there is no reason for a long period to elapse between the completion of Technical Review and "Public Comment (Begin)". The records indicated that the draft permit was posted anywhere from the same day as Technical Completion to almost one year later (348 days), with the average posting date being slightly more than 1 month after the Technical Review was completed (37 days). There was no notable difference between RCRA and non-RCRA authorized facilities, but the Treatment facility type had a delay of just over 2 months (73 days), while the Post-Closure facilities had almost no delay (10 days) between the two review processes.

It is a conclusion of this study that these unplanned delays are the result of behind the scenes discussions within the Department regarding completion of CEQA review and completion of the Public Participation plan. Recommendation 5-1 should move both issues to the start of the permit process, largely eliminating these delays.

Part of the Technical Review process includes the issuance of Notice of Deficiencies (NOD), which was not included in the table above since it only applies to facilities that need to add or correct information, or address deficiencies in their application. The analysis for the NODs involved identifying the ratio of facilities receiving NOD's and the total number of NOD's documented overall, and within each authority and facility type as seen in Table 18. When reviewing the records, if a response to a NOD was received and there was no corresponding NOD documented, a NOD was entered with the date of 1/1/yyyy with the year that the response was received. If a NOD was missing within a line of NOD's (i.e. – NOD 1 and 3 were documented, but NOD 2 was missing) – a fake date was input as a place holder to obtain the most accurate count of NODs as possible.

In doing so we can see that 87.0% of all permit applications received one Notice of Deficiency, while 38.9% received two, and only 16.7% received three.

Table 18: NOD Frequency by Facility Authority, Type, and Size

		NOD 1	NOD 2	NOD 3
OVERALL		47/54 =87.0%	21/54 =38.9%	9/54 =16.7%
Permit Authority	RCRA	28/34 = 82.4%	15/34 = 44.1%	7/34 = 20.6%
	Standard	18/19 = 94.7%	6/19 = 31.6%	2/19 = 10.5%
Facility Type	Treatment Facility	16/16 = 100%	7/16 = 43.8%	4/16 = 25%
	Storage/ Transfer Facility	18/21 = 85.7%	5/21 = 23.8%	1/21 = 4.8%
	Land Disposal	N/A	N/A	N/A
	Post Closure	12/16 = 75.0%	9/16 = 56.3%	4/16 = 25.0%

Note: One First NOD that did not have facility type identified

The Standard authorized permittees received a higher incidence of first NOD's, but the RCRA authorized permittees received higher incidences of both second and third NOD's, with 20% of facilities requiring a third NOD, compared to only 10% of the Standard facilities. The Treatment (100%), Storage/Transfer (86%), and Post Closure (75%) facilities all received high incidences of first NOD's. The Treatment and Post Closure facilities decreased at approximately the same rate with 25% of facilities in each type receiving a third NOD compared to approximately 5% for the Storage/Transfer facilities. This is likely a reflection of their greater possible threat to health and human safety than transfer facilities. It is also perhaps a reflection of the perceived greater public scrutiny they will receive.

In addition to identifying overall patterns in the need for NODs, it is useful to identify the facilities that require frequent NODs to assist in project planning. These facilities may require more employee hours or be more challenging and require more expertise. Table 19 shows the top 5 facilities based on the number of NODs issued and documented since January, 2007, all of which received all three NODs during their most recent permit renewal process.

Table 19: Facilities with the most frequent NODs

Facility Name	Authority	Type	Size	Total NODs	NOD 1	NOD 2	NOD 3
Ducommun Aerostructures	RCRA	Post Closure	Large Post Closure	**3**	1	1	1
P Kay Metal Inc.	STATE	Treatment	Standardized Series B	3	1	1	1
San Diego Gas & Electric	STATE	Storage/Transfer	Standardized Series A	3	1	1	1
E I Dupont De Nemours & C	RCRA	Post Closure	Large Post Closure	3	1	1	1
Tesoro Refining and Marketing	RCRA	Post Closure	Large Post Closure	3	1	1	1

The NODS from the top 5 above account for approximately 19.5% of the NOD's issued after January, 2007 with the RCRA Large Post-Closure Facilities dominating the list.

- **Finding:** It is a conclusion of this study that both Permitting staff and the interested public are unclear about the intended meaning and use of Notices of Deficiency, and the legal requirements for use, and for action after issuance of three. This finding underscores the importance of Recommendation 6-2, noted earlier in this study, and calling for categorizing NOD's that should be prejudicial from those that should not.

Public Comment/Review:

The Public Comment Review segment begins where the Technical Review period ended. The time lapsed between the Technical Review and the Public Comment was assessed as part of the Technical review and this segment focuses on four measurable time frames, as described below and presented in Table 20.

1. *How long after the public posting was a Public Hearing/Meeting held* – measured if public meetings were held at least 30 days after public posting.
2. *How long was the Posting up for Public Review* – measured the length of time a permit was up for public review and assessed if met the minimum requirement of 45 days.
3. *How long after Closing Comments was the Permit Completed* – measures length of time between closing the public comment period and documenting the permit is completed.
4. *How long did the Public Review segment take from Start to Finish* – measured how long the process took from the end of the Technical Review to the close of the Public Comment period.

Table 20: Key Measurements in Public Review Period

		How long after Posting was a Public Hearing/ Meeting held?	How long was the Posting up for Public Review?	How long after Closing comments was the Permit Completed?	How long did the Public review segment take from Start to Finish?
OVERALL		*M* = 30 days (*SD = 10)* (0 to 51 days)	*M* = 46 days (*SD = 10)* (0 to 95 days)	*M* = 56 days (*SD =47)* (5 to 181 days)	*M* = 195 days (*SD = 279)* (51 to 1,536 days)
Permit Authority	RCRA	*M* = 32 days (*SD =8)* (17 to 51 days)	*M* = 48 days (*SD = 9)* (44 to 95 days)	*M* = 45 days (*SD =39)* (5 to 148 days)	*M* = 135 days (*SD = 74)* (51 to 331 days)
Permit Authority	Standard	*M* = 26 days (*SD = 12)* (0 to 36 days)	*M* = 44 days (*SD = 11)* (0 to 55 days)	*M* = 80 days (*SD =54)* (16 to 181 days)	*M* = 301 days (*SD = 443)* (64 to 1,536 days)
Facility Type	Treatment Facility	*M* = 34 days (*SD = 5)* (29 to 41 days)	*M* = 46 days (*SD = 3)* (44 to 55 days)	*M* = 69 days (*SD =50)* (11 to 181 days)	*M* = 177 days (*SD = 120)* (62 to 487 days)
Facility Type	Storage/ Transfer Facility	*M* = 24 days (*SD = 12)* (0 to 36 days)	*M* = 43 days (*SD = 11)* (0 to 48 days)	*M* = 55 days (*SD =54)* (8 to 179 days)	*M* = 295 days (*SD = 453)* (64 to 1,536 days)
Facility Type	Land Disposal	N/A	N/A	N/A	N/A
Facility Type	Post Closure	*M* = 33 days (*SD = 10)* (19 to 51 days)	*M* = 50 days (*SD = 13)* (44 to 95 days)	*M* = 48 days (*SD =39)* (5 to 127 days)	*M* = 112 days (*SD = 48)* (51 to 194 days)

The purpose of posting the draft permit decision for public review is to allow the public to voice any concerns or questions. The draft permit decision should be posted for a minimum of 45 days with a public meeting to discuss the permit no less than 30 days after the draft permit is posted. However, records indicate that the permits were posted from 0 to 95 days, with an average of 46 days, with the public meeting being held anywhere from 0 to 51 days, with an average of 30 days, after posting. Although the averages meet the requirements, the ranges for both indicate that some facilities have no or abbreviated public review periods, which limits the ability of the public to review the permit decision, provide feedback, or ask questions.

The RCRA authorized permits met or slightly exceeded the expected time frames for the public hearing and the length of time open for public comment, while the Standard permits were slightly below on both. Similarly, the Post Closure and Treatment facility permits met both standards, while the Storage/Transfer facilities were slightly below on both. There was not sufficient data to assess Land Disposals.

- **Finding:** The EnviroStor record reviewed as a part of this study indicates that in some cases the public is not getting 45 days for public comment as requires by 22 CCR Section 66271.9(b)(1). It is not clear from the analysis whether this apparent non-conformance is the result of inaccurate data recordation, or if the on-conforming period was precedent to or subsequent to a conforming period[45]. In any case, Recommendation 9-1 instructs Permitting to ensure entry of benchmark operational measures, including those relevant to the public comment period, and Recommendation 1-1 instructs Permitting Supervisors to ensure accurate entry of key dates, and to take responsibility for meeting process requirements. If followed, any misreporting or accidental non-conformance will be eliminated.

There is no set standard for how quickly the permitting staff has to complete the permit once the public comment period ends, but based on these records, there is approximately a two month delay between the end of the public comment and the finalization of the permit. The Standard permits (80 days) take almost twice as long to finalize as the RCRA permits (45 days), but the differences are not as different when breaking down the facility types where the Treatment facilities take approximately 15 days longer than the Storage/Transfer facilities and 20 days longer than the Post Closure Facilities.

Although there is no set minimum time frame for the overall public comment period, due to the above mentioned regulations, it needs to be at least 45 days. The records indicated a range from the minimal 51 days to just over a four years (1,536 days), averaging out to approximately 6.5 months (195 days). However, this range includes the time from the completion of the Technical Review but prior to the posting of the draft permit and any time after the public comment period closed and permitting staff is finalizing the permit which would include final approval and documentation from other divisions. Similar to the prior measurement, the Standard facilities took notably longer (301 days) compared to the RCRA facilities (135 days), The Storage and Transfer facilities also had a longer public review period than the Treatment or Post Closure facilities. The Standard and Storage/Transfer facilities had Public Review periods that were 2 to 3 times as long as the review periods for the RCRA authority, and other facility types. This is a direct reflection of facility records that had 3 to 4 years between closing the public comment and finalizing the permit. For example, Evergreen Oil (Davis) closed public comment on 8/1/08, had an appeal decision made on 7/20/09, but the permit was not documented as completed until 10/2/12, and not effective until 11/6/12.

Extensive delays in the permitting process can be remedied through the implementation of better processes and decision criteria (Recommendation 5-1) and confusion on these documented delays can be minimized through detailed documentation in Envirostor (Recommendation 1-1).

[45] EnviroStor only allows for a single public comment period entry and field audits found at least one instance where a non-conforming public comment period was "re-noticed" to ensure that it conformed with legal requirements.

Appeals Process Review:

The appeals process had significantly fewer data points and so the results are presented for the department overall and by authority type only. The facility type was just a duplicate of the authority type with one data point for an RCRA Post Closure and a couple data points for Standard Storage/Transfer facilities. The appeals process begins with the receipt of an appeal and ends once a decision is made. Table 21 breaks down the appeals process into two measurable time frames, and provides the range and average processing time overall and for each of the sub-groupings. The two questions are as follows.

1. How quickly were appeals received – measured how many days after the final permit was posted that an appeal was received.
2. How quickly were decisions made regarding appeals – measured how many days after receiving the appeal was a decision/response provided.

Table 21: Summary of Appeals and Decision time frames

		How quickly were appeals received?	How quickly were decisions made on appeals?
OVERALL		*M* = 31 days (30 to 31 days)	*M* = 284 days (189 to 566 days)
Permit Authority	RCRA	*M* = 31 days	*M* = 189 days
	Standard	*M* = 31 days (30 to 31 days)	*M* = 308 days (198 to 566 days)

Appeals can be filed only on information that changed between the draft and the final permit, and it must be filed within 30 days of the final permit posting. Records indicate that appeals were typically received or recorded on the final day of the appeals window. There were no identified guidelines pertaining to how fast an appeal must be answered, and records show that it took anywhere from 189 to 566 days (6 months to 1.5 years) to respond. Decisions on appeals took about 3.5 months longer for Standard authorized permits than RCRA authorized permits in these documented instances, but an overall generalization cannot be confirmed with so few data points.

The Appeals process could be improved through the following implementations.

1. Enforce the 30 day appeals limit so that staff does not get tied up in appeals that were not timely. (*Findings do not show that this is currently an issue, but as a principle, it could avoid issues in the future.)*
2. Set guidelines or regulations to respond within a reasonable timeframe and enforce those timelines to avoid the potential of having a permit expire while the appeal waits to be decided upon.

Overall Process Review:

The overall process started with the earlier of either the expiration of the prior permit or the receipt of the Part B application and concluded after the Public Comment period with the documentation of the permit completion, but prior to the Appeals process. Table 22 breaks down the overall process into three measurable time frames, and provides the range and average processing time overall and for each of the sub-groupings. The three timeframes are as follows.

1. How long was the Permit Process from Administrative Start to Permit Completion – measured the length of time it took from the earlier date of either the expiration of the prior permit or receipt of Part B application until the earliest of either permit staff documenting the permit was completed or the new permit becoming effective.
2. Was there a latent period between Permit Completion and Permit effective dates – measured if there was time passing after permit was completed but before it became effective.
3. How long was the permit in Administrative extension – measured the number of days the facility permit was in an expired status before the new permit took effect.

Table 22: Summary of Overall Permitting Process time frames

		How long was the Permit process from Admin. Start to Permit Completion?	Was there a latent period between the Permit Completion and Permit Effective Dates?	How long was the permit in Administrative extension?
OVERALL		*M* = 4.3 years (*M* =1,564 days; *SD=1,275*) (294 to 5,866 days)	*M* = 29 days (*SD* = *49*) (0 to 290 days)	*M = 3.6 years* (*M* =1,294 days; *SD =1,270*) (199 to 4,719 days)
Permit Authority	RCRA	*M* = 5.0 years (*M* =1,811 days; *SD=1,451*) (294 to 5,866 days)	*M* = 18 days (*SD* = *17*) (0 to 37 days)	*M = 4.4 years* (*M* =1,621 days; *SD =1,354*) (199 to 4,719 days)
Permit Authority	Standard	*M* = 3.1 years (*M* =1,134 days; *SD=744*) (441 to 3,080 days)	*M* = 49 days (*SD* = *77*) (0 to 290 days)	*M = 2.3 years* (*M* =836 days; *SD =647*) (332 to 2,746 days)
Facility Type	Treatment Facility	*M* = 6.0 years (*M* =2,177 days; *SD=1,590*) (750 to 5,866 days)	*M* = 22 days (*SD* = *16*) (0 to 37 days)	*M = 5.3 years* (*M* =1,944 days; *SD =1,425*) (376 to 4,719 days)
Facility Type	Storage/ Transfer Facility	*M* = 3.3 years (*M* =1,208 days; *SD=716*) (435 to 2,840 days)	*M* = 44 days (*SD* = *78*) (0 to 290 days)	*M = 2.4 years* (*M* =879 days; *SD =652*) (286 to 2,186 days)
Facility Type	Land Disposal	N/A	N/A	N/A
Facility Type	Post Closure	*M* = 4.1 years (*M* =1,490 days; *SD=1,345*) (294 to 4,516 days)	*M* = 17 days (*SD* = *17*) (0 to 36 days)	*M = 2.3 years* (*M* =833 days; *SD =789*) (199 to 2,294 days)

Overall, the permitting process from the start of the Administrative Review through the completion of the permit took as short as approximately 10 months (294 days) to over 16 years (5,866 days), averaging out to 4.3 years (1,564 days). Given that the process takes over 4 years on average, but the call-in letter to initiate the process is sent out only 1.5 years prior to expiration, it makes sense that all the permits end up expiring prior to the new permit taking effect. The third time frame shows that permits were in Administrative extension from as short as six months (199 days) to over 12 years (4,719 days), averaging out to approximately 3.6 years that facilities are operating without a current permit.

With the permits expiring before the renewed permit becomes effective, there should be little to no time in between permit completion and permit effective dates. Contrary to this expectation, the second timeframe demonstrates that there was on average approximately 1 month in between the permit completion date and the permit effective date overall and in every subgroup. Efforts should be made to identify what is causing this delay and see if it can be eliminated. Since all the facilities appear to be working on expired permits at the time of renewal enforces the idea that the entire permitting process needs to be defined, updated, and streamlined when possible.

Similar to identifying facilities that need frequent NOD's to better plan permitting work, it is advantageous to identify types or even specific facilities that have quick versus more lengthy overall permitting processes. Table 23 demonstrates the difference in timing between those facilities who have a quick turnaround and those who require more extensive processing with the ten shortest and ten longest permit processes.

Table 23: Longest and Shortest Permit Process Times

Facility Name	Authority	Type	Billing Size	Time to complete Permit Process	Year Completed
Shortest Permitting Processes					
Montezuma Hills Facility	RCRA	Post Closure	Large Post Closure	294 days (0.8 years)	2008
Occidental of Elk Hills Inc.	RCRA	Post Closure	Large Post Closure	418 days (1.2 years)	2008
Honeywell International Inc.	RCRA	Post Closure	Medium Post Closure	434 days (1.2 years)	2010
Raytheon Space and Airborne Systems	RCRA	Storage/ Transfer	Small Storage	435 days (1.2 years)	2007
Asbury Environmental Services	Standard	Storage/ Transfer	Standardized Series C	441 days (1.2 years)	2009
International Light Metal	RCRA	Post Closure	Large Post Closure	461 days (1.3 years)	2013
United Technologies	RCRA	Storage/ Transfer	Large Storage	470 days (1.3 years)	2007
Safety-Kleen - Fresno	RCRA	Storage/ Transfer	Mini Storage	476 days (1.3 years)	2007
Big Blue Hills Pesticide	RCRA	Post Closure	Large Post Closure	494 days (1.4 years)	2007
Square D Company	RCRA	Post Closure	Medium Post Closure	544 days (1.5 years)	2009
Longest Permitting Processes					
Dept. of Air Force Vandenberg	RCRA	Treatment	Small Treatment	2519 days (6.9 years)	2008
Advanced Environmental Inc	Standard	Storage/ Transfer	Standardized Series B	2840 days (7.8 years)	2009
Los Angeles Refinery, Carson Plant	RCRA	Post Closure	Large Post Closure	3013 days (8.3 years)	2007
X-Strata Recycling Inc	Standard	Treatment	Standardized Series A	3080 days (8.4 years)	2012
Pacific Resource Recovery	RCRA	Treatment	Small Treatment	3219 days (8.8 years)	2012
Los Angeles Refinery, Wilmington Plant__	RCRA	Post Closure	Large Post Closure	3531 days (9.7 years)	2008
Veolia es Technical Solutions, LLC	RCRA	Treatment	Large Treatment	3693 days (10.1 years)	2011
Tesoro Refining & Marketing Company	RCRA	Post Closure	Large Post Closure	4516 days (12.4 years)	2011
Rho-Chem, LLC	RCRA	Treatment	Large Storage	4867 days (13.3 years)	2008
Clean Harbors – Los Angeles	RCRA	Treatment	Large Treatment	5,866 days (16.1 years)	2011

Determination of a Timely Standard for Permit Process

Looking at the previous analysis, there are nine permits that were renewed in a period of from 1.2 years to 1.5 years. This observation raises the prospect of the Department processing most permits within this period, as a realistic future goal.

However, this study sought several other means of evaluating whether this is indeed a realistic expectation. One approach was to again review the 54 data records accumulated for the period from fiscal year 2008 through the present, rejecting any renewal records that did not include valid data for each process segment from Administrative Review through the end of the Public Review Period to the Permit Completion date. This time frame does not include any Appeals since those typically occur after the permitting team completed the initial permit.

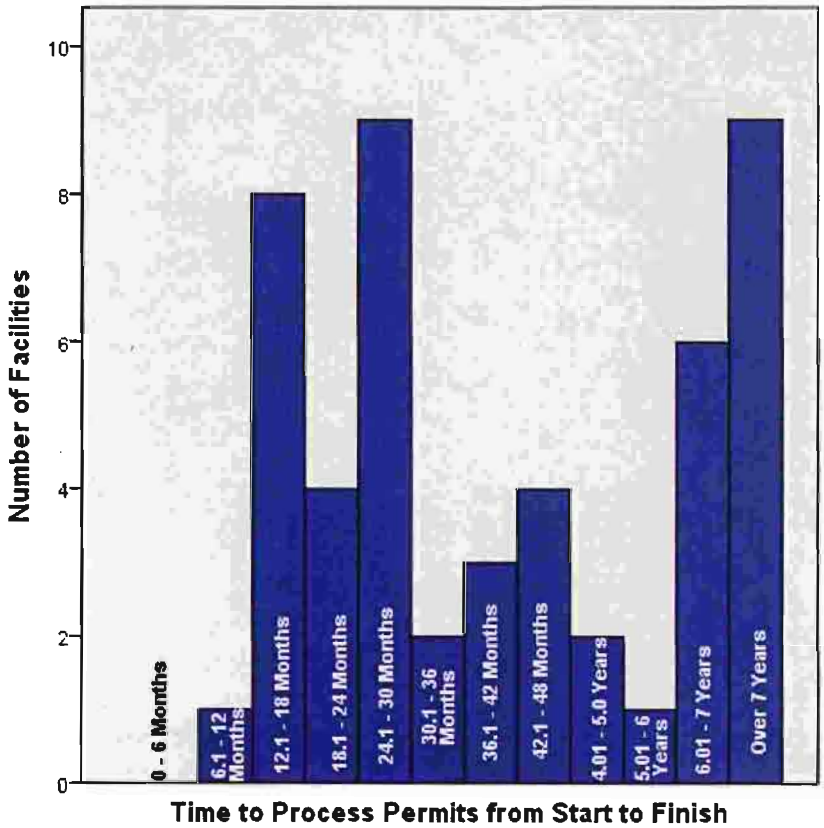
This produced 49 complete data records, of which approximately half were processed in less than 3.0 years, and 26.5% were renewed in less than two years. Table 24 presents the data broken into smaller time periods with the corresponding number of facilities and average processing time within each time frame.

Table 24: Time to Complete Permitting Process from Start to Finish

Time Frame	Number of Facilities	Average Days within Time Frame
0-6 Months	0	N/A
6.1 - 12 Months	1	294
12.1 - 18 Months	**8**	**467.3**
18.1 - 24 Months	4	669.5
24.1 - 30 Months	**9**	**799.8**
30.1 - 36 Months	2	971.5
36.1 - 42 Months	3	1173
42.1 - 48 Months	4	1347
4.01 - 5 years	2	1737.5
5.01 - 6 years	1	2089
6.01 - 7 years	6	2356.5
Over 7 years	9	3847.2

The distribution of the results is shown in Figure 11.

Figure 11: Distribution of Permitting Processing Time from Start to Finish



This study used the same data set to develop a reasonable expectation for the longest parts of the permit renewal process, including the Administrative Review and Technical review. Those results follow in Tables 25 and 26, respectively. Seven Administrative Review and two Technical Review records were removed as outliers, resulting in a slightly lower number of facilities in the following tables.

Table 25: Time to Complete Administrative Review Period

Time Frame	Number of Facilities	Average Days within Time Frame
0-1 Month	**16**	**18.1**
1.1 - 2 Months	6	43.2
2.1 - 3 Months	4	75.3
3.1 - 4 Months	3	102.7
4.1 - 5 Months	0	N/A
5.1 - 6 Months	2	167
6 - 12 Months	2	233.5
12.1 - 18 Months	2	422
18.1 - 24 Months	1	675
2 – 3 Years	4	894.3
Over 3 Years	2	1611.5

Table 26: Time to Complete Technical Review Period

Time Frame	Number of Facilities	Average Days within Time Frame
0-6 Months	0	N/A
6.1 - 12 Months	7	320.7
12.1 - 18 Months	7	500
18.1 - 24 Months	**10**	**632.5**
24.1 - 30 Months	**9**	**824**
30.1 - 36 Months	2	996
36.1 - 42 Months	2	1149.5
42.1 - 48 Months	3	1375
4.01 - 5 years	0	N/A
5.01 - 6 years	1	2045
6.01 - 7 years	1	2304
Over 7 years	5	3003.2

From these two tables it can be seen that most Administrative Reviews are completed within the first 30 days (average 18.1 days), and most Technical Reviews are completed within 18 – 30 months, with an average of 723.2 days. Based on these numbers, it is not unreasonable to aim for an overall average permit completion for the Administrative Review plus Technical Review of 741 days (the sum of 18.1 plus 723.2), which is approximately 2.0 years.

Analysis of the permit process from start to finish showed that a larger portion of permits are completed between 12.1 and 18 months (average of 467.3 days) or between 24.1 and 30 months (average of 799.8). Even using the larger number and rounding to 800 days it would be equivalent to 2.2 years.

While the path to accomplishment of that goal is not entirely known, the recommendations made within the body of this report should assist in this process.

In addition, the US EPA Region IX Office was contacted to identify some other states that have toxic waste permit programs that are viewed as achieving good results, and from which valid comparative agency information could be obtained. Their recommendations included Arizona, Alabama, and Florida, and contact was made with representatives of each permitting office. The Arizona Department of Environmental Quality (ADEQ) permitting department completes permits for air, water, and waste facilities with their permitting handbook available online[46] for review which outlined the entire process. A representative of ADEQ's hazardous waste permitting reported that its

[46] http://www.azdeq.gov/function/forms/download/handbook/fullhandbookw.pdf

process takes longer than California, with averages varying by type of permit application from 7.5 to 9.6 years.

Two other states reported significantly shorter averages with the Alabama Department of Environmental Management website indicating "Hazardous waste TSDF permits and municipal solid waste landfill permits **may** take more than two years to review and fully process. It stated that other permits may take only 60-90 days to reach a final decision.[47]" A representative from the Alabama Office of Permitting said their average is anywhere from six months to two years.

The Florida Department of Environmental Protection website states under Hazardous Waste Permitting, "The hazardous waste staff would suggest a pre-application meeting to discuss hazardous waste permit application requirements if a hazardous waste permit is being sought.[48]" Speaking with a representative from the Florida Department of Environmental Protection, the average processing time to review a permit application through the end of the Technical Review is 170 days. The permitting staff is held accountable by upper management who becomes involved if the permitting process is taking longer than six months. However, it is common to reach out to facilities to submit a draft application for an informal review prior to the official submission of the application. The facilities are allowed to initiate modifications during the draft review process, but not during the normal review period unless it is due to extenuating circumstances. This informal draft review is not counted as a part of the 170 days, nor is the public review period as they cannot expedite this timeframe due to regulations.

- **Finding:** The analysis conducted in this study leads to the belief that an average processing time of from 1.5 to 2.2 years should be achievable, and should be a goal of the California permitting program.

Based only on the field audits conducted as part of this study, it is theorized that those permit renewals that require permit modifications, partial closures, or corrective action on the same facility as the renewal request, have the greatest complexity, and take the longest time to complete. If this theory is proved correct, it might raise the possibility of separating out the permit renewal requests with this kind of complexity from those that do not. The specifics of the changes required can only be guessed at from the information at hand, and will not be addressed in this report. At the very least, the measurement of time required for processing such permits should be adjusted to reflect periods during which the renewal action was essentially halted, while prerequisite actions related to the continuing suitability of the entire facility are completed.

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47 http://www.adem.alabama.gov/programs/land/permitRegistration.cnt

48 http://www.dep.state.fl.us/waste/categories/hwRegulation/pages/Permitting.htm

9) Analysis of Program Metrics

This section of the report is responsive to the contract scope requirement to identify, review, and analyze available program metrics to answer the question: What should be measured in the permitting program in the future? This Chapter deals primarily with performance measures for the Permitting program, and workload will be analyzed in the next chapter. Several types of performance measures are explored in this chapter, including operational measures, outputs, and outcomes.

Operational Measures

Operational measures are those that are used for oversight and management of program operations. Most important in the current context is a system that will show timely and appropriate permitting action, and resolve concerns regarding facilities operating under expired permits for long periods of time. Management currently depends on the data in the EnviroStor tracking system for this purpose. However, as noted in the Field Audit findings (see page 15) just 85% of the most critical data fields have been entered in EnviroStor and just 43% of the identified critical data fields could be verified against actual records in the available Administrative Record. So while this system is the best available for operational metrics, improvements in its consistent use and verification is required, as follows.

This study has determined that the key process steps are not consistently and routinely recorded in the official record of operations, EnviroStor, and that the correct entry of dates of completion should be entered by the project manager and verified by a supervisor, as noted in Recommendation 1-1. The corresponding permit milestones for tracking follow:

- Call in letter – sent
- Application Parts A/B Received
- Administrative Review complete
- Final Part A and B
- Draft Permit Renewal
- Technical Complete Letter
- Public Comment – Begin
- Public Comment – End
- Final Permit Effective

One additional and important time measure (identified in the in-depth analysis of permitting time elapsed in Chapter 8) is that of a **latent time period** between the end of the Technical Review and the beginning of Public Review, as designated by "Public Comment – Begin". Initially, the initiation of the Public Comment period was assumed to take place at the time of, or immediately after, issuance of the Technical Completion Letter, or entry into EnviroStor of a "Final Part A/B". It was not expected that there would be a delay in between the completion of the Technical Review and the posting of the draft permit for Public Review.

However, when the record was reviewed, a variable and sometimes long period of time had elapsed between the end of Technical Review and the "Public Comment (Begin)" entry. This period was identified as "latent" time in this review. While no formal analysis of this lost time was performed as a part of this study, this delay is likely the result of either difficulty in getting CEQA negative declarations issued, or planning time regarding the structure and timeline to be allowed for the public comment period, as discussed in Chapter 8, pages 84-85. In either case, this would appear to be unplanned and non-value add time that can be eliminated in the future. Since this latent time was measured at from 0 to 348 days in the permit renewal records reviewed (See Table 17, Chapter 8) this represents a significant possible improvement in process flow.

A second area of delay was identified between the completion of the permit and the permit effective date. Those records indicating a formal appeal were modified to remove the time period recorded for that formal appeal. However, a variable amount of time ranging from 0 to 290 days, averaging out to approximately 1 month, elapsed between the date of "Final Permit" and "Final Permit (Effective)". This study did not find any reason for that delay, beyond a short period reserved for interested parties to file appeals. It seems that the most lengthy periods (i.e. 290 days) reflect additional areas for process improvement.

Consistent with Recommendation 1-1, Office Supervisors must take responsibility for ensuring accurate entry of these benchmark dates, and intervening to assist with problem resolution when untimely processing occurs. This should include tracking to the described "latent period", which should be eliminated after implementation of a standard permitting process as referenced in Recommendation 5-1. Each of these terms must be defined (as covered in Recommendation 5-7).

Output Measures

The measures of permit program output are reflected both in a timely final action, and in timely completion of key portions of its review process. Many of these measures are noted in the previous Chapter. They include:

- Years /months per permit renewal
- Annual average of years/months of all permits renewed (Overall, by permit authority, and by permit type.)
- Current annual percent of permits renewed that took more than five years; four years; three years; and two years (Calculated annually, for all permits renewed in that year)
- Administrative extension (time between the existing permit expiring and the new permit taking effect) (Calculated annually, for all permits renewed in that year)
- Number of months in Administrative Review (Average, calculated annually)
- Number of months in Technical Review (Average, calculated annually)

Project Managers and their project teams must ultimately be held accountable for their timely results, and primary measures of that include three of those just mentioned, including:

- Number of months in Administrative Review
- Number of months in Technical Review
- Latent period
- Years /months per permit renewal

Each of these measures should be calculated for each project managed, and included as a part of annual performance evaluation. While rigid devotion to average or arbitrary timelines does not reflect the special circumstances or levels of complexity of specific assignments, Recommendation 5-6 calls for the project manager to develop and post a timeline for each project, with a projected timeline. This timeline should be approved by their supervisor and the completion of each project timeline should be measured against the results of the noted metrics. This will allow a reasonable variation of project timelines that are specific to assignments, and valid. Such metrics would also have to be equally balanced with an overall evaluation of technical completeness of work. In other words, metrics by themselves should not be the sole basis of an annual evaluation.

Outcome Metrics

The last category of measures relate to outcomes – the overall benefit of the permit program to the economy and people of California. Like many regulatory programs, the success of the permitting program is best seen in a zero incidence of any threat – in this case from exposure to hazardous waste materials. But even though the elimination of threats is desired, a non-occurrence is impossible to measure. As a result, other options must be developed.

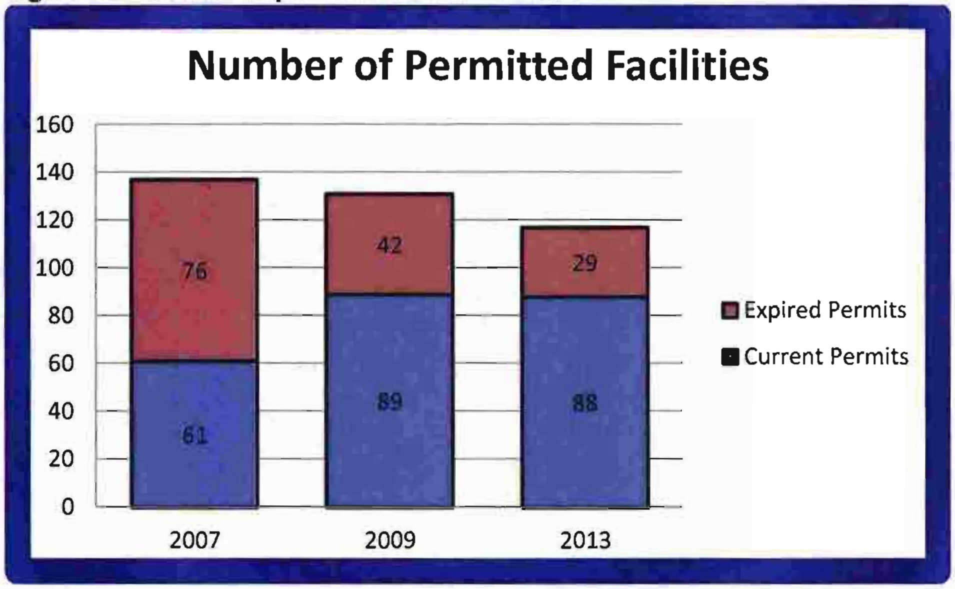
As noted in Chapter 6, while stakeholders were able to define many factors about permitting which they were dissatisfied with, they were unable to clearly define any objective, measurable factors they associated with a "good result" of permitting. The lack of any measurable program outcome metrics is a significant concern, because it creates a perception of a lack of delivered value by DTSC generally, and the permitting program specifically. Long-term, Permitting may be able to incorporate some of the measures developed by the Office of Environmental Health Hazard Assessments, and its CalEnviroScreen mapping of the cumulative impacts of multiple pollutants by zip codes. In that regard it may someday be possible to show a reduction of the pollution burden near the permitted facility.

At the very least, the timely completion of permits is one basic measure that should be used. While the "Administrative Extension" metric (explained above) shows how long permits are pending after expiration of the previously issues permit, the number of operating facilities with "current" permits would be a good outcome measure, showing program "quality". This measure is something of a "rolling average" that shows an outcome of operational effectiveness. Indeed, this measure has been slowly improving since the year 2000, and every effort should be made to keep that improvement moving into the future.

Table 27: Operating Permit Summary

	2007	2009	2013
Number of permitted facilities	137	131	117
Number of operating facilities With "current" permits	61 (45%)	89 (68%)	88 (75%)

Figure 12: Ratio of Expired to Current Permits



A related outcome measure might show clean-up progress on corrective actions at permitted facilities. This might best be measured in gallons or tons of material removed, and the percent of ordered work completed. Advisory Committee member Bill Magavern noted that, "What is important is how much threat remains to the community, so what contamination remains there is more important than how much was removed." It is unknown whether information relative to this performance is routinely gathered, and thus, whether such a measure could feasibly be implemented.

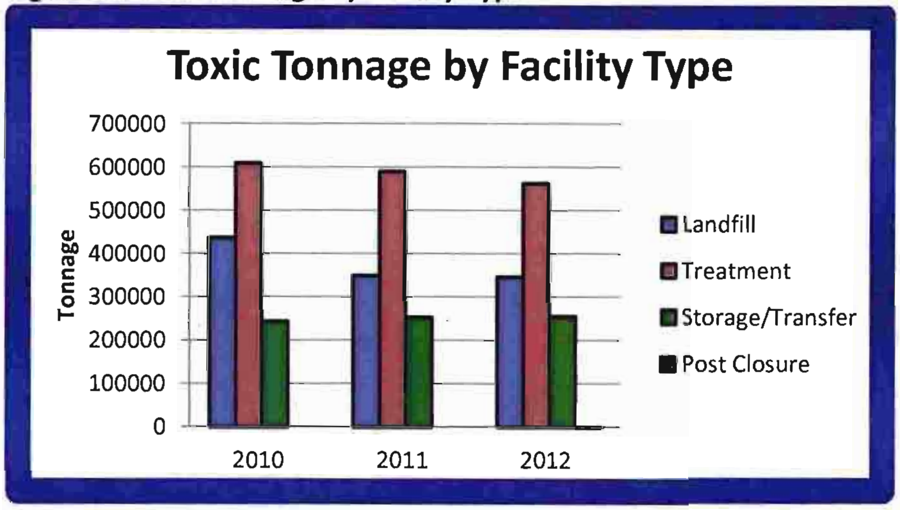
The outcome of the work of the Office of Permitting also authorizes operation of the facilities that serve as a safe "end point" for hazardous wastes generated by California businesses and households. As such, the total tonnage safely delivered per year is a positive and persuasive measure of the positive worth of the program. The following is the recent Department result, made possible through the work of the permitting program.

Disregarding the tonnage received into storage/ transfer facilities, there were 909,848 tons of hazardous waste received and processed by California treatment facilities or landfills in 2012, and verified by manifests. This amounts to 1.82 billion pounds of toxics that were processed according to DTSC statutory and regulatory standards, representing safe disposal. 62% of that total (563,087 tons) was treated to the point where it no longer met toxic requirements, and 38% placed in landfills.

Table 28: Total CA Manifested Tons by Facility Type

	2010	2011	2012	# Facilities
Landfill	437,564.9	349,428.6	346,760.6	3
Treatment	609,804.1	590,655.3	563,087.0	41
Storage/Transfer	243,758.8	253,561.6	255,878.8	43
Post Closure	--	--	15.0	28

Figure 13: Toxic Tonnage by Facility Type



Even though the Toxic Tonnage treated and moved to landfills is generally positive, It is noted that the Department's long-term goal is to reduce the total annual toxic waste stream, while preventing accidents, spills, and lost loads.

- **Finding:** The Department could and should make significant improvement in data entry and validation, and in the routine and effective use program measures, based on analysis of that data. A focus on performance measures is foundational to improved program results.

  Recommendation 9-1: The Office of Permitting should review and implement measures of operation, output, and outcome as recommended, and routinely report its results.

10) Workload Analysis

This Chapter provides a review of the adequacy of DTSC permitting staff. The historic and present staffing of the permitting program is provided in Table 1: "DTSC – Permitting Division Staffing Levels" on page 26. Significant program staffing reductions from 2007 to the present, combined with a continuing long processing time, have raised a question over whether adequate staffing exists.

It is noted that there was a reduction in the staffing of the Office of Permitting from its 95.8 authorized positions in FY 2007, to just 24.6 in FY2009. That represented a 74.3% reduction incurred over two years, which has remained largely unchanged since that time. This 2013 fiscal year (ending June 30, 2013) provided just 29 position years to that office.

This study had proposed to estimate permit renewal staffing requirements by first categorizing the primary tasks associated with permitting, and then working with experienced staff to quantify reasonable time per task standards. Once that was done, it was anticipated that an estimated number of permitting tasks per year could be developed, allowing for total workload to be calculated through the product of estimated tasks and time-per-task standards. Unfortunately, the review of work process was unable to define standard, quantifiable tasks as the basis of workload projections.

As a result, several alternative methods of analyzing work requirements were developed as follows.

Permitting Processing Rates 2007-2012

The number of permits processed on an annual basis can be tracked for past years using Envirostor records and projected for future years using current permit expiration dates and average processing times from past years. It is worthy of note that the work of permitting staff is not limited to permit renewals, but must also include permit modifications, partial closures, corrective actions, and similar activity. The study accounted for this by assuming that these activities are related tasks and an associated part of the whole body of work associated with each permit renewal, and driven primarily by the number of renewals. The observation of the EnviroStor data record seems to confirm this assumption.

The calculations presented are based primarily only on the completed permits each year, adjusted by the number of staff available to do the work. This results in the development of an "average processing time per employee per year" estimate. This is believed to be valid even though permit renewals occur over a multi-year cycle, primarily because the staffing per year has been relatively stable for a number of years, and the expiration cycle of permits does not have large increases or decreases from year-to-year. So if 10 permits were completed this year, they would have been in progress over the previous 4.3 years[49], even though all were completed this year. However, it is likely

[49] Average processing time from macro-analysis.

the permitting staff would have initiated or worked on additional permits that will be finished in future years. This balance of initiating, working on, and completing permits provides a good estimate when staffing is relatively consistent across the years. A high degree of variation in staffing would throw off the reliability of the estimate, especially if the estimate is based on a single year in which the staffing level may be higher or lower than typical. The likelihood of error is greatly reduced when staffing is relatively stable, and when the production of multiple years is used as the basis of future worker productivity. This is what was done in the presented analysis.

The first method of developing the "average processing time per employee per year" estimate used the Envirostor records of completed permits. A list of 51 facilities with permitting processes completed during Fiscal Years 2008 through 2012[50] was identified, broken down by fiscal year. This study had previously calculated the current and historic position utilization in the Permitting Office as noted in Table 1, page 26. This baseline information then yields the average number of permits each employee can process in a year, as noted in the following table.

Table 29: Average Number of Permits Completed Per Employee Per Fiscal Year

	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
Number Staff	72.8	24.6	22.1	22	26.1
Permits Completed	14	16	10	5	6
Average Permits Per Employee	**0.19**	**0.65**	**0.45**	**0.23**	**0.23**

This data shows a five-year average of **<u>35% of a permit</u>** (0.35 permits) per employee per year. The apparent variation in annual productivity could be a result of the temporarily high productivity generated by the permit renewal team[51] in FY2009 and 2010, or it could be due to variation from the permits worked on each year over that period, as discussed previously.

The examination of the permit renewal team closure report provides a second method for determining an average permit completion rate per employee per year, and acts as a validation of the above database. The permit renewal team closure report described the success of the team, consisting of 15 active members[52], in completing a total of 38 permits over a 29 month period from February 2007 to June 2009. The database was validated as complete by the presence of the same number of completed permits (38) within those dates as mentioned by the Department report. The

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[50] Included the most recent permitting cycle for new, renewal, or post-closure permits. Modifications were not included in this data set.

[51] See explanation of this team on pages 28 – 29. The Permit Renewal Team Closure Report is provided as Appendix E.

[52] There was also a Support Team of 9 toxicologists, attorneys, geologists, public participation specialists, CEQA, and enforcement staff available when necessary.

calculations[53] resulted in each team member completing an average of **1.05 permits per employee, per year**.

This is a faster processing rate than was calculated in the first method, but aligns with the idea discussed in Chapter 8 that this team was processing the easier permits in order to get a larger number of permits completed and into "current" status. Given that the selected permits were presumed to be less complicated than is typical, its average processing time should be viewed either as a maximum processing expectation under current circumstances, or perhaps as an achievable stretch goal if process improvements are achieved. In either case this processing time should be considered an optimal speed, not expected to be immediately applicable to all permitting processes.

A third method for establishing an average processing time is based on derivation of actual permit processing hours input into the Department's "Daily Log", a database that records billable employee time on permit actions. Development of the following records were based on the same six permit renewal actions randomly selected for data field validation, and described in "Field Audit of Permit Renewals" section of Chapter 1, on pages 14-16. The data developed in Table 30 shows the actual billable hours devoted to the specific named projects by all permitting program employees for the period of time over which they were renewed (from the date the Part B application was received through the completion of the permit). A full breakdown of hours spent by review period is provided in Appendix U.

Table 30: Time Spent on Six Field Audit Permitting Processes

	Total Hours Spent Processing Permit	# of Years to complete permit	Percentage of permit process completed each year per employee
AERC	576.3	3.58	2.23
AEROJET	3922.55	2.50	0.33
McCormick	2,064.6	4.13	0.62
Naval Air	5,058.3	4.19	0.25
Rho Chem	8,819.1	13.4	0.15
Shell Oil	3,703.1	3.51	0.35
AVERAGE	**4,024.0**	**5.96**	**0.32**

Looking at all six sample cases, it took an average of 4,024 hours to complete each permit process. However, it is noted that two of the six selected permits included the hours for only the Technical and Public Review periods as the records were not able to confirm the start of the Administrative Review period (receipt of Part B). Of these two, one of the processes was more complex as it took over 13

[53] 38 permits/29 months = approximately 1.31 permits per month x 12 months = 15.72 permits per year/15 employees = approximately 1.05 permits per employee, per year

years to complete due to extenuating circumstances (change of ownership) and the complexity of this particular permit, so the hours spent could be longer than the average processing time.

It must be noted that this workload analysis methodology is different from the previous method in that it is reporting actual hours in direct work related to the named permits, rather than simply allocating the number of permits completed to all employee hours for a year. The difference is that the actual hours method does not reflect the fact that not every minute of every day of a work year is spent on direct permit activity. Specifically, it must allow for "other hours" in a year, including leave time, sick time, holidays, and time spent in administrative and work tasks unrelated to permits. As a result, the actual hours method can only draw on the share of all time that the employee is actually able to devote to permit tasks. That is done through the "Available Work Year" calculation.

Available Work Year

The available work year for the Department of Toxic Substances Control - Permitting staff is a calculation of the amount of time that staff is on-duty and in the office. It is calculated by taking the base work year (52 weeks per year and 40 hours per week – 2080 hours) and adjusting it to remove annual leave, vacation, and sick leave.

In this study, consultants were provided with the actual staff time charged to Direct, Indirect, and Leave Times, as defined below, within the Office of Permitting for FY's 2011 and 2012. At the time of this study, final numbers for FY 2013 were not available.

- Direct Time – Hours charged to complete activities or tasks directly involved in the processing of facility permits.
- Indirect Time – Hours charged to Staff meetings, overhead, training, and any other tasks which are work related, but NOT directly involved in the processing of facility permits.
- Leave Time – Hours charged to vacation, sick leave, holidays, etc. in which the employees were paid but not actually in the office performing work tasks.

The overall calculated use of hours by the Office of Permitting staff is presented in Table 31, with a more specific breakdown of time used in each category in Table 32.

Table 31: Overall Average Hours Used by the Office of Permitting staff

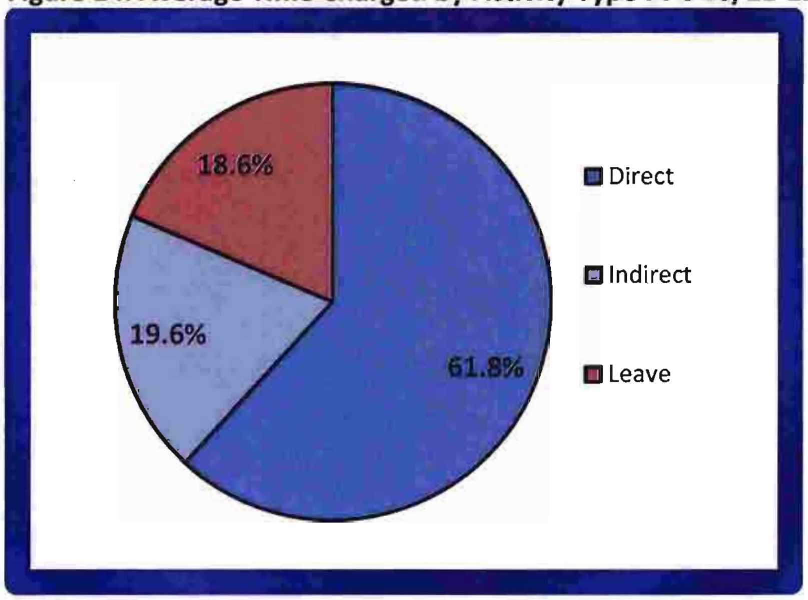
	Number of Used PY	Total possible regular work hours per year	Total Hours Charged per employee	Overtime Hours Worked per employee	Percentage of Overtime Hours Worked
FY 10/11	22	2080	2097.36	17.36	0.8%
FY 11/12	26.1	2080	2120.81	40.81	1.9%

Table 32: Average Time Charged by Activity Type for the Office of Permitting staff

	Number of Used PY	Total Hours Charged per employee	Number Direct Hours	Percentage Direct Hours	Number Indirect Hours	Percentage Indirect Hours	Number Leave Hours	Percentage Leave Hours
FY 10/11	22	2097.36	1244.30	59.3%	408.62	19.5%	444.44	21.2%
FY 11/12	26.1	2120.81	1363.04	64.3%	419.52	19.8%	338.26	15.9%

Figure 14 provides a two year average with approximately 81.4% of time is spent on regular work activities, including both Direct and Indirect Hours (78.8% in 10/11 and 84% in 11/12). Using a standard work year of 2,080 hours per employee, this ends up being approximately *1,693 (2,080*.814) available work hours per employee each year* split between Direct and Indirect activities. This is slightly less than the average of direct hours spent across the two years since those totals included the small amount of overtime used.

Figure 14: Average Time Charged by Activity Type FY's 10/11-11/12



Looking at the breakdown of time, approximately 20%, or the equivalent of 1 full work day a week, is spent on Indirect activities or tasks. Alternately, after all other kinds of demands on time, Permitting employees have been able to spend just 61.8% of all time on direct permit renewal activity. We can only therefore assume that each employee can spend 1,285 hours (2080*.618) on permit renewal activities per year.

Given that employees spend 1,285 hours a year on billable/direct work – this method of analysis predicts they would be able to complete **32% of a permit** each year.

Conclusion Regarding Permits per Employee per Year

Given that the above calculation of 32% of a permit per year was based on six randomly selected permits, while the former calculation of 35% of a permit (0.35 permits) per employee per year is based on a 100% sample of the permits completed over a five-year period, the latter figure will be presumed correct in the calculation of required staffing. The close proximity of the two numbers is considered validation of the accuracy of the latter number, with the deviation attributable to variation in the sample selection.

Calculating Needed Personnel

In order to calculate the needed personnel levels, the anticipated permitting work for each fiscal year had to be determined. The Envirostor database was used to identify the facilities that were currently in the midst of the permitting renewal process or were due for renewal between FY's 2014 and 2022 in order to identify how many permits needed to be processed. Based on the average processing rates determined in the analysis of completion rates from 2007 to 2012 (35% of a permit per employee, per year) and the six sample facilities (32% of a permit completed per employee, per year), it was determined that it should take approximately 3 years to complete a permit. The current average processing rate is 4.3 years, but prior to 2007-2008, the average processing time was 3.2 years and it is believed that the permitting staff can achieve and improve upon the prior rate with the implementation of the suggestions in this report.

Using the existing permit expiration dates from Envirostor, each of the facilities was plotted on a graph starting with the receipt of the Part B application, due six months prior to the permit expiration, and ending 3 years later to identify the time frames that each facility was scheduled for renewal[54]. This graph is presented in Appendix V, broken into 6 month periods. Given the 3 year processing time, approximately 34% (1/3) of a permit process is completed every year. The number of permits scheduled to be worked on within each fiscal year was totaled to identify the number of permits anticipated for each year. For example, if six facilities were scheduled to be involved in the permit renewal process in FY 14, it would result in 6 times .34 – which would result in the workload of approximately two full permits (even though it is spread across six facilities). The number of anticipated permits using this methodology is presented in the second column of Table 33.

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[54] If a permit was started more than three years ago and was still in process, they were given almost two additional years to complete the process, with a tentative end date of June 30, 2015. If staff completes the permit prior to this two years, their attention can be shifted to other permits or assisting in the implementation of other recommendations as suggested in Recommendation 7-2. Overdue permits with no current actions were "scheduled" to start in January 2014, allowing staff to send out Call-in letters in the fall of 2013.

Table 33: Number of Anticipated Permit Completions and Needed Employees by Fiscal Year

	Anticipated work – Number of Permits each year	Projected Needed Employees Based on 2007 – 2012 Completion Rates: 0.35 per year
FY 13/14	10.5	30.0
FY 14/15	11.7	33.4
FY 15/16	7.65	21.9
FY 16/17	11.2	32.0
FY 17/18	13.8	39.4
FY 18/19	15.3	43.7
FY 19/20	12.6	36.0
FY 20/21	9.52	27.2
FY 21/22	6.97	19.9

Several factors are relevant and important to appropriate future staffing in the Office of Permitting. Realizing that the hiring and training of new personnel will require the time and mentoring of other, current staff persons, it cannot be assumed that as soon as a person is hired they will be productive at the assumed rate. A training and transition period must be allowed. It is apparent, however, that the 30 personnel needed to stay current in FY2014 should be on staff now, and approximately one-quarter of this fiscal year already gone.[55] This ensures that even if there were no backlog of work at the start of our study, that such a backlog would be developing at this time. A backlog in the current context of work should be interpreted to mean an increase in average permit time.

It is also recognized that appropriate staffing of the office of permitting will require stable staffing over time, rather than allowing sharp increases or decreases. Looking forward we can see that the necessary five-year average staffing level would be 31.34 positions, and the nine-year average staffing level would be 31.5 positions. Theses noted staffing levels are based on utilized rather than authorized positions, and must be adjusted upwards to reflect vacancy rates. In other words, an agency that wishes to have 50 personnel working for a year, but suffers from a 10% vacancy rate, must obtain 55 authorized positions to meet its labor requirement at year end.

While this study did not develop a vacancy rate for DTSC or Permitting, it can note that the 29 authorized positions in FY2012 and 2013 were only able to be filled at a 26.1 level in FY2012. This implies a 9% vacancy rate. Applying a 9% vacancy rate to a desired 31.5 PY staffing rate would require 34.6 authorized positions in the unit, beginning immediately.

[55] This comment was based on a Oct. 1, 2013 calendar date.

- **Finding:** The Department of Toxic Substances Control will need to immediately increase its staffing in the Office of Permitting to avoid significant increases in permit processing time, and a reduction in the number of toxic waste facilities operating without a permit.

  Recommendation 10-1: The Department should immediately seek authorization through the budget process for 35 positions, and should seek to hire and train those positions as quickly as possible – a 20% increase in its current staffing authorization. This hiring strategy will be necessary to avoid an increase in average permit processing time, and an increase in the number of toxic waste facilities operating without a permit. While permit processing times and productivity per staff person may be expected to be improve through process improvements recommended as a part of this study, it will take multiple years to bring average processing time to a more acceptable.

Summary of Recommendations

Recommendation	Urgency of Implementation • Required to eliminate identified program issues. • Highly Recommended to respond to identified program issues. • Recommended best practice.
Recommendation 1-1: The Department must initiate supervisory confirmation of all milestone dates input into EnviroStor as a double-check to the current practice of independent project manager entry, to ensure accurate input that matches the operational record. This practice will also confirm supervisor awareness of the completion of key permit process milestones, and invite their intervention when prompt processing is delayed.	**Required**
Recommendation 1-2: Develop a network file including templates and samples of best-quality permitting work products, including model permits and a best practice call in letter, to support the adopted standard process.	**Recommended**
Recommendation 2-1: Formally articulate the objectives and purposes of the Permitting Program based on law, and ensure that these objectives are disseminated and understood by the permitting staff and the broader public. The lack of a clearly stated objectives and purposes is creating an uncertainty in the actions of the Department, and a lack of clarity in public expectations about the Permitting Program. These objectives and purposes should specifically address three policy questions including: What constitutes a timely permitting action; Under what circumstances lengthy permit renewals are in compliance with law, and; When and how the enforcement and required clean-up actions of recorded violations are adequately considered in permit renewal? Once developed, the objectives and purposes should be reviewed and affirmed by Cal-EPA Secretariat, and the relevant Legislative Oversight Committees.	**Required**

Recommendation	Urgency of Implementation • Required to eliminate identified program issues. • Highly Recommended to respond to identified program issues. • Recommended best practice.
Recommendation 4-1: DTSC should establish a clear and predictable organizational structure for permitting that is focused on in-person meetings, in-office work, and updated training. Telecommuting should be severely limited or revoked for at least a six-month period while these necessary improvements take place and the objectives and purposes in Recommendation 2-1 are implemented. All permit staff duty statements should be brought up-to-date along with goals and performance appraisals during this period. Necessary updates to standard templates, work aids, and work processes should be achieved. Work units should use this time to build solid relationships with their supervisors. Maintaining traditional in-office work groups, with a supervisor at each location, will improve communication and assist with re-establishment of efficient processes and work production.	**Highly Recommended**
Recommendation 5-1: Adopt the revised process flow for permitting proposed in this report, or a similar standard process flow. Require notes on the criteria for each decision and the sign-off standards for each process (or project) step. Specify a clear logic for any alterations in dates or tasks. Such a process must respond to the grey areas identified earlier as follows: • A defined and coordinate initial process review by DTSC CEQA staff and DTSC Community Involvement staff; • Initial and regular/as needed consultation between enforcement and permitting; • A mandatory permit renewal meeting with the appropriate DTSC technical team and the permit applicant; • A site visit between the appropriate DTSC technical team and the permit applicant early in the Technical Review.	**Required**
Recommendation 5-2: The Permitting Office should develop instructional and guidance materials to support the Technical Review process flow. This should include clear and written decision-making criteria associated with each Section, and processing check sheets to match the process steps on the Part B flowchart. The U.S. EPA materials should be used as a reference.	**Required**

Recommendation	Urgency of Implementation • **Required** to eliminate identified program issues. • **Highly Recommended** to respond to identified program issues. • **Recommended** best practice.
Recommendation 5-3: DTSC should enter into a cooperative agreement with EPA to: 1) Access its technical assistance in revision and design of permit processing procedures; 2) Provide materials and training on Technical Review; 3) Participate in regional permitting discussions and training.	**Recommended**
Recommendation 5-4: Future changes in management at the civil service level should be discouraged, to allow time for the recommendations of this report to be implemented and for leadership to be held accountable for those changes.	**Recommended**
Recommendation 5-5: Each project manager should initiate a project "charter" at the time of the 'call-in letter', and should complete that charter by the time a complete permit renewal application is received. A project charter structure will direct the project manager to consider and plan for all project variables, and should address: • the significant objectives to be addressed; • what is "in scope" and "out of scope" for the action; • the specific deliverables that will be produced; • the estimated effort, cost and duration of the effort; • the required project team and what roles they will have; • the communications plan for the project team; • the stakeholders and any role they will have; • the renewal project assumptions, constraints, threats and necessary approvals. The charter will help in structuring the project team and in development of the project plan.	**Highly Recommended**
Recommendation 5-6: Immediately after completion of a charter, the project manager should develop and post a project plan for each renewal. The project plan should show all major tasks, and a timeline for completion of each. This project plan should be reviewed and approved by a supervisor and a team lead for that type of renewal.	**Required**

Recommendation	Urgency of Implementation • **Required** to eliminate identified program issues. • **Highly Recommended** to respond to identified program issues. • **Recommended** best practice.
Recommendation 5-7: Develop a standard lexicon of terms regarding permit renewal actions, so terms such as Notice of Deficiency are not used during Administrative Review, and so that a common, standard process is consistently described in all departmental communication.	**Recommended**
Recommendation 6-1: The Department should develop a new system of categorizing violations that reflects whether they present an immediate and direct threat to human health and safety, versus a less urgent threat that can be mitigated or resolved through further actions of the Department. The Department's current definition of "Class 1 violations", although mandated by law, includes both violations that pose immediate and direct threats along with many that are relatively low- or long-term threats. Until the Department has a system of violations that can distinguish between significant threats to human health and safety and lesser threats, it will not be able to provide an objective standard to guide its own staff actions and to inform the public that the significant threats have been mitigated through actions such as permit modification, denial or revocation.	**Required**
Recommendation 6-2: The Department should distinguish between Notices of Deficiency that are prejudicial from those that are not, with grounds for prejudice being defined by the language in HSC 25200.8, including "substantially incomplete or substantially unsatisfactory information", or an untimely response. This change should be pursued as a change to Administrative Law. (The definition of "prejudicial" in the context of this recommendation is that an action to revoke a permit or renewal action would be **required** after a maximum of three such actions.)	**Required**
Recommendation 6-3: DTSC should develop and adopt a risk standard for permitting, consistent with stakeholder input that the program must have a standard to demonstrate a clear, documented threat to public safety, human health, or environmental preservation, as a primary driver of appropriate permitting action.	**Highly Recommended**

Recommendation	Urgency of Implementation • **Required** to eliminate identified program issues. • **Highly Recommended** to respond to identified program issues. • **Recommended** best practice.
Recommendation 6-4: Expand the specialized staffing of the Financial Responsibility Unit to allow for its independent review of clean-up costs and financial assurance obligations, and require sign-off prior to permit renewal. Require compliance with Department policy to update financial assurance every five years. As an interim measure, DTSC should contract out the financial assurance function of the permitting program to an entity that possesses the appropriate knowledge on the topic.	**Highly Recommended**
Recommendation 7-1: As soon as Recommendations 5-1 and 5-2 are substantially addressed, Permitting should re-offer its 2012 training materials with appropriate updates. This training should be provided to all employees in 90-minute segments, in person and by video conference, on a regular twice-a-month schedule. This should be used as an opportunity to refresh training and to further identify process areas that need attention.	**Required**
Recommendation 7-2: The Permit Office Manager and Supervisors should develop a list of tasks and actions called for as a part of the improvements recommended by this study, in priority and chronological order, and periodically review it with all staff, possibly at the twice-a-month training meetings. Volunteer assistance should be solicited to develop all materials, and draft products reviewed and approved by designated groups of two or three subject matter experts.	**Highly Recommended**
Recommendation 8-1: The Department should research whether and how to change its requirements to make the Part B Application due 180 days prior to the expiration of the existing permit. This objective and purpose should be reviewed and affirmed by Cal EPA Secretariat, and if agreed to, recommended to the appropriate Legislative Committees for statutory revision.	**Recommended**
Recommendation 9-1: The Office of Permitting should review and implement measures of operation, output, and outcome as recommended, and routinely report its results.	**Recommended**

Recommendation	Urgency of Implementation • <u>**Required**</u> to eliminate identified program issues. • <u>**Highly Recommended**</u> to respond to identified program issues. • <u>**Recommended**</u> best practice.
Recommendation 10-1: The Department should immediately **seek authorization through the budget process** for 35 positions, and should seek to hire and train those positions as quickly as possible – a 20% increase in its current staffing authorization. This hiring strategy will be necessary to avoid an increase in average permit processing time, and an increase in the number of toxic waste facilities operating without a permit. While permit processing times and productivity per staff person may be expected to be improve through process improvements recommended as a part of this study, it will take multiple years to bring average processing time to a more acceptable.	**Required**

APP. L

PROCEEDINGS

SENATOR DUTTON: Thank you all for joining us. We're going to go ahead and start as a subcommittee of Rules. There's other Members who will be joining us as quickly as possible; but in the interest of everybody's time, we want to go ahead and get started.

I'm going to go ahead and go out of order on the agenda, and so what I'd like to do is start with item number 2, Senator Simitian's legislation request involving SJR 23.

(Discussion off the record re SJR 23.)

SENATOR DUTTON: Let's establish a quorum.

MS. BROWN: Senator Alquist.

SENATOR ALQUIST: Here.

MS. BROWN: Alquist here.

De León.

Fuller.

SENATOR FULLER: Here.

MS. BROWN: Fuller here.

Dutton.

SENATOR DUTTON: Here.

MS. BROWN: Dutton here.

Steinberg.

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(Continued discussion off the record re SJR 23.)

SENATOR DUTTON: This would be an appropriate time for a motion.

SENATOR ALQUIST: I move.

SENATOR DUTTON: Moved by Senator Alquist.

Will you please take the roll.

MS. BROWN: Senator Alquist.

SENATOR ALQUIST: Aye.

MS. BROWN: Alquist aye.

De León.

SENATOR De LEÓN: Aye.

MS. BROWN: De León aye.

Fuller.

SENATOR FULLER: Aye.

MS. BROWN: Fuller aye.

Dutton.

SENATOR DUTTON: Aye.

MS. BROWN: Dutton aye.

Steinberg.

CHAIRMAN STEINBERG: Aye.

MS. BROWN: Steinberg aye.

SENATOR SIMITIAN: Thank you, Mr. Chairman, plural, and I appreciate the support.

CHAIRMAN STEINBERG: Thank you, Senator

Simitian.

Thank you, Senator Dutton, for chairing and getting the meeting started.

Let us move now to governor's appointees appearing today and begin with Deborah O. Raphael as the director of the Department of Toxic Substances Control.

Welcome to you.

MS. RAPHAEL: All right.

CHAIRMAN STEINBERG: Please take the hot seat in the middle.

MS. RAPHAEL: It's a great one.

CHAIRMAN STEINBERG: We want to welcome you, Ms. Raphael, and invite you to introduce any member of your family or special guest, to make a brief opening statement, and then we'll commence questioning.

MS. RAPHAEL: Thank you, Senator, and Members of the Rules Committee. I'm deeply honored to be here today. I would like to introduce my family members who are here. My husband, Miles; my daughter, Katie; and my son, Brian; my nephew, Grant; and my children's godfather even came, Scott. So I feel I'm in good hands, knowing they're behind me.

CHAIRMAN STEINBERG: Well supported. Welcome to all of you.

MS. RAPHAEL: As I said, I'm deeply honored to be here. I feel this is ultimately the best place for me to be in my career. I am a lifelong Californian. I'm the daughter of a physicist, so science has been in my blood from the very first moments of my life.

I spent my undergraduate years at U.C. Berkeley and my graduate years at UCLA where I fully intended to pursue a life of science. Instead I found a different life, a compatible life in public service, and for the past 20 years I have found for me the perfect nexus of science and changing the world, which is, in fact, the public sector.

Today as DTSC director, I feel perfectly positioned to execute those responsibilities that are at the nexus of science and public policy. I find myself at the helm of this organization at a particularly difficult time in California right now, whether it's financial or, certainly, a crisis of confidence in government; and I believe it is my passion in public service and my commitment to good, pragmatic, scientifically based decisions that will see me forward during the next years.

DTSC has a particularly unique charge where we are held with the responsibility of managing hazardous waste, managing toxins in the environment. We do that by looking at the problems and the challenges of yesterday, which is cleanup of brownfields, for example, the challenges of today, which, as we all know in this room, are exemplified by the permitting of hazardous waste landfills, as well as the permitting and enforcement of operations that use hazardous materials.

In addition, we're looking forward, and in terms of hazardous waste, we're looking at what are the wastes of the future, whether those be solar panels or other electronics that come to the end of life. It's our job to create workable solutions and manage those toxins that are in the everyday products, but that challenge comes with some particular competing interests. Some think that we're asking too little; some think we're asking too much.

So it's a tough mandate to find that nexus, to find that pragmatic space where we can balance the interest of different entities and find solutions that benefit the entire state of California. And in order to find that balance, I do not stay behind my desk on the 25th floor in the CalEPA building in Sacramento. Whenever I can, I get out into the community, because it's only there where I can get a true sense and understanding for the impacts of the decisions I need to make. I ask hard questions, I bring in all viewpoints, and I'm not afraid to make the tough decisions, from Indian lands, to farm lands, to the inner-city. I'm listening carefully, for that is the information I use, juxtaposed with my legal authorities, my scientific/technical expertise, and the advice of my staff, to make my decisions forward.

One solution clearly is that we need to generate less of this hazardous waste to begin with, and the department is positioned at a very unique place in time right now with the regulations that we are working on to actually change the way toxic chemicals are used in the design of consumer products. But in the meantime, we face some difficult issues, and I want you to know that I commit that in the work I do, communities will have their health protected, that businesses will be treated fairly, and that government under me will operate predictably and professionally, because if we do it right, we will have a better and safer environment for all of those who come.

So in short, I want to leave you with what I believe in: I believe in the rights of communities to participate in the decisions that affect them; I believe in the power of science to offer solutions; and I believe that a strong economy and strong environmental regulations must coexist.

As director of DTSC, I have one goal, and that goal is to protect people and to do that with decisions that in the long run build fresh confidence not only in DTSC but in the State of California as well.

With that, again, I'm honored to be here, and I am excited and interested to answer your questions.

CHAIRMAN STEINBERG: Okay. Thank you again. I know I have a series of questions, but I think I'm going to ask my colleagues to go first and see where it goes.

Senator Alquist.

SENATOR ALQUIST: Thank you, Mr. Chair.

Welcome, Ms. Raphael. Two weeks ago I asked the director of the Department of Public Health what type of followup work DPH is doing in Kettleman City. I know this is my big question. Several weeks ago, I asked Secretary Rodriquez questions about Kettleman City; and by now I hope everyone is well aware of the relatively high number of severe birth defects in this small town.

The mission of your department is to protect the public health and the environment from the harmful effects of toxic substances. I doubt that all the residents of Kettleman City believe their health is being protected. And this issue has been going on for many years, way before you were there, but it's important that we talk about it and solve the situation. So I have basically two or three questions.

What work and community outreach have you done during your tenure as director of the Department of Toxic -- TSC with Kettleman City, would be my first question.

MS. RAPHAEL: Okay. Thank you.

Clearly, the issue of what to do with hazardous waste, where does it go, touches no community more deeply than that of Kettleman City. They live three and a half miles from the state's largest facility as an end point for the hazardous waste that is not generated in their community, that is generated across the state of California. That is a significant burden to such a small community of people.

Well before I took this job, I was aware of the challenges and the problems in that small town, and the burden that they face. So very early on in my tenure -- I've been here a little over ten months -- I traveled to Kettleman, and I wanted to go in two directions when I was there. Number one, I wanted to see the community itself and talk to the residents; and, number two, I needed to see the facility. This is the place that we regulate that I, as the director, have the responsibility to make and the decision to make to ensure it operates safely and it obeys the law. In order to do that, I needed to see the facility with my own eyes.

So I spent almost a day at the facility, looking at the various operational aspects, talking with the people who run it, talking with my enforcement team and my inspectors to understand what is it that they are doing at the facility, and where would my confidence be that this is a facility that could operate or could not operate.

So in terms of my own personal connection, I've spent time at the facility; I've spent time on a number of occasions with residents, either in the Kettleman area or when we would meet in other locations in the Central Valley, as well as in my offices in Sacramento. My door has always been open to community members and members of the activist community. I take this responsibility very personally, and I want to make sure I have the best information.

SENATOR ALQUIST: Thank you.

Your department is one of three coordinating the use of biomonitoring programs. The legislature established biomonitoring to assess exposure to chemicals that cause, among other things, birth defects, which we know is a quite high rate in this small town.

So to date, biomonitoring has not happened in Kettleman City, so -- this would be my last question, but it's two or three questions in here. So I would ask you: Why has it not occurred; what role should it play; and how important could it be to Kettleman City?

MS. RAPHAEL: We are blessed in California, because we have a state biomonitoring program. That is not something any other state in the nation can say that they have, and that was at the behest of the legislature who passed that law and gave it to three departments. So DTSC, OEHHA, and Department of Public Health share that responsibility.

DTSC has used biomonitoring extensively as a way to have an early warning signal when toxic chemicals are showing up in wildlife and in people. So, clearly, there could be a nexus here in looking at impacted communities.

To this moment in time, biomonitoring has not actually -- You are correct in saying biomonitoring has not been offered to the residents of Kettleman. What I will commit to and am excited to do is to go deeper into the why on that and to work with the Department of Public Health to ask the question: Is this an appropriate place for biomonitoring? If not, why not? Let's talk to the community members, bring them into the conversation to get a realistic view of what could biomonitoring -- how could it help; what kind of information could it give to the community members that they don't already have. The idea of finding out what's in their bodies, can we link it to anything in the environment, are the chemicals that they're being exposed to even -- sorry -- contained in their bodies, that some of the pesticides won't be picked up in biomonitoring, is what I want to say.

SENATOR ALQUIST: Would you commit to, in the next three months, asking these questions?

MS. RAPHAEL: I will.

SENATOR ALQUIST: And at that point, putting out a statement after you evaluate the answers to those questions, stating either specifically why biomonitoring would not be a good thing to use in Kettleman City, or why it would be to implement the process.

MS. RAPHAEL: Yes. I would -- So a piece of that, along with that, is the report on birth defects, and when that comes out and is finalized, and we can take a look at if there are significant patterns of birth defects that might point us to particular chemicals that we want to biomonitor for, that will inform that decision.

I'm committing to do what you say. The three months, I don't know when the report is coming out, so I want to make sure whatever conversation we have is robust.

SENATOR ALQUIST: Thank you very much.

CHAIRMAN STEINBERG: Senator Fuller.

SENATOR FULLER: I really appreciated the time you took yesterday to explain the green chemistry initiative. Unfortunately, not through your fault, but I was a bit overwhelmed. I still have some questions in that area.

One of the things that you made very clear was the value of the scientific process to analyze potential harms of the chemicals concerned, as well as the potential harms of any alternatives to the chemicals. And I'm hoping you can briefly just kind of go over a little bit again the importance of the alternative analysis so that we don't get into a situation where -- I think you called it "regrettable substitution," and we'll move to a couple more questions on this area, so we'll kind of go briefly. But I want to try to get us through the sequence, how hard this is going to be, and how we find a way together to make it palatable.

The first thing is, if we don't do something in a thoughtful way with a scientific process, we end up with a regrettable substitution. Can you briefly explain the importance of the alternative analysis process to avoid that?

MS. RAPHAEL: I think, perhaps, the most important element of AB 1879, the law that put this regulation in motion, is introducing the idea of alternatives analysis. What can happen when somebody says, "I want to get formaldehyde out of this product," they just put anything in that's not formaldehyde, for example. The problem with that, as we said in our conversation, is you could actually substitute something worse off than the formaldehyde itself. And we call that -- maybe it's a euphemism -- a "regrettable substitute," because you end up regretting the fact that you made that change.

So how do you know something is safer? That's really the question that the alternative analysis is trying to tackle. When you say we have identified there's a problematic chemical in a product that has the potential to expose a population, how do we know that what we're replacing it with is, in fact, safer for the environment, for humans? The only way to do that is to look at what would you be substituting, a range of alternatives, and asking for each one: Does that one cause cancer? Does that one have a different impact? Because what you don't want to do is substitute an air pollutant for a water pollutant, right? That's the classic case of MTBE that we're all painfully aware of. And so by having a number of criteria by which you use to compare things, and if you compare each one using the same, then you end up with an array of information that points you in the direction of a safer alternative.

The real power of this law is that you don't stop there. It's not enough to say something is safer. It also has to be feasible. It has to be practical. You have to be able to meet performance standards. So you cannot, for example, get rid of a solvent to take paint off with water, right? Water would be less toxic, but if it doesn't remove the paint, you haven't really gotten a real alternative.

So the beauty of this law is that it directs our department to not only look at the science of the alternatives and their safety, but also the pragmatic aspects: Are they real alternatives? Are they technologically feasible? Are they financially feasible? And all of that is required in part of this analysis.

SENATOR FULLER: And so that leads us to the conclusion that it's preferable to do this process compared to having individual laws banning the use of a specific chemical in order to be able to get at exactly in what particular environment it is. In other words, you are saying that in some environments the chemical is not toxic, but in other environments it is, depending on the kind of contact it has for individuals.

So one of the concerns I'm still struggling with little bit, and I hope you can help me understand, last year you supported legislation banning the use of a single chemical, BPA, and stated it was prudent to restrict its use in a narrow range of products, but yet the Office of Environmental Health has since reported that the replacements for BPA are showing the potential to be more problematic from a public health perspective. In fact, one member of the biomonitoring California Scientific Guidance Panel, who is a U.C. Berkeley researcher, expressed concern that the alternatives to BPA are equally problematic or worse. So that's exactly the situation that you're trying to stay out of. Going forward, how are we going to avoid getting in that place again?

MS. RAPHAEL: In that letter, the point I was trying to make is that while -- First, the process that we're working on regulations on is not in place yet. Once it's in place, the legislature will have an offering. You will have a place to move this kind of question so that it is a more thoughtful, long kind of issue. The process is not in place, and even once it is in place, there will be times where the legislature will want to act.

In the case of BPA, what was important about the law as it was adopted in the state of California is that it talked about the alternatives, that the alternatives cannot be worse off than the Bisphenol A. Part of the problem in the past is that we would just write the ban language without any mention of alternatives, and so the BPA ban was very narrow. And it was also on a -- I'm not sure how much we want to go -- I think what you're trying to get at are those mutually exclusive ideas.

SENATOR FULLER: Yes. And at the time you put out the letter, it seems that you felt that was a problematic chemical, but yet we didn't seem to have found in technology a chemical that was better, and there wasn't a process to identify that. And it seems like the whole process of 2,100 chemicals that are listed is going to take a really long time, and I'm kind of afraid we'll continually end up in that situation where we haven't gotten guidance on the technology that will allow us to take the proper alternative and that the process itself takes so long.

So you're sitting in that chair where you will have that dilemma to correct, and I hope you can explain and give me some feeling of how we can get from here to there.

MS. RAPHAEL: I hope I can answer the question to give you confidence in my ability to make those determinations.

The way the process will work -- Assuming the 2,100 chemicals is, in fact, the list that is there, those are all chemicals that have known problems. We identify them with a product that has exposure. In the case of BPA, it was the baby bottle. It wasn't all uses of BPA. It was simply baby bottles. So we would identify a product category, and then we would put that out for public comment.

So we would say: Here are three, four, five potential products that we are considering looking at. Let's get feedback from the manufacturers. Are there alternatives out there now? Are those -- Do we know enough to say there's a safer alternative out there? Maybe we shouldn't pick something of those five if there isn't a right alternative, if you will, or maybe we do pick something because it drives the research that way.

It's a very flexible outcome. It's not just a ban, which is the other beautiful part of this. It's not an all-or-nothing. If we were to choose something like BPA, the end regulatory response could be more study, that we need some specific more information.

So my job as director will be to take in the science, make the best determinations we can for which product chemical combinations are the most important to California, put that out for public comment, taking that information back, and then proceed from there.

SENATOR FULLER: Thank you.

MS. RAPHAEL: Thank you.

CHAIRMAN STEINBERG: I may have some followup on that line of questioning in a moment, but Senator Dutton.

SENATOR DUTTON: Thank you, Mr. Chairman.

I want to thank you for taking the time. I enjoyed discussing the agency and what your thoughts are with regard to how you plan to run it or direct it, as the case may be. I guess that leads to one of my questions.

Oftentimes, the kind of calls I get into my office regarding businesses that are trying to work with various agencies in the state is that it almost seems like the people at the ground level, at the local level, have power and try to have all the power, and sometimes it almost appears as though -- I'm not saying they do -- but it appears as though they may have a little bit too much freedom.

I was curious from your perspective, do you feel you have the authority and power to be able to run the agency and make sure that people all the way down the line actually are in compliance with the policies and protocols that you're going to put into place?

MS. RAPHAEL: The short answer is: Absolutely, yes. The "how" I do that is an interesting journey. One of the --

When I was speaking with Governor Brown about this job, he said to me, "I would like you to approach this job with two words," and he said, "'genuine inquiry.' I want you to ask the hard questions." And that's a place I'm very comfortable in being.

So when I came to the department, I started asking those questions, and I found a number of answers, depending on the questions. I found an incredible willingness to work with me and to join me in asking questions. And one of the things I uncovered, one of the challenges we have is inconsistency. We have policies. We have hierarchies, and yet we aren't -- haven't done a good enough job of communicating that down, and I, as a director, need to make sure that is happening in a way that is understandable, my expectations, all the way up and down the agency. And that's tough when you've got 980 employees across eight sites across the state. We're doing that. And I'm very encouraged by what we're seeing, because I'm encouraging the bottom-up to ask those same questions too, because they may be frustrated by those inconsistencies as well.

So when you have a constituent come to you and say, "I don't think I'm being treated fairly. I don't think DTSC staff are treating me the same way they are treating someone else," that's exactly what I need to know, because I can respond to that immediately. And it's those conversations that I'm committed to having. Thank you.

SENATOR DUTTON: Will you be performing an economic analysis on the proposed regs that will be coming up here shortly regarding green chemistry and so forth?

MS. RAPHAEL: Indeed. We did -- There was a preliminary economic analysis done for the first round. We have now asked the team of outside experts to look back on the revised regulation, to let us know -- I'm assuming they need to update that economic analysis, and when we release the regulations, whenever that is, that will also be released as well. Absolutely.

SENATOR DUTTON: One of the challenges that I found personally as a -- now, a ten-year legislator, is that sometimes you have a long, unintended consequence. Sometimes a little bit better analysis on the front end could save you some trouble. So that was my concern in that area there.

I noted that in your support for the confirmation, there's very few businesses on the list. And now I have an updated list, but it seems mostly larger organizations. What do you plan to do to reach out to the small business community of our state to make sure they have an understanding and clarity, or -- and also they have the opportunity to provide input?

MS. RAPHAEL: When I joined public service, I joined at the local level, so for most of my 20 years I have been working in local government, City of Santa Monica, City of San Francisco, and in that capacity I became very familiar with local chambers of commerce and small business commissions. So my history is an affinity to that size of an organization, and I fully understand the importance they play in the state of California.

Now that I find myself in the state capital, it feels a little distant from that face-to-face with small businesses. It's very easy for me to have interactions with the larger businesses. They have their lobbyists; they have a presence here. The Chamber of Commerce is here. Those are easy relationships to build.

The small business relationships are more challenging, and those are the ones I've been working on on a steady state. So I am looking for partners to help me get out in front of small businesses. I have met with small businesses across the state on individual levels. We've given awards to plating shops in Southern California. I have met with auto shops when we're talking about automotive products, and I've met with small manufacturers who are parts of alliances looking at sustainable production. I have a lot more I can do on that, and I'm very excited to do that, especially in the context of these regulations, because it is the small business that we're most concerned with in terms of their ability to meet the expectations.

SENATOR DUTTON: I made the offer in our office, and I'll make it in public too. I'll be more than happy to facilitate workshops down in my district. The Inland Empire is basically a manufacturing and industrial-type area, so I think maybe having a better working relationship between the small business community down in those areas -- I was sincere yesterday. Publicly, I'm going to say it again. I'll be more than happy to work with you to put together some workshops down in my district to help to give the small business community a little bit better understanding of your agency and what it is you are trying to achieve.

MS. RAPHAEL: Senator, I will publicly say I will take you up on that offer and very much look forward to it.

SENATOR DUTTON: Thank you.

CHAIRMAN STEINBERG: Senator De León.

SENATOR De LEÓN: Thank you very much, Mr. Pro Tem.

Ms. Raphael, I know we met yesterday. We had a good meeting. You have a very impressive resumé. I know we mentioned, obviously, you worked in Santa Monica as well as San Francisco. I know that you have a B.A. from UCLA, as well as a master's degree from Cal. We talked about yesterday you have a B.A. in physiological plant ecology.

MS. RAPHAEL: Right. Very helpful subject.

SENATOR De LEÓN: Let me rephrase that. You have a master's in physiological plant ecology.

MS. RAPHAEL: Yes.

SENATOR De LEÓN: And all but the dissertation for your Ph.D., and, obviously, biology as well as ecology, your B.A. at University of California at Berkeley.

Given -- Touching upon a little of Senator Alquist's line of questioning, given that it's a very difficult period economically, obviously, the budget has been cut and department heads are being told to squeeze their budgets even tighter, to do more with less, I want to talk to you about your plan specifically to ensure that disadvantaged communities are protected.

Obviously, we know that these are communities that are disproportionately impacted by chemicals, by chemical plants, because of their zoning laws at the local/county levels. We don't always exactly know, but for whatever reasons, there was junkyards and chemical plants all over the place, and if you live in another income -- zip code area where there were -- there's green parks and open space, but they're closer to a tire dumping center or a junkyard.

With that tighter budget, give us a ballpark figure -- I'm not asking you to give us a magic solution. I know it's difficult right now, but what are you going to do as the head of this department to ensure that these communities that have disproportional impact to their health, that they will be protected?

MS. RAPHAEL: That's the central question. And this actually, in my mind, gets back to Senator Dutton's question on how can I be sure that at the ground level -- do I have enough authority at the ground level as the director.

It really gets back to the idea that as the director, I set the vision, and I set the expectation, and while that expectation has to do with consistency and performance, it also has to do with commitment to environmental justice and commitment to protection of communities. That starts with me. That is my most important role as director. How I manifest that is not only in my words, but in my actions.

One of the things I have done is put people in place who I believe share that same commitment. My deputy for enforcement, my chief counsel, my deputy for cleanup, these are all people who I know at their very core believe that this is their responsibility and are driven to prioritize this with their staff.

So as we contract, which we will at DTSC, because our budget is not looking terribly good, as we contract and lose positions, certainly lose vacancies, we must set those priorities so that that doesn't fall off, that becomes the mission of every single person. Whether they're in my legal shop, my admin shop, my lab, everyone carries that around as their central responsibility.

The other place we're focusing to make sure those needs are not lost is within our public outreach, our community liaison. Those people know that it is their job to not sit behind a desk but to get out in the community. If I may, I'd love to give you an example of how we're going to do that in a more effective way.

SENATOR De LEÓN: Let me ask another question before you get to that. You made an interesting point. Is that the current culture, if you will, of your department, and you see the challenges in front of you, and you want to make folks more proactive, or do you have a sense that -- or, rather, do you have proactive bodies that don't sit behind a desk but are actively engaged in their community? Please be candid.

MS. RAPHAEL: Candidly, it's a mix. Candidly, it's a mix. We have some of the most impressive, dedicated staff. In fact, the example I was going to give was one in the Imperial Valley where there's something called the IVAN database, and what that is -- IVAN is "Imperial Valley -- " and I just blanked out what the A-N stands for, so I apologize. The point of that is that it's a community-driven set of eyes where the community looks out in their neighborhoods and identifies the blight, identifies the things that are most upsetting to them, whether it's illegal dumping, or an air emissions problem, or a water pollution problem. Whatever it is, they put it in a central database that comes to DTSC's office in El Centro, California, and there we have identified a community problem-solver. That's a person who wears many hats. One of them is community problem-solver. That DTSC employee takes that information and acts as a hub, because not all those problems are related to DTSC. They could be under the authority of other jurisdictions, but because of that fractured nature of government, we serve as the hub.

That idea did not come from me. That came from that employee working with community members. And Luis Almada (phonetic) and his team of people down in the Imperial County came up with those ideas. So it's a mix of people. We have the very best, and we have people who, perhaps, need a little push.

SENATOR De LEÓN: Sure. Thank you for your answer and for your candidness.

I was struck by your answer about a set of core values that you adhere to, and, obviously, that will be manifested in your management style and the vision you bring to this department.

At the core -- I would make the assumption, please correct me if I'm wrong, your upper management folks that you have selected share those core values. Obviously, they share your philosophy and that, obviously, of the governor.

So how does that -- Walk me through sort of management leadership 101. How does the very top, obviously, through your leadership as being the head of this department, sort of penetrate, trickle down, if you will, to the very bottom? Because sometimes -- I enjoy what you're saying. I'm with you 100 percent. I'm cheering you on. It's great, theoretically, great for folks to teach in class at a theoretical level, you know, but how it actually is practiced, how it's executed, top to bottom, bottom up, if you will, walk us through that.

MS. RAPHAEL: There's so many levels to that. So jumping to the end, how do I know I've done it. The emails I get back from people saying how they are looking at their job differently. So I know it's working. I'll jump to the bottom. How have I been doing it? I do it by honestly setting expectations clearly, clearly saying, "This behavior is not acceptable. This is not a professional example, and this is." And I ask people to think of it through a very simple lens -- it's a one-word lens -- and that is "confidence."

I have asked every individual in our department to ask: Is this action they're taking building confidence or eroding confidence? That's a very, very powerful frame. And as we talk and meet, and I meet with staff -- I meet with staff one-on-one, with 15-minute conversations with any staff who wants to meet with me. So I get the truth, not the filtered truth, through staff meetings, through problem solving and prioritization. I have a white board where all the problems that stakeholders bring to me, the decisions we haven't made, frustrations they have with the department, are up on my white board. And I call, and we have committees for each one of those to solve them.

So people see action, and they understand the word "confidence." And that's been a very effective and powerful frame for our department. And, frankly, I think the staff at our department are hungry for this and are responding. And I'm very proud of the work we're doing.

SENATOR De LEÓN: Okay. I know we had, yesterday, a little bit of conversation to some degree on Kettleman City. I know Senator Alquist had a -- broached that subject, and I know that we're waiting for data still from the federal EPA so -- before some action items could be put forth.

Mr. President, just one last question.

I know we broached this yesterday, and this is with regard to a letter, obviously, that I sent, I believe to you, with regards to the potential relocation of a lab in downtown Los Angeles. Could you give us an update on what's happening? And the reason why -- my background, obviously -- the background. I shouldn't say mine.

Tough economic times. You have families right now not knowing what's going to happen. Do they have to relocate to Northern California, Berkeley? They have roots in Southern California. Are they going to be, you know, rooted elsewhere throughout Southern California? Some sense of uncertainty, I would suspect. So what's happening with that?

MS. RAPHAEL: We have a lab. One of our facilities is a very old, ancient, outdated laboratory facility in downtown Los Angeles. I've been there twice to meet with staff. We have about 11 staff members who work there now. It's not an appropriate place for our staff to work. I do not believe it's a healthy environment for them, and so we are committed to moving them. In fact, we must, because DPH occupies the lease on that, and they are closing it down in six months.

So we're now looking at facilities across Southern California, as well, as you mentioned, in Berkeley, and looking at the cost estimates of that move, and the plusses and minuses. What do we lose if we move and consolidate everything to Northern California? What is important for our enforcement team to have present for them in Southern California with respect to the lab?

We made a map of where everybody lives who works there, and then we looked at various facilities. And the problem, as you know, with Southern California, it's a big place, and it's very hard to find something that's centrally located and doesn't impact one of those families. Our commitment is to do our very best to keep it in Southern California, if we can.

SENATOR De LEÓN: Have you or someone in management been in touch, obviously, with the staff members who would be impacted?

MS. RAPHAEL: Yes. Frequently.

SENATOR De LEÓN: All right. Thank you very much.

MS. RAPHAEL: Thank you.

CHAIRMAN STEINBERG: Thank you, Senators.

A couple follow-up questions for myself. Ms. Raphael, I know there are a number of people here from in and around the Kettleman City area I believe who will testify in a few minutes. It might be an opportunity to clarify a few things, understanding a couple of things: Number one, that your department has limited jurisdiction over the overall issue in Kettleman City; two, I'm appreciative of your earlier testimony that you've been there, and you've talked to residents, and you've surveyed the situation yourself. And there's some facts here unrelated, again, to anything that you have been involved in that are just unreal to me --

MS. RAPHAEL: Okay.

CHAIRMAN STEINBERG: -- that in 1994, residents filed a civil rights complaint with the U.S. EPA around their claim of toxic exposure, and this is 2012, and they have never received a response on their claims.

Now I understand, in part from your advocacy and the advocacy of the community, that they have now committed to providing such a report by the 31st of August of 2012, a response to the claim of a disproportionate number of birth defects as a result of toxic exposure.

Now you have this regulatory responsibility, if you will, over the hazardous waste project. Do you want to say anything here today publicly? Not, obviously, about what decision you're going to make, because this isn't the place to do it, and you have to obey the law, but the timing of your decision versus the receipt of that response, 18-years-late response, from the United States Environmental Protection Agency?

MS. RAPHAEL: I'm glad that timing wasn't on my shoulders.

CHAIRMAN STEINBERG: No, it isn't.
MS. RAPHAEL: I think what -- But what it points to is: What do I need, as a director, to make a decision? What are those factors that have to become clear to me in order to have confidence that we are making the right decision?
There are two main -- There are a number of things that we're working on, because a decision has not been made. And I am very clear on that. We are still at the discussion of whether or not a permit expansion will be adopted, will be granted. We are in that process of gathering information.
In order to have that information, we're going to need to know about birth defects; we're going to need to know what happened since the 2010 study that looked up 2007 and 2008, so we're going to need that information before.
CHAIRMAN STEINBERG: How will you obtain that information?
MS. RAPHAEL: That is Department of Public Health, and I believe they committed to this group a couple weeks ago to have that out shortly. I'm looking forward to seeing that.
The second thing would be then -- the piece would be the resolution of this complaint that was

filed in 1994 that U.S. EPA has been sitting on for all those years. If it takes till August, I will wait until August, because I think it's incumbent upon me as the director to be able to answer those -- the charges that were brought in the complaint about DTSC's performance. Even though those charges were from 1994, if we can get information on how we are to proceed now and how we need to proceed in light of those, I need to know that.

CHAIRMAN STEINBERG: What about some additional CEQA evaluation regarding the facility; is that something you plan to do before making a decision?

MS. RAPHAEL: So those were the two documents that are not in my control, that are not in DTSC's control. One is the resolution of the Title 6 complaint, the civil rights complaint, and one is the birth defects. What is in DTSC's control is how we evaluate and use the CEQA process to get a broader feel for what is going on in Kettleman.

We need to -- Part of CEQA is looking at cumulative impacts. So since the time that the previous CEQA document was completed, which was 2007, we need to take additional information into account, look at what other facilities have been cited around the Kettleman community, look at the issue of birth defects, look at pesticide exposures, to try to have an idea of what -- paint a picture of the reality of the situation for the residents of Kettleman, and how does the facility play into that. And that's part of the additional work that we are working on right now.

CHAIRMAN STEINBERG: Thank you.

One other set of questions, if I might, on green chemistry and the DTSC's responsibility. Senator Fuller, I think, questioned you about it at length, and Senator Dutton, I believe, to balance and consider individual chemicals to determine their safety. My friend, Senator Fuller, my colleague, Senator Fuller -- I'm not sure, and, obviously, the question is not directed to you, but I just want to understand how you see this. If the concern is that the legislature is doing one-offs here, or that the green chemistry initiative itself is not good, sound public policy. Because I know in opposing -- some Members of the minority party ended up opposing the Bisphenol A bans. Point two, the fact that we have a process in place now --

MS. RAPHAEL: Hopefully.

CHAIRMAN STEINBERG: Hopefully. So I think clarifying what the concern is, if there is a concern, would be helpful to my understanding. But maybe you can elaborate a little bit more about how you see the relationship between the process that is now established as a regulatory process to evaluate the safety and the alternatives around specific chemicals, and the legislature's, sometimes, desire to get into the fray, especially when it comes to a high-profile product, especially given the fact that you have, if I'm reading this correctly -- how many thousands of -- 3,000 chemicals of concern that you potentially -- your department might potentially look at over time, which means that if number 2,500 is really important, you're not going to get to it for a long while.

So how do you guide the legislature here in determining whether to take up any of these chemical issues legislatively versus giving you, as the regulator, the responsibility to weigh that balance?

MS. RAPHAEL: So I think the short answer is: Urgency and timing. The law 1879 was written with no shortcuts in it. It was written to be very deliberative. A list of chemicals of concern are identified. They're paired with products, because you can't -- the way I talk about this is, it answers the question. It's law. By the way, we don't have the system set up yet. We have a law in place. We have no regulations in place. So at this point in time, there is still no offer of the legislature in terms of doing this kind of analysis.

The analysis was written to have no shortcuts, so once a chemical and product is identified, like BPA in baby bottles, for example, then an alternatives analysis is done. That is done in a very deliberative process. It can take up to a couple of years. Then you have a regulatory response process. That takes time. There may be a situation, and we'll use the BPA example since that's the one at hand, where 11 other states have already banned this product, and, wherein the case of baby bottles, the only place BPA baby bottles were being sold in the state of California is in 99 Cent stores. So it becomes an access issue, not one of a level playing field for the public.

There may be times when there's a need to move quickly, that the legislature still wants to have a role. So that's where I see these as together. The preferable place will be the more deliberative process, the process whereby we have the time to look at alternatives, especially for ones where we're not sure exactly what the alternative might be, and we want to work with industry to ask the question *Is it necessary?* and look for those alternatives.

Did that help?

CHAIRMAN STEINBERG: Yes, it did.

MS. RAPHAEL: Okay.

CHAIRMAN STEINBERG: Please, Senator Fuller.

SENATOR FULLER: If I can shed any clarity on your question, it's exactly that, that in some instances in our earlier action, we seemed to have jumped to *"This is a harmful chemical,"* but we didn't have a safer alternative, and because we didn't have one we landed on something that might have been worse. So now we have this process for that not to happen, but we have a list of, like, 3,000 chemicals, and I don't think it's going to get done in the near -- I know it's not the final list, but this is a starting point. There's a long period of time to look at it. I'm just saying: How do we get from here to there over time?

CHAIRMAN STEINBERG: I think you've done a good job, in my view, sort of describing at least an analytical framework for how we might look at it. Senator Fuller and others, we might agree or disagree with that, but I think it's clear. What you're saying is your process is the preferred process.

Where there's a matter of urgency, especially given the backlog, then it's appropriate for the legislature to consider it.

Of course, it's pretty obvious that a lot of bills introduced in the legislature, they don't all get through and signed by the governor, right? So there is a filter there. We just don't say, "Yes, we want this done," you know, "Do it."

MS. RAPHAEL: There's a process.

CHAIRMAN STEINBERG: Yes. Very good.

Let's hear from witnesses in support of the nomination.

MR. MALAN: Mr. Pro Tem, Members, Justin Malan on behalf of two organizations today. I'll try to be brief. They're somewhat disparate groups, and I think it reflects the merits of this candidate today. With regard to the health directors association of the local environmental health directors that do most of the hazardous waste work for the local level, and -- we want to commend the administration for choosing this candidate to fulfill that position. It's critically important that the state and the local jurisdictions work in concert on these issues, whatever they are, particularly as it pertains to disadvantaged communities or any

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State of California

Appendix 13.1

Department of Toxic Substances Control

Memorandum

: Ted N. Rauh
Deputy Director
Hazardous Waste Management Program

Date: July 20, 1993

From : Office of Legal Counsel
324-5780

Subject: Revision of OPP 87-15, Permit Denial Policy

In March or April you asked me to revise OPP 87-15, Permit Denial Policy. I did a draft revision about the time Jim Pappas' workgroup was finalizing the Permit Writer Handbook. Now that I'm getting back to the policy and comparing it to the handbook, I realize that most of what is in the policy is already in the handbook.

The main piece that is not in the handbook concerns the criteria for permit decisions, which is attached to this memo as Attachment 1. This section covers the criteria for taking action based on a disclosure statement, which we discussed with Bill Carter in March. At that point, we intended to add it to the revised Permit Denial Policy. Attachment 1 could be added to the handbook or issued as a separate policy.

There are several miscellaneous issues that may or may not be covered in the handbook. I thought Jim could tell me more quickly than I could go through the handbook. I will include the text on the miscellaneous issues as Attachment 2, and we can clarify these issues with Jim.

Please let Jim and me know if you want Attachment 1 included in the handbook or issued separately. I will ask Jim by copy of this memo about the issues raised in Attachment 2.

Michael Shepard
Senior Staff Attorney

Attachments

cc: See next page.

cc: Jim Pappas
Region 1

Odette Madriago
Headquarters

Colleen Murphy
Office of Legal Counsel

ATTACHMENT 1

CRITERIA FOR PERMIT DECISIONS

The department has substantial discretion in deciding whether to grant or deny a permit application or to revoke a permit:

A. Health and Safety Code (HSC), Section 25186

HSC section 25186 allows denial or revocation of a permit based on (a) violations of or noncompliance with environmental protection statutes and regulations, if the violation or noncompliance shows a repeating or recurring pattern or may pose a threat to public health or safety or the environment, (b) aiding, abetting, or permitting such violations, (c) violation of or noncompliance with administrative or court orders, (d) misrepresentation or omission of significant information in information reported to the Department, (e) activities resulting in conviction of a crime significantly related to the applicant's fitness to perform under the permit, and (f) activities resulting in the revocation or suspension of any related permit.

B. 22 California Code of Regulations (CCR) Section 66270.43

Title 22 CCR section 66270.43 lists four criteria for revocation or denial:

1. Any cause specified in HSC section 25186.

2. Noncompliance by the applicant with any condition of a permit.

   This criterion allows the Department to deny a permit application from a facility that has not been operating in compliance with its permit. The violations should be significant in nature to serve as a basis for denial, should be well documented over a period of time by the Department, Regional Water Quality Control Board (RWQCB), or USEPA inspection reports, and the facility should have been notified of the violations in writing well before the denial decision is made. Some examples of violations that would generally be considered significant and are the type of violation that could support a denial decision include:

(a) Failure to install an adequate environmental monitoring system;

(b) Failure to construct the facility properly, for example, inadequate containment systems; inadequate run-on/run-off collection systems; systems that do not meet seismic and precipitation design standards; or use of construction materials that are incompatible with wastes being handled; and

(c) Failure to manage waste handled at the facility property, e.g., failure to comply with waste analysis requirements; failure to maintain adequate security; improper handling of incompatible reactive or ignitable wastes; or spillage of wastes onto soil.

3. The applicant's failure, in the application or during the permit issuance process, to disclose fully all relevant facts or the permittee's misrepresentation of any relevant facts at any time.

Failure of an applicant to provide adequate information in the Part B application, failure to respond to a notice of deficiency (NOD), or misrepresenting any facts in the Part B are grounds for denial. Only significant violations will support a denial. Failure of a facility to submit a complete Part B application in the original submittal generally should not be used as a basis for denial. A NOD should be issued to facilities in these situations. Failure to respond to a NOD or submittal of a response that is grossly inadequate can (and should be) used as a basis for denial. It is important, however, that the NOD address all significant Part B deficiencies to maximize the Department's basis for denial if the facility fails to respond or does not respond adequately. Keep in mind the fact that HSC section 25200.8 requires the

Department to initiate denial of an application if the facility does not respond to three or more NODs.

4. A determination that the permitted activity endangers human health or the environment and cannot be adequately regulated under a permit.

All facilities should be evaluated to determine if they can operate (or continue to operate) without posing a threat to public health and the environment. This evaluation will focus primarily on the potential for releases of hazardous wastes to occur at significant levels, but other environmental impacts should be considered as well. Two key documents, the Part B application and the Environmental Impact Report (EIR) or Initial Study (IS), will provide most of the information that will be used to identify potential or actual impacts. The EIR/IS can be particularly useful because the scope is broader than the Part B application. The EIR/IS may provide information on significant impacts that are not directly associated with releases of hazardous waste. Other important sources of data and information that may help in determining the potential for impacts or identifying actual impacts include surveillance and enforcement inspection reports, RWQCB inspection reports (including comprehensive groundwater monitoring evaluations), and exposure information reports submitted by disposal facilities pursuant to RCRA.

Some examples of situations that could serve as grounds for denial under this criterion are provided below:

(a) "Existing" landfills are not required to meet any specific manufactured liner standards, but must meet the containment performance standard specified in 22 CCR section 66264.31. This situation means that natural geological conditions at the unit must be sufficient to contain the hazardous waste and prevent contamination of the vadose zone and groundwater. If migration of wastes is documented through groundwater monitoring data, inspection reports, or any other reliable source, the Department might conclude that the best way to "adequately regulate" the unit would be to deny the permit application and require the facility to close. As part of closure, the facility would be required to install a low permeability cap over the landfill to prevent any further influx of precipitation and to monitor the groundwater.

(b) Large amounts of hazardous wastes can be released via evaporation from surface impoundments located in areas with high evapotranspiration rates. The Department could deny an application if these atmospheric releases would be high enough to impact adversely the health of individuals living or working in the area of the hazardous waste facility.

(c) Significant impacts not directly associated with releases of wastes from a facility can be identified through the IS or EIR process. Vehicular traffic associated with the operation of a facility, for example, can have a severe impact on some communities. This situation would primarily be associated with large, commercial, off-site hazardous waste facilities that create a large flow of heavy truck traffic over extended periods. The Department could deny a permit application in this situation, if the truck traffic were forced to move through a relatively quiet commercial or residential area to get to the facility because of the lack of any other access route.

(d) Failure of an incineration facility to meet the standards for a trial burn. The Department could deny an application based on failure to meet technical criteria (e.g., excessive HCL in exhaust) or failure to comply with the required protocol standards (e.g., waste flow rate too low).

C. General Considerations

There are two different types of criteria listed in the statute and regulations discussed above as a basis for permit decisions.

First, HSC Sections 25186(a) and 25200(a) require a permit applicant and holder to comply with the requirements established in statute and regulation for a hazardous waste facility permit. In addition 22 Cal. Code Regs. Section 66270.43(b)(3) specifies that a permit may be denied or revoked if the Department determines that the permitted activity will endanger human health or the environment and cannot be adequately regulated under a permit. Under this type of criteria the specific reason cited for denying or revoking a permit will be a technical requirement, usually one found in the regulations, as described above.

Second, HSC Section 25186 and 22 Cal. Code Regs. Section 66270.43(b)(1) and (2) provide that a permit may be denied or revoked on the basis of the acts and omissions of the permit applicant or holder. While the statute and regulation establish criteria, they do not provide a clear yes or no answer to the question whether to grant, deny, or revoke a permit based on the behavior of the permit applicant or holder. In evaluating behavior, the following factors should be considered:

1. The nature and seriousness of a violation, noncompliance, failure to disclose or misrepresentation of information, etc.

2. The date of the event referred to in #1.

3. Whether the event referred to in #1 was an isolated or repeated incident.

4. Whether the event referred to in #1 was an intentional or negligent act.

5. The nature and seriousness of any potential threat to public health or the environment.

6. The circumstances surrounding the behavior.

Generally denial or revocation of a permit should only be considered when an act of the permit applicant or holder poses a threat to public health or the environment, results in conviction of a crime significantly related to fitness to perform under the permit, is a violation of an administrative or court order, shows a clear unwillingness or inability to comply with environmental laws, or results in the revocation or suspension of any related permit.

ATTACHMENT 2

OTHER ISSUES

A. Multiple Units at a Single Facility

Multiple-unit facilities may be permitted by: (1) a single decision to permit all units or to deny all units; (2) a single decision to permit some units and to deny the other units; or (3) separate decisions to issue or deny permits for individual units or groups of units (in this case, all interim status units not addressed in the permit decision remain under interim status).

The administrative procedure for making the final permit decision is the same for all three of these scenarios. When a single decision is used to permit some units and any others, all documentation prepared should clearly identify the units being permitted, those being denied, and the basis for reaching the decision for each unit.

B. Permit Conditions

When the Department grants a permit with conditions, the conditions are in effect a partial denial of the permit application that may be appealed by the applicant.

If the applicant comments on and petitions for review of permit conditions, the Department will treat the contested conditions as a permit denial.

C. The Relationship Between Permit Denial and Facility Closure

Interim status terminates on the date the Department's final permit decision becomes effective for an interim status facility. This date may vary from 30 days after service of the final permit decision, if no petition for review is filed, to 30 days after service of the final decision after a review.

A closure plan be submitted within 15 days of the date on which interim status terminates (22 CCR section 66265.11c(d)(3)(A)). Facilities in the latter category must resubmit a closure plan due to the fact that the one in the Part B is based on 22 CCR, div. 4.5. chapter 14, rather than chapter 15 standards. More importantly it does not reflect closure of the units in accordance with the date on which interim status terminates. These plans are then reviewed, determined to be complete, public noticed, and approved following the regular closure plan approval process.

Facilities that are having some units permitted and other denied are more complicated. In this situation (as a permit condition), the facility must submit a revised Part B that incudes a closure plan reflecting only the permitted units. The facility must also submit a closure plan, as discussed in (C) above, for the denied units. These plans can then be reviewed together, public noticed as both a permit modification and closure plan approval, and approved. (Note: if post-closure will be required for the units closing under interim status, a separate post-closure permit can be issued or the operating permit can be modified to include post-closure requirements for these units.)

D. The Relationship Between Denial and Issuance of a Post-Closure Permit

No specific time requirement for submittal of a post-closure permit application following denial is established in regulations. Therefore, a fair amount of flexibility exists in triggering the post-closure permitting process. Three different strategies are generally available, including:

1. The post-closure permit application can be called in at the same time as the closure plan. Both documents can then be reviewed and approved together.

2. The post-closure permit application can be called in after the closure plan has been approved and the permit can be issued prior to completion of closure. Once the facility completes closure, it moves directly into post-closure.

3. The post-closure permit application can be called in after the closure plan has been approved and the permit can be issued after completion of closure. In this situation, the facility must be

directed (usually in the closure plan approval letter) to comply with interim status post-closure requirements following completion of closure and until a post-closure permit is issued.

Issuance of a post-closure permit subsequent to a denial action follows the same review, public notice, and approval process as for an operating permit. As noted above, facilities that have some units permitted and some denied can be handled two different ways with regard to issuance of a post-closure permit: (1) a separate post-closure permit addressing only the denied units requiring post-closure can be issued, or (2) the facility's operating permit can be modified (via a major modification) to include post-closure requirements for the denied units.

APP. N

CENTER ON RACE, POVERTY & THE ENVIRONMENT

KETTLEMAN CITY HEALTH QUESTIONNAIRE
Summary of Results

October 24, 2013

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Introduction

During the week of September 16, 2013, employees of the Center on Race, Poverty & the Environment, Greenaction for Health and Environmental Justice and members of El Pueblo Para El Aire y Agua Limpio visited the homes of Kettleman City residents to inform them of an upcoming public hearing on the expansion of the nearby Kettleman Hills hazardous waste facility. Residents were also asked to share any concerns they had about the proposed expansion. During these home visits, an unexpected number of residents reported that they had recently been diagnosed with cancer. In fact, in a one block radius on 9th Street, nine residents reported that they had cancer; several had been diagnosed just that week. Residents also expressed concern about high birth defect rates, miscarriages, anemia, asthma, and valley fever that they perceived may be linked to environmental contamination from the existing Kettleman Hills Hazardous Waste Landfill and other sources of pollution.

Based on this information, the Center on Race, Poverty & the Environment determined that a comprehensive health survey of Kettleman City was necessary to determine whether rates of illness in Kettleman City were higher than would be expected. Despite requests from Kettleman City residents, no local, State or Federal agency has conducted a comprehensive health survey in Kettleman City. CRPE determined that while it did not have necessary resources to conduct a comprehensive health survey, it did have the resources to gather more information about Kettleman City resident health through a more focused health questionnaire. CRPE conducted the questionnaire with support from Greenaction for Health and Environmental Justice and El Pueblo para el Aire y Agua Limpio.

This questionnaire is not meant to be scientific, establish causation, or be a replacement for a comprehensive health survey. Rather the questionnaire is designed to provide additional information to the Department of Toxic Substances Control and other agencies to aid them in permitting decisions and other decisions that may affect the health of Kettleman City residents. It also should provide agency decision-makers with additional information on specific vulnerabilities experienced by Kettleman City residents that may be exacerbated by adding more pollution in the area. CRPE hopes that the results of this questionnaire will prompt the Department of Toxic Substances Control and/or other agencies to conduct a comprehensive health survey in order to fully assess the health of Kettleman City residents and determine whether illnesses and ailments in Kettleman City may be linked to environmental factors.

Methodology

Questionnaire administrators spent a total of three evenings in Kettleman City asking Kettleman City residents a series of questions about whether they had experienced illnesses and ailments commonly associated with environmental factors. Administrators randomly selected homes in Kettleman City to visit. If a resident answered the door, administrators verbally asked him or her a series of questions and recorded the responses on a questionnaire sheet. Administrators asked participants questions in the primary language of the participants. The majority of residents elected to be given the questionnaire in Spanish. Administrators asked residents to provide answers based on their knowledge of the health of all members of the household. All questionnaires are anonymous; administrators included no identifying information with a resident's responses. In total, 88 residents completed the questionnaire. This represents a little over a quarter of the 350 total households in Kettleman City.

The questionnaire included the following topics:

- Cancer diagnoses
- Birth defect incidences
- Miscarriages

- Anemia
- Valley fever

The question topics were developed based on feedback by members of El Pueblo para el Aire y Agua Limpio and other Kettleman City residents. Residents have expressed concern about a number of illnesses and ailments they believe to be elevated in the town. Ailments that have already been well-documented in Kettleman City, such as asthma, were not specifically included in the questionnaire. However, residents were asked to share any other health concerns they had in order to capture possible illness and ailments that were not specifically included in the questionnaire.

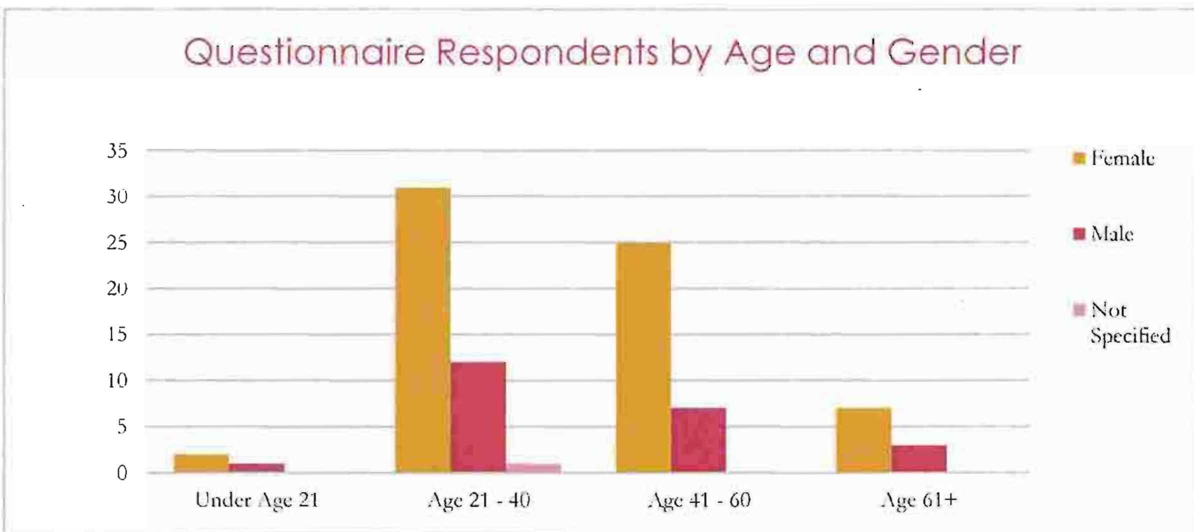
If participants indicated that someone within the household experienced a particular illness or ailment, they were asked follow-up questions to gather additional information specific to that ailment or illness.

The questionnaire administrators checked returned surveys for missing information and responses that would cause scanning errors. After scanning, the responses were imported into Qualtrics. Data analysis was completed using Qualtrics and Microsoft Excel.

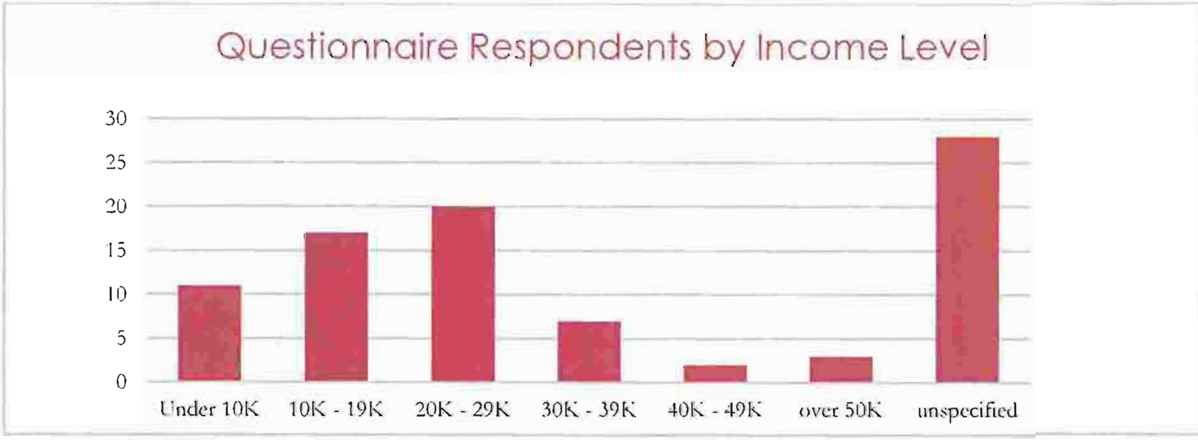
Demographics

Questionnaire responses are broken out by several demographic categories, as follows:

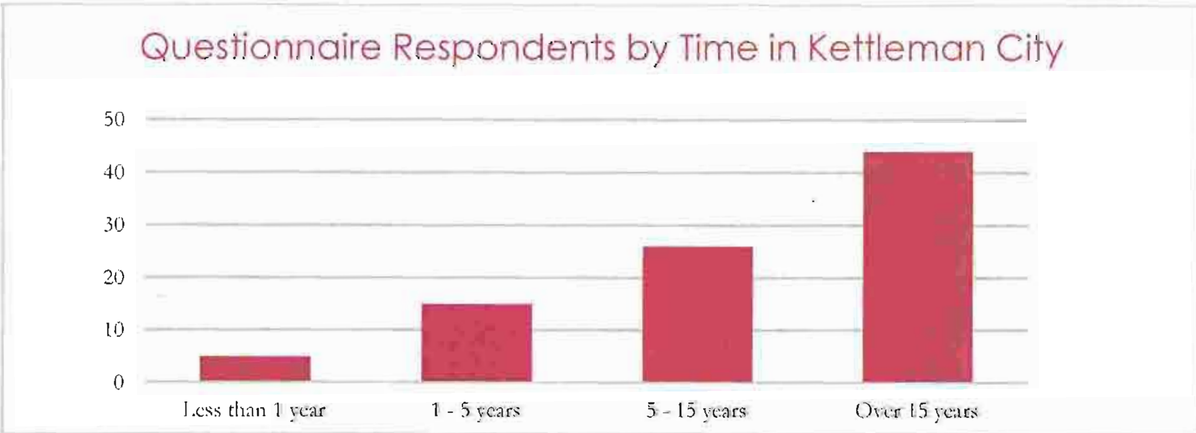
- The percentage of respondents are broken out by:
  - Under age 20
  - Age 21 to 40
  - Age 41 - 60
  - Age 61 and above
- Gender
- Income
- Years of residency in Kettleman City



The vast majority of responders were females between the ages of 30 and 60. Generally, questionnaire administrators asked that the resident participants be over the age of 18. However, one participant was under the age of 18.



According to the 2010 Census, the median income in Kettleman City is $22,409 per household. The household incomes of questionnaire respondents mirrored the Census results with the vast majority of participants indicating a total annual household income of less than $30,000. Many participants that did specify an exact income level reported that they did not work or did not have an income.



Questionnaire participants were weighted heavily toward longer-term residents. Fifty percent of participants reported that they had lived in Kettleman City for over 15 years. Only five participants reported that they had lived in Kettleman City for less than a year.

Questionnaire administrators also asked participants about their race/ethnicity. One hundred percent of participants indicated that they were Mexican, Latino, or Hispanic.

Questionnaire Results

Cancer Incidence in the Household

Response	Count and percent
Yes	20 (23%)
No	68 (77%)

Several households indicated more than one cancer, bringing the total identified incidence to 24. Residents reported a range of cancers including kidney (x3), uterus (x3), breast (x2), ovarian (x2), mouth (x2), leukemia (x2), cervix, colon, stomach, prostate, lung, and bone. One resident reported a noncancerous brain tumor in a child; this incidence is not included in the cancer incidence statistics.

There was a wide range of the age at diagnosis, ranging from 6 to 64. However, 83% of the cancers were diagnosed in residents when they were under the age of 55.

Birth Defect Incidence in the Household

Response	Count and percent
Yes	6 (7%)
No	78 (93%)

Residents reported various birth defects including missing limbs, heart defects, incomplete formation of the eyelid, defects of the cornea, down's syndrome, hearing defects, cleft palate and cerebral palsy. Several households experienced more than one birth defect, bringing the total reported number of children born with defects to ten. Several of these defects occurred after the state released its birth defect investigation, including one in 2010 and two in 2011. Others occurred in 1993, 2004, 2005, 2007, 2008, and 2009(x2). All of the babies survived.

Miscarriage Incidence in the Household

Response	Count and percent
Yes	18 (21%)
No	66 (79%)

Expectant mothers were in various stages of their pregnancies when the miscarriages occurred, ranging from one month to seven months. Most occurred in the third or fourth months of pregnancy. Several households experienced multiple miscarriages, bringing the total number of miscarriages to 26. The miscarriages occurred between 1989 to 2013, with a majority occurring after 2005 (61%).

Valley Fever Incidence in the Household

Response	Count and percent
Yes	17 (20%)
No	71 (80%)

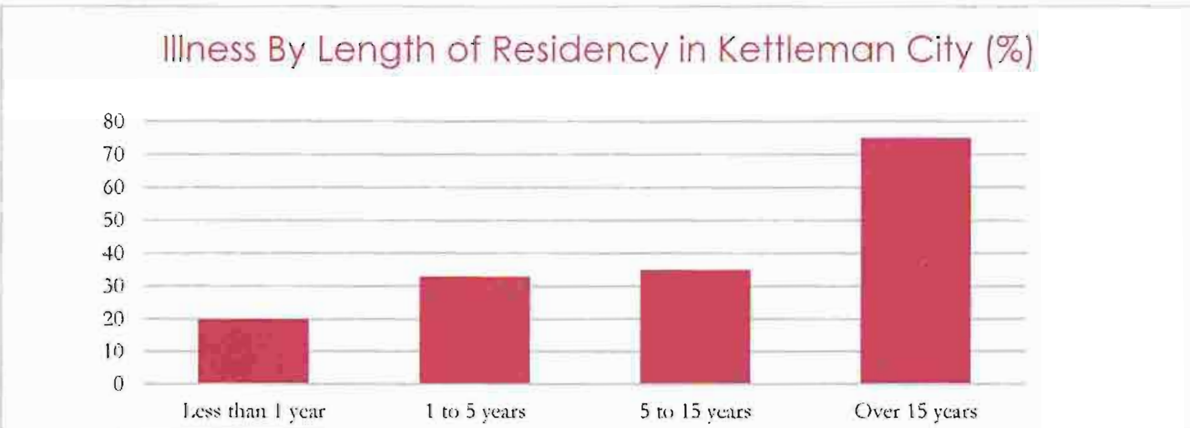
Number of Households Experiencing at Least One Illness or Ailment[1]

Response	Count and percent
Yes	48 (55%)
No	40 (45%)

Over half of the questionnaire participants indicated that at least one person in the household experienced an illness or ailment that is commonly associated with environmental factors. Many participants reported more than one ailment or illness in the household. The questionnaire invited participants to share any other ailments or illness experienced in the household. Asthma was by far the most common response, followed by allergies. Other residents identified respiratory problems, reproductive problems, diabetes, and headaches in the household. Though the questionnaire did not specifically ask residents about asthma incidence, many residents reported asthma in addition to the other illnesses and ailments specifically included in the questionnaire.

Illness and Ailments by Length of Residency in Kettleman City

Amount of Time in Kettleman City	Percent experiencing illness or ailment
Less than 1 year	1 out of 5 (20%)
1 to 5 years	5 out of 15 (33%)
5 to 15 years	9 out of 26 (35%)
Over 15 years	33 out of 44 (75%)



Residents who reported living in Kettleman City the longest also reported the highest levels of illnesses and ailments. Seventy-five percent of residents who have lived in Kettleman City for over 15 years reported at least one person in the household suffered from an illness or ailment

[1] For purposes of the Questionnaire Results section, all references to "illness or ailment" refer only to the five indicators covered specifically in the questionnaire: cancer, birth defect, miscarriage, anemia, and valley fever.

that is commonly associated with environmental factors. Of those, about half indicated multiple illness or ailments in the household. Only one resident who had lived in Kettleman City for less than one year reported an illness or ailment.

Conclusion

The questionnaire confirms that Kettleman City residents are right to be concerned about illnesses and ailments that may be caused by environmental factors. Many households in Kettleman City appear to be coping with at least one serious illness or ailment that would affect the family's health and financial well-being. Many of the affected households were low or very low income and, therefore, least equipped to defray expensive medical costs associated with illness and ailments.

Families that have lived in Kettleman City the longest, appear to be at greatest risk from ailments and illness. Based on these data, one could infer that living in Kettleman City is a causal factor in developing these illnesses and ailments.

Based on the composite responses to the questionnaire, CRPE believes that the Department of Toxic Substances Control should complete a comprehensive health survey of Kettleman City to determine the extent of illness and ailments in town that are commonly associated with environmental factors. In addition to the illness and ailments covered by this questionnaire, the comprehensive health survey should include questions about asthma, respiratory problems, and allergies.

The Department of Toxic Substances Control and the Department of Public Health should evaluate and notify Kettleman City residents what the expected rates of these illness and ailments would be in a town the size of Kettleman City.

Agencies should not permit additional polluting facilities in or near Kettleman until a full comprehensive health survey is complete. If the health survey confirms that illness and ailments that are commonly linked to environmental factors are elevated in Kettleman City, agencies must not permit additional sources of pollution and instead must take steps to reduce the pollution burden in Kettleman City. Agencies must provide additional health resources to help residents cope with elevated levels of illness and ailments in town.

APP. O

[Federal Register Volume 75, Number 26 (Tuesday, February 9, 2010)]
[Rules and Regulations]
[Pages 6473-6537]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2010-1990]

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Part III

Environmental Protection Agency

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40 CFR Parts 50 and 58

Primary National Ambient Air Quality Standards for Nitrogen Dioxide; Final Rule

Federal Register / Vol. 75, No. 26 / Tuesday, February 9, 2010 / Rules and Regulations

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 58

[EPA-HQ-OAR-2006-0922; FRL 9107-9]
RIN 2060-AO19

Primary National Ambient Air Quality Standards for Nitrogen Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria for oxides of nitrogen and the primary national ambient air quality standard (NAAQS) for oxides of nitrogen as measured by nitrogen dioxide (NO2), EPA is making revisions to the primary NO2 NAAQS in order to provide requisite protection of public health. Specifically, EPA is establishing a new 1-hour standard at a level of 100 ppb, based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations, to supplement the existing annual standard. EPA is also establishing requirements for an NO2 monitoring network that will include monitors at locations where maximum NO2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO2 concentrations that occur more broadly across communities.

DATES: This final rule is effective on April 12, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2006-0922. All documents in the docket are listed on the http://www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through http://www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Dr. Scott Jenkins, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-1167; fax: 919-541-0237; e-mail: jenkins.scott@epa.gov.

SUPPLEMENTARY INFORMATION:

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The following topics are discussed in this preamble:

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I. Background

A. Summary of Revisions to the NO2 Primary NAAQS

Based on its review of the air quality criteria for oxides of nitrogen and the primary national ambient air quality standard (NAAQS) for oxides of nitrogen as measured by nitrogen dioxide (NO2), EPA is making revisions to the primary NO2 NAAQS in order to provide requisite protection of public health as appropriate under section 109 of the Clean Air Act (Act or CAA). Specifically, EPA is supplementing the existing annual standard for NO2 of 53 parts per billion (ppb) by establishing a new short-term standard based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. EPA is setting the level of this new standard at 100 ppb. EPA is making changes in data handling conventions for NO2 by adding provisions for this new 1-hour primary standard. EPA is also establishing requirements for an NO2 monitoring network. These new provisions require monitors at locations where maximum NO2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO2 concentrations that occur more broadly across communities. EPA is making conforming changes to the air quality index (AQI).

B. Legislative Requirements

Two sections of the CAA govern the establishment and revision of the NAAQS. Section 108 of the Act directs the Administrator to identify and list air pollutants that meet certain criteria, including that the air pollutant ``in [her] judgment, cause[s] or contribute[s] to air pollution which may reasonably be anticipated to endanger public health and welfare'' and ``the presence of which in the ambient air results from numerous or diverse mobile or stationary sources.'' 42 U.S.C. 21 7408(a)(1)(A) & (B). For those air pollutants listed, section 108 requires the Administrator to issue air quality criteria that ``accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *'' 42 U.S.C. 7408(2).

Section 109(a) of the Act directs the Administrator to promulgate ``primary'' and ``secondary'' NAAQS for pollutants for which air quality criteria have been issued. 42 U.S.C. 7409(1).\1\ Section 109(b)(1) defines a primary standard as one ``the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' \2\ 42 U.S.C. 7409(b)(1). A secondary standard, in turn, must ``specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such pollutant in the ambient air.'' \3\ 42 U.S.C. 7409(b)(2).

\1\ EPA notes that as the promulgation of a NAAQS is identified in section 307(d)(1) of the Clean Air Act, all of the provisions of this rulemaking are subject to the requirements of section 307(d) of the Clean Air Act.

\2\ The legislative history of section 109 indicates that a primary standard is to be set at ``the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ``reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10(1970).

\3\ EPA is currently conducting a separate review of the secondary NO2 NAAQS jointly with a review of the secondary SO2 NAAQS.

The requirement that primary standards include an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Lead Industries Association v. EPA, 647 F.2d 1130, 1154 (DC Cir 1980), cert. denied, 449 U.S.

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1042 (1980); American Petroleum Institute v. Costle, 665 F.2d 1176, 1186 (DC Cir. 1981), cert. denied, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In addressing the requirement for a margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. Lead Industries Association v. EPA, supra, 647 F.2d at 1161-62.

In setting standards that are ``requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. Whitman v. American Trucking Associations, 531 U.S. 457, 471, 475-76 (2001).

Section 109(d)(1) of the Act requires the Administrator to periodically undertake a thorough review of the air quality criteria published under section 108 and the NAAQS and to revise the criteria and standards as may be appropriate. 42 U.S.C. 7409(d)(1). The Act also requires the Administrator to appoint an independent scientific review committee composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies, to review the air quality criteria and NAAQS and to ``recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.'' 42 U.S.C. 7409(d)(2). This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Related NO2 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program that covers these pollutants. See 42 U.S.C. 7470-7479. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521-7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

Currently there are no areas in the United States that are designated as nonattainment of the NO2 NAAQS. With the revisions to the NO2 NAAQS that result from this review, however, some areas could be classified as non-attainment. Certain States will be required to develop SIPs that identify and implement specific air pollution control measures to reduce ambient NO2 concentrations to attain and maintain the revised NO2 NAAQS, most likely by requiring air pollution controls on sources that emit oxides of nitrogen (NOX).\4\

\4\ In this document, the terms ``oxides of nitrogen'' and ``nitrogen oxides'' (NOX) refer to all forms of oxidized nitrogen (N) compounds, including NO, NO2, and all other oxidized N-containing compounds formed from NO and NO2. This follows usage in the Clean Air Act Section 108(c): ``Such criteria [for oxides of nitrogen] shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.'' By contrast, within the air pollution research and control communities, the terms ``oxides of nitrogen'' and ``nitrogen oxides'' are restricted to refer only to the sum of NO and NO2, and this sum is commonly abbreviated as NOX. The category label used by this community for the sum of all forms of oxidized nitrogen compounds including those listed in Section 108(c) is NOY.

While NOX is emitted from a wide variety of source types, the top three categories of sources of NOX emissions are on-road mobile sources, electricity generating units, and non-road mobile sources. EPA anticipates that NOX emissions will decrease substantially over the next 20 years as a result of the ongoing implementation of mobile source emissions standards. In particular, Tier 2 NOX emission standards for light-duty vehicle emissions began phasing into the fleet beginning with model year 2004, in combination with low-sulfur gasoline fuel standards. For heavy-duty engines, new NOX standards are phasing in between the 2007 and 2010 model years, following the introduction of ultra-low sulfur diesel fuel. Lower NOX standards for nonroad diesel engines, locomotives, and certain marine engines are becoming effective throughout the next decade. In future decades, these lower-NOX vehicles and engines will become an increasingly large fraction of in-use mobile sources, effecting large NOX emission reductions.

D. Review of the Air Quality Criteria and Standards for Oxides of Nitrogen

On April 30, 1971, EPA promulgated identical primary and secondary NAAQS for NO2 under section 109 of the Act. The standards were set at 0.053 parts per million (ppm) (53 ppb), annual average (36 FR 8186). EPA completed reviews of the air quality criteria and NO2 standards in 1985 and 1996 with decisions to retain the standard (50 FR 25532, June 19, 1985; 61 FR 52852, October 8, 1996).

EPA initiated the current review of the air quality criteria for oxides of nitrogen and the NO2 primary NAAQS on December 9, 2005 (70 FR 73236) with a general call for information. EPA's draft Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide (EPA, 2007a) was made available in February, 2007 for public comment and was discussed by the CASAC via a publicly accessible teleconference on May 11, 2007. As noted in that plan, NOX includes multiple gaseous (e.g., NO2, NO) and particulate (e.g., nitrate) species. Because the health effects associated with particulate species of NOX have been considered within the context of the health effects of ambient particles in the Agency's review of the NAAQS for particulate matter (PM), the current review of the primary NO2 NAAQS is focused on the gaseous species of NOX and is not intended to address health effects directly associated with particulate species.

The first draft of the Integrated Science Assessment for Oxides of Nitrogen-Health Criteria (ISA) and the Nitrogen Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment (EPA, 2007b) were reviewed by CASAC at a public meeting held on October 24-25, 2007. Based on comments received from CASAC and the public, EPA developed the second

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draft of the ISA and the first draft of the Risk and Exposure Assessment to Support the Review of the NO2 Primary National Ambient Air Quality Standard (Risk and Exposure Assessment (REA)). These documents were reviewed by CASAC at a public meeting held on May 1-2, 2008. Based on comments received from CASAC and the public at this meeting, EPA released the final ISA in July of 2008 (EPA, 2008a). In addition, comments received were considered in developing the second draft of the REA, which was released for public review and comment in two parts. The first part of this document, containing chapters 1-7, 9 and appendices A and C as well as part of appendix B, was released in August 2008. The second part of this document, containing chapter 8 (describing the Atlanta exposure assessment) and a completed appendix B, was released in October of 2008. This document was the subject of CASAC reviews at public meetings on September 9 and 10, 2008 (for the first part) and on October 22, 2008 (for the second part). In preparing the final REA (EPA, 2008b), EPA considered comments received from the CASAC and the public at those meetings.

In the course of reviewing the second draft REA, CASAC expressed the view that the document would be incomplete without the addition of a policy assessment chapter presenting an integration of evidence-based considerations and risk and exposure assessment results. CASAC stated that such a chapter would be ``critical for considering options for the NAAQS for NO2'' (Samet, 2008a). In addition, within the period of CASAC's review of the second draft REA, EPA's Deputy Administrator indicated in a letter to the chair of CASAC, addressing earlier CASAC comments on the NAAQS review process, that the risk and exposure assessment will include ``a broader discussion of the science and how uncertainties may effect decisions on the standard'' and ``all analyses and approaches for considering the level of the standard under review, including risk assessment and weight of evidence methodologies'' (Peacock, 2008, p. 3; September 8, 2008).

Accordingly, the final REA included a new policy assessment chapter. This policy assessment chapter considered the scientific evidence in the ISA and the exposure and risk characterization results presented in other chapters of the REA as they relate to the adequacy of the current NO2 primary NAAQS and potential alternative primary NO2 standards. In considering the current and potential alternative standards, the policy assessment chapter of the final REA focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: Indicator, averaging time, form,\5\ and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the health protection afforded. CASAC discussed the final version of the REA, with an emphasis on the policy assessment chapter, during a public teleconference held on December 5, 2008. Following that teleconference, CASAC offered comments and advice on the NO2 primary NAAQS in a letter to the Administrator (Samet, 2008b).

\5\ The ``form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

The schedule for completion of this review is governed by a judicial order resolving a lawsuit filed in September 2005, concerning the timing of the current review. The order that now governs this review, entered by the court in August 2007 and amended in December 2008, provides that the Administrator will sign, for publication, notices of proposed and final rulemaking concerning the review of the primary NO2 NAAQS no later than June 26, 2009 and January 22, 2010, respectively. In accordance with this schedule, the Administrator signed a notice of proposed rulemaking on June 26, 2009 (FR 74 34404). This action presents the Administrator's final decisions on the primary NO2 standard.

E. Summary of Proposed Revisions to the NO2 Primary NAAQS

For the reasons discussed in the preamble of the proposal for the NO2 primary NAAQS (74 FR 34404), EPA proposed to make revisions to the primary NO2 NAAQS and to make related revisions for NO2 data handling conventions in order to provide requisite protection of public health. EPA also proposed to make corresponding changes to the AQI for NO2. Specifically, EPA proposed to supplement the current annual standard by establishing a new short-term NO2 standard that would reflect the maximum allowable NO2 concentration anywhere in an area. EPA proposed that this new short-term standard would be based on the 3-year average of the 99th percentile (or 4th highest) of the yearly distribution of 1[dash]hour daily maximum NO2 concentrations and solicited comment on using the 3-year average of the 98th percentile (or 7th or 8th highest) of the yearly distribution of 1-hour daily maximum NO2 concentrations. EPA proposed to set the level of this new 1-hour standard within the range of 80 to 100 ppb and solicited comment on standard levels as low as 65 ppb and as high as 150 ppb. EPA proposed to specify the level of the standard to the nearest ppb. EPA also proposed to establish requirements for an NO2 monitoring network at locations where maximum NO2 concentrations are expected to occur, including monitors within 50 meters of major roadways, as well as area-wide monitors sited to measure the NO2 concentrations that can occur more broadly across communities. EPA also solicited comment on the alternative approach of setting a 1-hour standard that would reflect the allowable area-wide NO2 concentration.

F. Organization and Approach to Final NO2 Primary NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current NO2 primary NAAQS. Revisions to the primary NAAQS for NO2, and the rationale supporting those revisions, are described below in section II. Requirements for the NO2 ambient monitoring network are described in section III. Related requirements for data completeness, data handling, data reporting, rounding conventions, and exceptional events are described in section IV. Implementation of the revised NO2 primary NAAQS is discussed in sections V and VI. Communication of public health information through the AQI is discussed in section VII and a discussion of statutory and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the ISA of scientific information on known and potential human health effects associated with exposure to NO2 in the air. These final decisions also take into account: (1) Assessments in the REA of the most policy-relevant information in the ISA as well as quantitative exposure and risk analyses based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator and its public discussions of the ISA, the REA, and the notice of proposed rulemaking; (3) public comments received during the development of ISA and REA; and (4) public comments received on the proposed rulemaking.

Some commenters have referred to and discussed individual scientific analyses on the health effects of NO2 that were not included in the ISA (EPA, 2008a) (``new studies''). In considering

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and responding to comments for which such ``new studies'' were cited in support, EPA has provisionally considered the cited studies in the context of the findings of the ISA.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the ISA and staff's policy assessment, which have undergone CASAC and public review. In this NO2 NAAQS review, staff's policy assessment was presented in the form of a policy assessment chapter of the REA (EPA, 2008b). The studies assessed in the ISA and REA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. EPA's provisional consideration of ``new studies'' did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone (O3), ``new studies'' may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013-13014, March 9, 1993). In the present case, EPA's provisional consideration of ``new studies'' concludes that, taken in context, the ``new'' information and findings do not materially change any of the broad scientific conclusions regarding the health effects of NO2 made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the NO2 air quality criteria that have undergone CASAC and public review. EPA will consider the ``new studies'' for purposes of decision-making in the next periodic review of the NO2 NAAQS, which will provide the opportunity to fully assess these studies through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these ``new studies'' can be found below, in section II.E, and in the Response to Comments document.

II. Rationale for Final Decisions on the NO2 Primary Standard

This section presents the rationale for the Administrator's decision to revise the existing NO2 primary standard by supplementing the current annual standard with a new 1-hour standard. In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence on human health effects associated with the presence of NO2 in the air. As summarized below in section II.B, this body of evidence addresses a broad range of health endpoints associated with exposure to NO2. In considering this entire body of evidence, EPA focuses in particular on those health endpoints for which the ISA finds associations with NO2 to be causal or likely causal. This rationale also draws upon the results of quantitative exposure and risk assessments, summarized below in section II.C.

As discussed below, a substantial amount of new research has been conducted since the last review of the NO2 NAAQS, with important new information coming from epidemiologic studies in particular. The newly available research studies evaluated in the ISA have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. While important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to exposure to ambient NO2, the review of this information has been extensive and deliberate.

The remainder of this section provides background information that informed the Administrator's decisions on the primary standard and discusses the rationale for those decisions. Section II.A presents a discussion of NO2 air quality. Section II.B includes an overview of the scientific evidence related to health effects associated with NO2 exposure. This overview includes discussion of the health endpoints and at-risk populations considered in the ISA. Section II.C discusses the approaches taken by EPA to assess exposures and health risks associated with NO2, including a discussion of key results. Section II.D summarizes the approach that was used in the current review of the NO2 NAAQS with regard to consideration of the scientific evidence and exposure-/risk-based results related to the adequacy of the current standard and potential alternative standards. Sections II.E-II.G discuss the Administrator's decisions regarding the adequacy of the current standard, elements of a new 1-hour standard, and retention of the current annual standard, respectively, taking into consideration public comments on the proposed decisions. Section II.H summarizes the Administrator's decisions with regard to the NO2 primary NAAQS.

A. Characterization of NO2 Air Quality

1. Current Patterns of NO2 Air Quality

The size of the State and local NO2 monitoring network has remained relatively stable since the early 1980s, and currently has approximately 400 monitors reporting data to EPA's Air Quality System (AQS) database.\6\ At present, there are no minimum monitoring requirements for NO2 in 40 CFR part 58 Appendix D, other than a requirement for EPA Regional Administrator approval before removing any existing monitors, and that any ongoing NO2 monitoring must have at least one monitor sited to measure the maximum concentration of NO2 in that area (though, as discussed below monitors in the current network do not measure peak concentrations associated with on-road mobile sources that can occur near major roadways because the network was not designed for this purpose). EPA removed the specific

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minimum monitoring requirements for NO2 of two monitoring sites per area with a population of 1,000,000 or more in the 2006 monitoring rule revisions (71 FR 61236), based on the fact that there were no NO2 nonattainment areas at that time, coupled with trends evidence showing an increasing gap between national average NO2 concentrations and the current annual standard. Additionally, the minimum requirements were removed to provide State, local, and Tribal air monitoring agencies flexibility in meeting higher priority monitoring needs for pollutants such as O3 and PM2.5, or implementing the new multi-pollutant sites (NCore network) required by the 2006 rule revisions, by allowing them to discontinue lower priority monitoring. There are requirements in 40 CFR part 58 Appendix D for NO2 monitoring as part of the Photochemical Assessment Monitoring Stations (PAMS) network. However, of the approximately 400 NO2 monitors currently in operation, only about 10 percent may be due to the PAMS requirements.

\6\ It should be noted that the ISA (section 2.4.1) references a different number of active monitors in the NO2 network. The discrepancy between the ISA numbers and the number presented here is due to differing metrics used in pulling data from AQS. The ISA only references SLAMS, NAMS, and PAMS sites with defined monitoring objectives, while Watkins and Thompson (2008) considered all NO2 sites reporting data at any point during the year. Based on this approach, Watkins and Thompson (2008) also noted that the size of the NO2 monitoring network has remained relatively stable since the early 1980s.

An analysis of the approximately 400 monitors comprising the current NO2 monitoring network (Watkins and Thompson, 2008) indicates that the current NO2 network has largely remained unchanged in terms of size and target monitor objective categories since it was introduced in the May 10, 1979 monitoring rule (44 FR 27571). The review of the current network found that the assessment of concentrations for general population exposure and maximum concentrations at neighborhood and larger scales were the top objectives. A review of the distribution of listed spatial scales of representation shows that only approximately 3 monitors are described as microscale, representing an area on the order of several meters to 100 meters, and approximately 23 monitors are described as middle scale, which represents an area on the order of 100 to 500 meters. This low percentage of smaller spatially representative scale sites within the network of approximately 400 monitoring sites indicates that the majority of monitors have, in fact, been sited to assess area-wide exposures on the neighborhood, urban, and regional scales, as would be expected for a network sited to support the current annual NO2 standard and PAMS objectives. The current network does not include monitors placed near major roadways and, therefore, monitors in the current network do not necessarily measure the maximum concentrations that can occur on a localized scale near these roadways (as discussed in the next section). It should be noted that the network not only accommodates NAAQS related monitoring but also serves other monitoring objectives, such as support for photochemistry analysis, O3 modeling and forecasting, and particulate matter precursor tracking.

2. NO2 Air Quality and Gradients Around Roadways

On-road and non-road mobile sources account for approximately 60% of NOX emissions (ISA, table 2.2-1) and traffic-related exposures can dominate personal exposures to NO2 (ISA section 2.5.4). While driving, personal exposure concentrations in the cabin of a vehicle could be substantially higher than ambient concentrations measured nearby (ISA, section 2.5.4). For example, estimates presented in the REA suggest that on/near roadway NO2 concentrations could be approximately 80% (REA, section 7.3.2) higher on average across locations than concentrations away from roadways and that roadway-associated environments could be responsible for the majority of 1-hour peak NO2 exposures (REA, Figures 8-17 and 8-18). Because monitors in the current network are not sited to measure peak roadway-associated NO2 concentrations, individuals who spend time on and/or near major roadways could experience NO2 concentrations that are considerably higher than indicated by monitors in the current area-wide NO2 monitoring network.

Research suggests that the concentrations of on-road mobile source pollutants such as NOX, carbon monoxide (CO), directly emitted air toxics, and certain size distributions of particulate matter (PM), such as ultrafine PM, typically display peak concentrations on or immediately adjacent to roads (ISA, section 2.5). This situation typically produces a gradient in pollutant concentrations, with concentrations decreasing with increasing distance from the road, and concentrations generally decreasing to near area-wide ambient levels, or typical upwind urban background levels, within a few hundred meters downwind. While such a concentration gradient is present on almost all roads, the characteristics of the gradient, including the distance from the road that a mobile source pollutant signature can be differentiated from background concentrations, are heavily dependent on factors such as traffic volumes, local topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf, et al., 2009; Beckerman et al., 2008; Clements et al., 2008; Hagler et al., 2009; Janssen et al., 2001; Rodes and Holland, 1981; Roorda-Knape et al., 1998; Singer et al., 2004; Zhou and Levy, 2007).

Because NO2 in the ambient air is due largely to the atmospheric oxidation of NO emitted from combustion sources (ISA, section 2.2.1), elevated NO2 concentrations can extend farther away from roadways than the primary pollutants also emitted by on-road mobile sources. More specifically, review of the technical literature suggests that NO2 concentrations may return to area-wide or typical urban background concentrations within distances up to 500 meters of roads, though the actual distance will vary with topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf et al., 2009; Beckerman et al., 2008; Clements et al., 2008; Gilbert et al. 2003; Rodes and Holland, 1981; Singer et al., 2004; Zhou and Levy, 2007). Efforts to quantify the extent and slope of the concentration gradient that may exist from peak near-road concentrations to the typical urban background concentrations must consider the variability that exists across locations and for a given location over time. As a result, we have identified a range of concentration gradients in the technical literature which indicate that, on average, peak NO2 concentrations on or immediately adjacent to roads may typically be between 30 and 100 percent greater than concentrations monitored in the same area but farther away from the road (ISA, Section 2.5.4; Beckerman et al., 2008; Gilbert et al., 2003; Rodes and Holland, 1981; Roorda-Knape et al., 1998; Singer et al., 2004). This range of concentration gradients has implications for revising the NO2 primary standard and for the NO2 monitoring network (discussed in sections II.F.4 and III).

B. Health Effects Information

In the last review of the NO2 NAAQS, the 1993 NOX Air Quality Criteria Document (1993 AQCD) (EPA, 1993) concluded that there were two key health effects of greatest concern at ambient or near-ambient concentrations of NO2 (ISA, section 5.3.1). The first was increased airway responsiveness in asthmatic individuals after short-term exposures. The second was increased respiratory illness among children associated with longer-term exposures to NO2. Evidence also was found for increased risk of emphysema, but this appeared to be of major concern only with exposures to NO2 at levels much higher than then current ambient levels (ISA, section 5.3.1). Controlled human

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exposure and animal toxicological studies provided qualitative evidence for airway hyperresponsiveness and lung function changes while epidemiologic studies provided evidence for increased respiratory symptoms with increased indoor NO2 exposures. Animal toxicological findings of lung host defense system changes with NO2 exposure provided a biologically-plausible basis for the epidemiologic results. Subpopulations considered potentially more susceptible to the effects of NO2 exposure included persons with preexisting respiratory disease, children, and the elderly. The epidemiologic evidence for respiratory health effects was limited, and no studies had considered endpoints such as hospital admissions, emergency department visits, or mortality (ISA, section 5.3.1).

As summarized below and discussed more fully in section II.B of the proposal notice, evidence published since the last review generally has confirmed and extended the conclusions articulated in the 1993 AQCD (ISA, section 5.3.2). The epidemiologic evidence has grown substantially with the addition of field and panel studies, intervention studies, time-series studies of endpoints such as hospital admissions, and a substantial number of studies evaluating mortality risk associated with short-term NO2 exposures. While not as marked as the growth in the epidemiologic literature, a number of recent toxicological and controlled human exposure studies also provide insights into relationships between NO2 exposure and health effects. This body of evidence focuses the current review on NO2-related respiratory effects at lower ambient and exposure concentrations than considered in the previous review.

1. Adverse Respiratory Effects and Short-Term Exposure to NO2

The ISA concluded that the findings of epidemiologic, controlled human exposure, and animal toxicological studies provide evidence that is sufficient to infer a likely causal relationship for respiratory effects following short-term NO2 exposure (ISA, sections 3.1.7 and 5.3.2.1). The ISA (section 5.4) concluded that the strongest evidence for an association between NO2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms, emergency department visits, and hospital admissions. These studies include panel and field studies, studies that control for the effects of co-occurring pollutants, and studies conducted in areas where the whole distribution of ambient 24-hour average NO2 concentrations was below the current NAAQS level of 53 ppb (annual average). With regard to this evidence, the ISA concluded that NO2 epidemiologic studies provide ``little evidence of any effect threshold'' (ISA, section 5.3.2.9, p. 5-15). In studies that have evaluated concentration-response relationships, they appear linear within the observed range of data (ISA, section 5.3.2.9).

Overall, the epidemiologic evidence for respiratory effects has been characterized in the ISA as consistent, in that associations are reported in studies conducted in numerous locations with a variety of methodological approaches, and coherent, in that the studies report associations with respiratory health outcomes that are logically linked together. In addition, a number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1). These epidemiologic studies are supported by evidence from toxicological and controlled human exposure studies, particularly those that evaluated airway hyperresponsiveness in asthmatic individuals (ISA, section 5.4). The ISA concluded that together, the epidemiologic and experimental data sets form a plausible, consistent, and coherent description of a relationship between NO2 exposures and an array of adverse respiratory health effects that range from the onset of respiratory symptoms to hospital admissions.

In considering the uncertainties associated with the epidemiologic evidence, the ISA (section 5.4) noted that it is difficult to determine ``the extent to which NO2 is independently associated with respiratory effects or if NO2 is a marker for the effects of another traffic-related pollutant or mix of pollutants.'' On-road vehicle exhaust emissions are a widespread source of combustion pollutant mixtures that include NOX and are an important contributor to NO2 levels in near-road locations. Although the presence of other pollutants from vehicle exhaust emissions complicates efforts to quantify specific NO2-related health effects, a number of epidemiologic studies have evaluated associations with NO2 in models that also include co-occurring pollutants such as PM, O3, CO, and/or SO2. The evidence summarized in the ISA indicates that NO2 associations generally remain robust in these multi-pollutant models and supports a direct effect of short-term NO2 exposure on respiratory morbidity (see ISA Figures 3.1-7, 3.1-10, 3.1-11). The plausibility and coherence of these effects are also supported by epidemiologic studies of indoor NO2 as well as experimental (i.e., toxicological and controlled human exposure) studies that have evaluated host defense and immune system changes, airway inflammation, and airway responsiveness (see subsequent sections of this proposal and the ISA, section 5.3.2.1). The ISA (section 5.4) concluded that the robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO2 and other traffic related pollutants.

The epidemiologic and experimental studies encompass a number of respiratory-related health endpoints, including emergency department visits and hospitalizations, respiratory symptoms, airway hyperresponsiveness, airway inflammation, and lung function. The findings relevant to these endpoints, which provide the rationale to support the judgment of a likely causal relationship, are described in more detail in section II.B.1 of the proposal.

2. Other Effects With Short-Term Exposure to NO2

a. Mortality

The ISA concluded that the epidemiologic evidence is suggestive, but not sufficient, to infer a causal relationship between short-term exposure to NO2 and all-cause and cardiopulmonary-related mortality (ISA, section 5.3.2.3). Results from several large United States and European multicity studies and a meta-analysis study indicate positive associations between ambient NO2 concentrations and the risk of all-cause (nonaccidental) mortality, with effect estimates ranging from 0.5 to 3.6% excess risk in mortality per standardized increment (20 ppb for 24-hour averaging time, 30 ppb for 1-hour averaging time) (ISA, section 3.3.1, Figure 3.3-2, section 5.3.2.3). In general, the ISA concluded that NO2 effect estimates were robust to adjustment for co-pollutants. Both cardiovascular and respiratory mortality have been associated with increased NO2 concentrations in epidemiologic studies (ISA, Figure 3.3-3); however, similar associations were observed for other pollutants, including PM and SO2. The range of risk estimates for excess mortality is generally smaller than that for other pollutants such as PM. In addition, while NO2 exposure, alone or in conjunction with other pollutants,

may contribute to increased mortality, evaluation of the specificity of this effect is difficult. Clinical studies showing hematologic effects and animal toxicological studies showing biochemical, lung host defense, permeability, and inflammation changes with short-term exposures to NO2 provide limited evidence of plausible pathways by which risks of mortality may be increased, but no coherent picture is evident at this time (ISA, section 5.3.2.3).

b. Cardiovascular Effects

The ISA concluded that the available evidence on cardiovascular health effects following short-term exposure to NO2 is inadequate to infer the presence or absence of a causal relationship at this time (ISA, section 5.3.2.2). Evidence from epidemiologic studies of heart rate variability, repolarization changes, and cardiac rhythm disorders among heart patients with ischemic cardiac disease are inconsistent (ISA, section 5.3.2.2). In most studies, associations with PM were found to be similar or stronger than associations with NO2. Generally positive associations between ambient NO2 concentrations and hospital admissions or emergency department visits for cardiovascular disease have been reported in single-pollutant models (ISA, section 5.3.2.2); however, most of these effect estimate values were diminished in multi-pollutant models that also contained CO and PM indices (ISA, section 5.3.2.2). Mechanistic evidence of a role for NO2 in the development of cardiovascular diseases from studies of biomarkers of inflammation, cell adhesion, coagulation, and thrombosis is lacking (ISA, section 5.3.2.2). Furthermore, the effects of NO2 on various hematological parameters in animals are inconsistent and, thus, provide little biological plausibility for effects of NO2 on the cardiovascular system (ISA, section 5.3.2.2).

3. Health Effects With Long-Term Exposure to NO2

a. Respiratory Morbidity

The ISA concluded that overall, the epidemiologic and experimental evidence is suggestive, but not sufficient, to infer a causal relationship between long-term NO2 exposure and respiratory morbidity (ISA, section 5.3.2.4). The available database evaluating the relationship between respiratory illness in children and long-term exposures to NO2 has increased since the 1996 review of the NO2 NAAQS (see section II.B.3 of the proposal for a more detailed discussion). A number of epidemiologic studies have examined the effects of long-term exposure to NO2 and reported positive associations with decrements in lung function and partially irreversible decrements in lung function growth (ISA, section 3.4.1, Figures 3.4-1 and 3.4-2). While animal toxicological studies may provide biological plausibility for the chronic effects of NO2 that have been observed in epidemiologic studies (ISA, sections 3.4.5 and 5.3.2.4), the high correlation among traffic-related pollutants in epidemiologic studies makes it difficult to accurately estimate independent effects (ISA, section 5.3.2.4).

b. Mortality

The ISA concluded that the epidemiologic evidence is inadequate to infer the presence or absence of a causal relationship between long-term exposure to NO2 and mortality (ISA, section 5.3.2.6). In the United States and European cohort studies examining the relationship between long-term exposure to NO2 and mortality, results have been inconsistent (ISA, section 5.3.2.6). Further, when associations were suggested, they were not specific to NO2 but also implicated PM and other traffic indicators. The relatively high correlations reported between NO2 and PM indices make it difficult to interpret these observed associations at this time (ISA, section 5.3.2.6).

c. Carcinogenic, cardiovascular, and reproductive/developmental effects

The ISA concluded that the available epidemiologic and toxicological evidence is inadequate to infer the presence or absence of a causal relationship for carcinogenic, cardiovascular, and reproductive and developmental effects related to long-term NO2 exposure (ISA, section 5.3.2.5). Epidemiologic studies conducted in Europe have shown an association between long-term NO2 exposure and increased incidence of cancer (ISA, section 5.3.2.5). However, the animal toxicological studies have provided no clear evidence that NO2 acts as a carcinogen (ISA, section 5.3.2.5). The very limited epidemiologic and toxicological evidence do not suggest that long-term exposure to NO2 has cardiovascular effects (ISA, section 5.3.2.5). The epidemiologic evidence is not consistent for associations between NO2 exposure and fetal growth retardation; however, some evidence is accumulating for effects on preterm delivery (ISA, section 5.3.2.5). Scant animal evidence supports a weak association between NO2 exposure and adverse birth outcomes and provides little mechanistic information or biological plausibility for the epidemiologic findings.

4. NO2-related Impacts on Public Health

Specific groups within the general population are likely at increased risk for suffering adverse effects from NO2

exposure. This could occur because they are affected by lower levels of NO2 than the general population or because they experience a larger health impact than the general population to a given level of exposure (susceptibility) and/or because they are exposed to higher levels of NO2 than the general population (vulnerability).
The term susceptibility generally encompasses innate (e.g., genetic or developmental) and/or acquired (e.g., age or disease) factors that make individuals more likely to experience effects with exposure to pollutants. The severity of health effects experienced by a susceptible subgroup may be much greater than that experienced by the population at large. Factors that may influence susceptibility to the effects of air pollution include age (e.g., infants, children, elderly); gender; race/ ethnicity; genetic factors; and pre-existing disease/condition (e.g., obesity, diabetes, respiratory disease, asthma, chronic obstructive pulmonary disease (COPD), cardiovascular disease, airway hyperresponsiveness, respiratory infection, adverse birth outcome) (ISA, sections 4.3.1, 4.3.5, and 5.3.2.8). In addition, certain groups may experience relatively high exposure to NO2, thus forming a potentially vulnerable population (ISA, section 4.3.6). Factors that may influence susceptibility and vulnerability to air pollution include socioeconomic status (SES), education level, air conditioning use, proximity to roadways, geographic location, level of physical activity, and work environment (e.g., indoor versus outdoor) (ISA, section 4.3.5). The ISA discussed factors that can confer susceptibility and/or vulnerability to air pollution with most of the discussion devoted to factors for which NO2-specific evidence exists (ISA, section 4.3). These factors include pre-existing disease (e.g., asthma), age (i.e., infants, children, older adults), genetic factors, gender, socioeconomic status, and proximity to roadways (see section II.B.4 in proposal for more detailed discussion of these factors).

As discussed in more detail in the proposal (section II.B.4), the population potentially affected by NO2 is large. A considerable fraction of the population resides, works, or attends school near major roadways, and these individuals are likely to have increased exposure to NO2 (ISA, section 4.4). Based on data

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from the 2003 American Housing Survey, approximately 36 million individuals live within 300 feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).\7\ Furthermore, in California, 2.3% of schools, with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads, with a higher proportion of non-white and economically disadvantaged students attending those schools (ISA, section 4.4). Of this population, asthmatics and members of other susceptible groups discussed above will have even greater risks of experiencing health effects related to NO2 exposure. In the United States, approximately 10% of adults and 13% of children (approximately 22.2 million people in 2005) have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4). The prevalence and severity of asthma is higher among certain ethnic or racial groups such as Puerto Ricans, American Indians, Alaskan Natives, and African Americans (ISA, section 4.4). A higher prevalence of asthma among persons of lower SES and an excess burden of asthma hospitalizations and mortality in minority and inner-city communities have been observed (ISA, section 4.4). In addition, based on United States census data from 2000, about 72.3 million (26%) of the United States population are under 18 years of age, 18.3 million (7.4%) are under 5 years of age, and 35 million (12%) are 65 years of age or older. Therefore, large portions of the United States population are in age groups that are likely at-risk for health effects associated with exposure to ambient NO2. The size of the potentially at-risk population suggests that exposure to ambient NO2 could have a significant impact on public health in the United States.

\7\ The most current American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs.html) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary than do prior surveys. According to Table 1A-6 from that report (http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf), out of 128,203,000 total housing units in the United States, 20,016,000 were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.613% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306,330,199, that means that there would be 47.8 million people meeting the 300 foot criteria.

C. Human Exposure and Health Risk Characterization

To put judgments about NO2-associated health effects into a broader public health context, EPA has drawn upon the results of the quantitative exposure and risk assessments. Judgments reflecting the nature of the evidence and the overall weight of the evidence are taken into consideration in these quantitative exposure and risk assessments, discussed below. These assessments provide estimates of the likelihood that asthmatic individuals would experience exposures of potential concern and estimates of the incidence of NO2-associated respiratory emergency department visits under varying air quality scenarios (e.g., just meeting the current or alternative standards), as well as characterizations of the kind and degree of uncertainties inherent in such estimates. As discussed more fully in section II.C of the proposal, this section summarizes the approach taken in the REA to characterize NO2-related exposures and health risks. Goals of the REA included estimating short-term exposures and potential human health risks associated with (1) recent levels of ambient NO2; (2) NO2 levels adjusted to simulate just meeting the current standard; and (3) NO2 levels adjusted to simulate just meeting potential alternative standards.

For purposes of the quantitative characterization of NO2 health risks, the REA determined that it was appropriate to focus on endpoints for which the ISA concluded that the available evidence is sufficient to infer either a causal or a likely causal relationship. This was generally consistent with judgments made in other recent NAAQS reviews (e.g., see EPA, 2005). As noted above in section II.A, the only health effect category for which the evidence was judged in the ISA to be sufficient to infer either a causal or a likely causal relationship is respiratory morbidity following short-term NO2 exposure. Therefore, for purposes of characterizing health risks associated with NO2, the REA focused on respiratory morbidity endpoints that have been associated with short-term NO2 exposures.

In evaluating the appropriateness of specific endpoints for use in the NO2 risk characterization, the REA considered both epidemiologic and controlled human exposure studies. As described in more detail in the proposal (section II.C.1), the characterization of NO2-associated health risks was based on an epidemiology study conducted in Atlanta, Georgia by Tolbert et al. (2007) and a meta-analysis of controlled human exposure studies of NO2 and airway responsiveness in asthmatics (ISA, Table 3.1-3).\8\

\8\ The study by Tolbert et al. (2007) reported positive associations between 1-hour ambient NO2 concentrations and respiratory-related emergency department visits. The meta-analysis was included in the ISA and reported that short-term exposures to NO2 concentrations at or above 100 ppb increased airway responsiveness in most asthmatics.

As noted above, the purpose of the assessments described in the REA was to characterize air quality, exposures, and health risks associated with recent ambient levels of NO2, with NO2 levels that could be associated with just meeting the current NO2 NAAQS, and with NO2 levels that could be associated with just meeting potential alternative standards. To characterize health risks, the REA employed three approaches. In the first approach, for each air quality scenario, NO2 concentrations at fixed-site monitors and simulated concentrations on/near roadways were compared to potential health effect benchmark values derived from the controlled human exposure literature. In the second approach, modeled estimates of exposures in asthmatics were compared to potential health effect benchmarks. In the third approach, concentration-response relationships from an epidemiologic study were used in conjunction with baseline incidence data and recent or simulated ambient concentrations to estimate health impacts. An overview of the approaches to characterizing health risks is provided in the proposal (section II.C.2) and each approach, along with its limitations and uncertainties (see proposal, section II.C.3) has been described in more detail in the REA (chapters 6 through 9).

Chapters 7-9 of the REA estimated exposures and health risks associated with recent air quality and with air quality, as measured at monitors in the current area-wide network, which had been adjusted to simulate just meeting the current and potential alternative standards. The specific standard levels evaluated, for an area-wide standard based on the 3-year average of the 98th and 99th percentile 1-hour daily maximum NO2 concentrations, were 50, 100, 150, and 200 ppb. In interpreting these results within the context of the current revisions to the NO2 primary NAAQS (see below), we note that simulation of different standard levels was based on adjusting NO2 concentrations at available area-wide monitors. Therefore, the standard levels referred to above reflect the allowable area-wide NO2 concentrations, not the maximum allowable concentrations. As a consequence, the maximum concentrations in an area that just meets one of these standard levels would be expected to be higher than the standard level. For example, given that near-road

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NO2 concentrations can be 30% to 100% higher than area-wide concentrations (see section II.E.2), an area-wide concentration of 50 ppb could correspond to near-road concentrations from 65 to 100 ppb.

Key results of the air quality, exposure, and risk analyses were presented in the policy assessment chapter of the REA and summarized in the proposal (Table 1 in proposal). In considering these results, the policy assessment chapter of the REA concluded that the risks estimated to be associated with just meeting the current annual standard can be judged important from a public health perspective. The results for specific 1-hour standard levels estimate that limiting the 98th/99th percentile of the distribution of 1-hour daily maximum NO2 concentrations measured at area-wide monitors to 50 or 100 ppb could substantially reduce exposures to ambient NO2 and associated health risks (compared to just meeting the current standard). In contrast, limiting these area-wide NO2 concentrations to 150 or 200 ppb is estimated to result in similar, or in some cases higher, NO2-associated exposures and health risks than just meeting the current standard. The pattern of results was similar for standards just meeting either the 98th or the 99th percentile 1-hour daily maximum area-wide standards (REA, Chapters 7, 8, and 9).

D. Approach for Reviewing the Need To Retain or Revise the Current Standard

EPA notes that the final decision on retaining or revising the current primary NO2 standard is a public health policy judgment to be made by the Administrator. This judgment has been informed by a recognition that the available health effects evidence reflects a continuum consisting of ambient levels of NO2 at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. The Administrator's final decisions draw upon scientific information and analyses related to health effects, population exposures, and risks; judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses; and comments received from CASAC and the public.

To evaluate whether the current primary NO2 standard is requisite or whether consideration of revisions is appropriate, EPA has used an approach in this review that was described in the policy assessment chapter of the REA. This approach builds upon those used in reviews of other criteria pollutants, including the most recent reviews of the Pb, O3, and PM NAAQS (EPA, 2007c; EPA, 2007d; EPA, 2005), and reflects the body of evidence and information that is currently available. As in other recent reviews, EPA's considerations included the implications of placing more or less weight or emphasis on different aspects of the scientific evidence and the exposure/risk-based information, recognizing that the weight to be given to various elements of the evidence and exposure/risk information is part of the public health policy judgments that the Administrator will make in reaching decisions on the standard.

A series of general questions framed this approach to considering the scientific evidence and exposure-/risk-based information. First, EPA's consideration of the scientific evidence and exposure/risk information with regard to the adequacy of the current standard has been framed by the following questions:

To what extent does evidence that has become available since the last review reinforce or call into question evidence for NO2-associated effects that were identified in the last review?

To what extent has evidence for different health effects and/or sensitive populations become available since the last review?

To what extent have uncertainties identified in the last review been reduced and/or have new uncertainties emerged?

To what extent does evidence and exposure-/risk-based information that has become available since the last review reinforce or call into question any of the basic elements of the current standard?

To the extent that the available evidence and exposure-/risk-based information suggests it may be appropriate to consider revision of the current standard, EPA considers that evidence and information with regard to its support for consideration of a standard that is either more or less protective than the current standard. This evaluation has been framed by the following questions:

Is there evidence that associations, especially causal or likely causal associations, extend to ambient NO2 concentrations as low as, or lower than, the concentrations that have previously been associated with health effects? If so, what are the important uncertainties associated with that evidence?

Are exposures above benchmark levels and/or health risks estimated to occur in areas that meet the current standard? If so, are the estimated exposures and health risks important from a public health perspective? What are the important uncertainties associated with the estimated risks?

To the extent that there is support for consideration of a revised standard, EPA then considers the specific elements of the standard (indicator, averaging time, form, and level) within the context of the currently available information. In so doing, the Agency has addressed the following questions:

Does the evidence provide support for considering a different indicator for gaseous NOX?

Does the evidence provide support for considering different averaging times?

What ranges of levels and forms of alternative standards are supported by the evidence, and what are the associated uncertainties and limitations?

To what extent do specific averaging times, levels, and forms of alternative standards reduce the estimated exposures above benchmark levels and risks attributable to NO2, and what are the uncertainties associated with the estimated exposure and risk reductions?

The questions outlined above have been addressed in the REA, the proposal, and in this final rulemaking. The following sections present the rationale for proposed decisions, discussion of public comments, and the Administrator's conclusions on the adequacy of the current standard and potential alternative standards in terms of indicator, averaging time, form, and level.

E. Adequacy of the Current Standard

This section discusses considerations related to the decision as to whether the current NO2 primary NAAQS is requisite to protect public health with an adequate margin of safety. Specifically, section II.E.1 provides an overview of the rationale supporting the Administrator's conclusion in the proposal that the current standard alone does not provide adequate public health protection; section II.E.2 discusses comments received on the adequacy of the current standard; and section II.E.3 discusses the Administrator's final decision on whether the current NO2 primary NAAQS is requisite to protect public health with an adequate margin of safety.

1. Rationale for Proposed Decision

In reaching a conclusion regarding the adequacy of the current NO2 NAAQS in the proposal (section II.E.5), the Administrator considered the scientific evidence assessed in the ISA and the conclusions of the ISA, the exposure and risk information presented in the REA and the conclusions of the policy assessment chapter of the REA, and the views expressed by CASAC. These considerations are discussed in detail in the proposal (II.E.) and are summarized in this section. In the proposal, the

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Administrator noted the following in considering the adequacy of the current standard:

The ISA concluded that the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a relationship between NO2 exposures and respiratory endpoints, including respiratory symptoms and respiratory-related hospital admissions and emergency department visits, at ambient concentrations that are present in areas that meet the current NO2 NAAQS (ISA, section 5.4).

The policy assessment chapter of the REA concluded that risks estimated to be associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be judged important from a public health perspective (REA, section 10.3.3).

The policy assessment chapter of the REA concluded that exposure- and risk-based results reinforce the scientific evidence in supporting the conclusion that consideration should be given to revising the current NO2 NAAQS so as to provide increased public health protection, especially for at-risk groups, from NO2-related adverse health effects associated with short-term, and potential long-term, exposures (REA, section 10.3.3).

CASAC agreed that the current annual standard alone is not sufficient to protect public health against the types of exposures that could lead to these health effects. Specifically, in their letter to the Administrator on the final REA, they stated that ``CASAC concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised'' (Samet, 2008b).

Based on these considerations (discussed in more detail in the proposal, section II.E), the Administrator concluded in the proposal that the current NO2 primary NAAQS is not requisite to protect public health with an adequate margin of safety against adverse respiratory effects associated with short-term exposures. In considering approaches to revising the current standard, the Administrator concluded that it is appropriate to consider setting a new short-term standard in addition to retaining the current annual standard. The Administrator noted that such a short-term standard could provide increased public health protection, especially for members of at-risk groups, from effects described in both epidemiologic and controlled human exposure studies to be associated with short-term exposures to NO2.

2. Comments on the Adequacy of the Current Standard

This section discusses comments received from CASAC and public commenters on the proposal that either supported or opposed the Administrator's proposed decision to revise the current NO2 primary NAAQS. Comments on the adequacy of the current standard that focused on the scientific and/or the exposure/risk basis for the Administrator's proposed conclusions are discussed in sections II.E.2.a-II.E.2.c. Comments on the epidemiologic evidence are considered in section II.E.2.a. Comments on the controlled human exposure evidence are considered in section II.E.2.b. Comments on human exposure and health risk assessments are considered in section II.E.2.c. To the extent these comments on the evidence and information are also used to justify commenters' conclusions on decisions related to indicator, averaging time, level, or form, they are noted in the appropriate sections below (II.F.1-II.F.4).

In their comments on the proposal (Samet, 2009), CASAC reiterated their support for the need to revise the current annual NO2 NAAQS in order to increase public health protection. As noted above, in its letter to the Administrator on the final REA (Samet, 2008b) CASAC stated that it ``concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised.'' In supporting adoption of a more stringent NAAQS for NO2, CASAC considered the assessment of the scientific evidence presented in the ISA, the results of assessments presented in the REA, and the conclusions of the policy assessment chapter of the REA. As such, CASAC's rationale for revising the current standard was consistent with the Administrator's rationale as discussed in the proposal.

Many public commenters agreed with CASAC that, based on the available information, the current NO2 standard is not requisite to protect public health with an adequate margin of safety and that revisions to the standard are appropriate. Among those calling for revisions to the standard were environmental groups (e.g., Clean Air Council (CAC), Earth Justice (EJ), Environmental Defense Fund (EDF), Natural Resources Defense Council (NRDC), Group Against Smog and Pollution (GASP)); medical/public health organizations (e.g., American Lung Association (ALA), American Medical Association (AMA), American Thoracic Society (ATS), National Association for the Medical Direction of Respiratory Care (NAMDRC), National Association of Cardiovascular and Pulmonary Rehabilitation (NACPR), American College of Chest Physicians (ACCP)); a large number of State agencies and organizations (e.g., National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management (NESCAUM), and State or local agencies in CA, IA, IL, MI, MO, NC, NM, NY, TX, VA, WI); Tribes (e.g., National Tribal Air Association (NTAA), Fond du Lac Band of Lake Superior Chippewa (Fond du Lac)), and a number of individual commenters. These commenters concluded that the current NO2 standard needs to be revised and that a more stringent standard is needed to protect the health of sensitive population groups. In supporting the need to adopt a more stringent NAAQS for NO2, these commenters often referenced the conclusions of CASAC and relied on the evidence and information presented in the proposal. As such, similar to CASAC, the rationale offered by these commenters was consistent with that presented in the proposal to support the

Administrator's proposed decision to revise the current NO2 NAAQS.

Some industry commenters (e.g., Alliance of Automobile Manufacturers (AAM), American Petroleum Institute (API), Interstate Natural Gas Association of America (INGAA), Utility Air Regulatory Group (UARG)) and one State commenter (IN Department of Environmental Management) expressed support for retaining the current annual standard alone. In supporting this view, these commenters generally concluded that the current standard is requisite to protect public health with an adequate margin of safety and that the available evidence is not sufficient to support revision of the standard. For example, UARG stated that ``EPA has failed to demonstrate that the present NO2 NAAQS is no longer at the level requisite to protect public health with an adequate margin of safety.'' In addition, INGAA stated that

``* * * EPA should be compelled to retain the current standard and defer a decision on a new short-term standard until the science is more clearly defined.''

In support of their views, these commenters provided specific comments on the epidemiologic and controlled human exposure evidence as discussed below. In responding to these specific comments, we note that the Administrator relied in the proposal on the evidence, information and judgments contained in the ISA and the

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REA (including the policy assessment chapter) as well as on the advice of CASAC. In considering the evidence, information, and judgments of the ISA and the REA, the Agency notes that these documents have been reviewed extensively by CASAC and have been discussed by CASAC at multiple public meetings (see section I.D). In their letter to the Administrator regarding the second draft ISA (Henderson, 2008), CASAC noted the following:

Panel members concur with the primary conclusions reached in the ISA with regard to health risks that are associated with NO2 exposure. In particular, the Panel agrees with the conclusion that the current scientific evidence is ``sufficient to infer a likely causal relationship between short-term NO2 exposure and adverse effects on the respiratory system.'' The strongest evidence in support of this conclusion comes from epidemiology studies that show generally positive associations between NO2 and respiratory symptoms, hospitalizations or emergency department visits, as summarized in Figure 5.3.1.''

Similarly, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC noted the following:

Overall, CASAC found this version of the REA satisfactory in its approach to moving from the scientific foundation developed in the Integrated Science Assessment (ISA) to setting out evidence-based options for the NAAQS. The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure. It draws on toxicological and epidemiological evidence and addresses risk to an identified susceptible population, people with asthmatic conditions. EPA has also systematically described uncertainties associated with the risk assessments. We commend EPA for developing a succinct and thoughtfully developed synthesis in chapter 10. This summary chapter represents a long-needed and transparent model for linking a substantial body of scientific evidence to the four elements of the NAAQS.

Therefore, in discussing comments on the interpretation of the scientific evidence and exposure/risk information, we note that CASAC has endorsed the approaches and conclusions of the ISA and the REA. These approaches and conclusions are discussed below in more detail, within the context of specific public comments.

a. Comments on EPA's Interpretation of the Epidemiologic Evidence

Several industry groups (e.g., API, National Mining Association (NMA), American Chemistry Council (ACC), AAM, Annapolis Center for Science-Based Public Policy (ACSBPP), Engine Manufacturers Association (EMA), ExxonMobil (Exxon), National Association of Manufacturers (NAM)) commented that, given the presence of numerous co-pollutants in the air, epidemiologic studies do not support the contention that NO2 itself is causing health effects.

While EPA has recognized that multiple factors can contribute to the etiology of respiratory disease and that more than one air pollutant could independently impact respiratory health, we continue to judge, as discussed in the ISA, that the available evidence supports the conclusion that there is an independent effect of NO2 on respiratory morbidity. In reaching this judgment, we recognize that a major methodological issue affecting NO2 epidemiologic studies concerns the evaluation of the extent to which other air pollutants may confound or modify NO2-related effect estimates. The use of multipollutant regression models is the most common approach for controlling potential confounding by co-pollutants in epidemiologic studies. The issues related to confounding and the evidence of potential confounding by co-pollutants has been thoroughly reviewed in the ISA (see Figures 3.1-10 and 3.1-11) and in previous assessments (e.g., the criteria document for PM) (EPA, 2004). NO2 risk estimates for respiratory morbidity endpoints, in general, were not sensitive to the inclusion of co-pollutants, including particulate and gaseous pollutants. As observed in Figures 3.1-10 and 3.1-11 in the ISA, relative risks for hospital admissions or emergency department visits are generally unchanged, nor is their interpretation modified, upon inclusion of PM or gaseous co-pollutants in the models. Similarly, associations between short-term NO2 exposure and asthma symptoms are generally robust to adjustment for co-pollutants in multipollutant models, as shown in

Figures 3.1-5 and 3.1-7 of the ISA. These results, in conjunction with the results of a randomized intervention study evaluating respiratory effects of indoor exposure to NO2 (ISA, section 3.1.4.1), led to the conclusion that the effect of NO2 on respiratory health outcomes is robust and independent of the effects of other ambient co-pollutants.

In addition, experimental studies conducted in animals and humans provide support for the plausibility of the associations reported in epidemiologic studies. These controlled human exposure and animal toxicological studies have reported effects of NO2 on immune system function, lung host defense, airway inflammation, and airway responsiveness (ISA, section 5.4). These experimental study results support an independent contribution of NO2 to the respiratory health effects reported in epidemiologic studies (ISA Section 5.4).

In considering the entire body of evidence, including epidemiologic and experimental studies, the ISA (section 5.4, p. 5-16) concluded the following:

Although this [presence of co-pollutants] complicates the efforts to disentangle specific NO2-related health effects, the evidence summarized in this assessment indicates that NO2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS. The robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO2 and other traffic-related pollutants.

Comments on specific epidemiologic studies are discussed below.

The National Association of Manufacturers (NAM) commented that the final REA relied on an epidemiologic study (Delfino et al. 2002) not critically reviewed in the final ISA. Contrary to NAM's contention, the study by Delfino et al. (2002) was critically reviewed by EPA staff and pertinent information was extracted from the study. The respiratory health effects of NO2 on asthma reported in this study are included in Figure 5.3-1, Table 5.4-1, and Annex Table AX6.3-2 of the ISA. While NAM comments on the narrative discussion of this study in the final ISA, their contention that EPA scientists did not critically analyze the study while preparing the final ISA is incorrect. The inclusion of the study in the figures and tables in this ISA, as well as inclusion in the 2004 PM AQCD, indicate critical analysis of the study that was implemented throughout the review process. The narrative discussion in the ISA focused on multicity studies (specifically those by Schwartz et al. 1994, Mortimer et al. 2002 and Schildcrout et al. 2006), which provide substantial epidemiologic evidence for the respiratory health effects of NO2 on asthma among children.

Additional comments from NAM contend that EPA's interpretation of three individual epidemiologic studies (e.g. Krewski et al. 2000; Schildcrout et al. 2006; Mortimer et al. 2002) is inconsistent across different NAAQS reviews. The NAM comments on all three studies are discussed below.

NAM stated the following regarding the study by Krewski et al:

In the Final ISA, EPA cites the Krewski, et al. (2000) study as evidence of a significant

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association between NO2 exposure and mortality. Although EPA acknowledges that exposure to NO2 was ``highly correlated'' with other pollutants, including PM2.5 and SO2, EPA does not consider the analysis of the respective contributions of single pollutants in the same study that EPA included in its prior Staff Paper for Particulate Matter. In that document, EPA stated: ``In single-pollutant models, none of the gaseous co-pollutants was significantly associated with mortality except SO2.'' If EPA has not altered its scientific views concerning this study as expressed in the PM Staff Paper, it is entirely inappropriate for EPA to suggest that the Krewski, et al. (2000) study provides any evidence of an association between NO2 exposure and mortality.

In these comments, NAM fails to recognize that the report from Krewski et al. (2000) contains a reanalysis of two cohort studies, the Harvard Six Cities and the American Cancer Society (ACS) studies. The characterization in the NOX ISA of the study by Krewski et al. (2000), referenced by NAM in their comments, refers to the reanalysis of the Harvard Six Cities Study. As stated in the NOX ISA (p. 3-74):

Krewski et al. (2000) conducted a sensitivity analysis of the Harvard Six Cities study and examined associations between gaseous pollutants (i.e., O3, NO2, SO2, CO) and mortality. NO2 showed risk estimates similar to those for PM2.5 per ``low to high'' range increment with total (1.15 [95% CI: 1.04, 1.27] per 10-ppb increase), cardiopulmonary (1.17 [95% CI: 1.02, 1.34]), and lung cancer (1.09 [95% CI: 0.76, 1.57]) deaths; however, in this dataset NO2 was highly correlated with PM2.5 (r = 0.78), SO4 2- (r = 0.78), and SO2 (r = 0.84).

In contrast, the characterization in the PM Staff Paper (EPA, 2005) of the study by Krewski et al. (2000), referenced by NAM in their comments, refers to the results of the ACS study. Therefore, NAM appears to have confused the conclusions on the results of the reanalysis of the Harvard Six Cities Study in the NOX ISA with the conclusions on the results of the reanalysis of the ACS study in the PM Staff Paper.

Further, in considering the reanalysis of the ACS study by Krewski et al. (2000), the NOX ISA observed that ``NO2 showed no associations with mortality outcomes'' (ISA, p. 3-74). This statement is consistent with the interpretation of that reanalysis as discussed in the PM Staff Paper. Thus, there is no inconsistency in the interpretation of the results of the study by Krewski et al. (2000) in the PM Staff Paper (EPA, 2005) and the NOX ISA (EPA, 2008a).

NAM also commented that EPA has relied on a study by Schildcrout et al. (2006) in the NOX ISA but declined to rely on the same study for the previous review of the O3 NAAQS. NAM made the following comment regarding the study by Schildcrout et al:

Another example of how EPA has reached different scientific conclusions in the Final ISA than in prior NAAQS documents is provided by the Schildcrout, et al. (2006) study. In the Final ISA, EPA includes an extensive discussion of this study of asthmatic children and the relationship purportedly found in this study between NO2 and various respiratory symptoms. In contrast, as part of the NAAQS review for ozone, EPA expressly declined to rely on this same study because of specific limitations in the study design. Among the limitations EPA cites were the fact that the Schildcrout, et al. (2006) study included ``children in which the severity of their asthma was not clearly identified,'' and the use of a study population that was ``not comparable to other large multi-city studies.'' EPA must explain why it chose to discount the value of the Schildcrout, et al. (2006) study when evaluating the effects of ozone, but has relied on it extensively in the Final ISA for NO2.

The study by Schildcrout et al. (2006) appeared in the peer-review literature too late to be considered in the 2006 O3 AQCD; however, this study was included in the O3 Provisional Assessment. The purpose of the Provisional Assessment was to determine if new literature materially changed any of the broad scientific conclusions regarding the health effects of O3 exposure as stated in the 2006 O3 AQCD. EPA concluded that, taken in context, the ``new'' information and findings did not materially change any of the broad scientific conclusions regarding the health effects of O3 exposure made in the O3 AQCD. Therefore, NAM's contention that EPA ``declined'' to rely on the Schildcrout study for the O3 review because of limitations in study design is not correct.

The observations NAM draws from the O3 Provisional Assessment regarding severity of asthma and the study population do not indicate limitations that resulted in EPA ``discounting'' the study results. Rather, these observations were intended to put the study in perspective for purposes of interpreting the results within the context of the larger body of O3 health effects evidence. These observations were drawn from comments submitted by Dr. Schildcrout regarding the interpretation of the results of his study in the decision to revise the ozone standards (see docket ID EPA-HQ-OAR-2005-0172-6991). The results of this study are being fully considered in the ongoing review of the ozone NAAQS.

Finally, NAM contends that EPA reached differing scientific conclusions on the use of self-reported peak expiratory flow (PEF) depending on regulatory context, particularly in the large multi-city trial by Mortimer et al. (2002). We disagree with this contention. EPA consistently examines clinical measurements of lung function, which include PEF, forced expiratory flow in 1 second (FEV1), forced vital capacity (FVC), maximal midexpiratory flow (MMEF), maximal expiratory flow at 50% (MEF50), maximal expiratory flow at 25% (MEF25), and forced expiratory flow at 25 to 75% of FVC (FEF25-75). Evidence for all of these clinical measurements is considered before drawing a conclusion related to the association of lung function with a criteria pollutant. In different reviews, there may be more evidence from one of these clinical measurements than another. In the previous review of the O3 NAAQS, EPA identified statistically significant associations between increased ozone levels and morning PEF, which remained significant even when concentrations exceeding 0.08 ppm were excluded from the analysis (Mortimer et al. 2002). EPA considered this evidence, along with evidence of other clinical measurements of changes in lung function, in drawing conclusions on the relationship between ozone and lung function. Using a similar approach to weigh the evidence pertinent to lung function, including studies that produced no statistically significant results for PEF, the NOX ISA (section 3.1.5.3) states:

In summary, epidemiologic studies using data from supervised lung function measurements (spirometry or peak flow meters) report small decrements in lung function (Hoek and Brunekreef, 1994; Linn et al., 1996; Moshammer et al., 2006; Peacock et al., 2003; Schindler et al., 2001). No significant associations were reported in any studies using unsupervised, self-administered peak flow [PEF] measurements with portable devices.

The evaluation of the evidence in the NOX ISA is consistent with the way the evidence from multiple clinical measures of lung function was used in the review of the O3 NAAQS.

b. Comments on EPA's Interpretation of the Controlled Human Exposure Evidence

A number of industry groups (e.g., AAM, ACC, API, Dow Chemical Company (Dow), EMA, NAM, UARG) disagreed with EPA's reliance on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics. Based on this meta-analysis (ISA, Table 3.1-3 for results), the ISA concluded that ``small but significant increases in nonspecific airway hyperresponsiveness were

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observed * * * at 0.1 ppm NO2 for 60-min exposures in asthmatics'' (ISA, p. 5-11). Industry groups raised a number of objections to this analysis and the way in which it has been used in the current review.

Several of these industry groups concluded that, in relying on this analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. For example, as part of a Request for Correction submitted under EPA's Information Quality Guidelines, NAM stated that ``EPA's substantial reliance on an unpublished assessment described as a ``meta-analysis'' of the relation between NO2 exposure and changes in airway responsiveness violates EPA Guidelines requiring ``transparency about data and methods.''

EPA disagrees with this characterization of the updated meta-analysis included in the final ISA. As described in the ISA (p. 3-16), this meta-analysis is based on an earlier analysis by Folinsbee (1992) that has been subject to peer-review, that was published in a scientific journal (Toxicol Ind Health. 8:1-11, 1992), and that was reviewed by CASAC as part of the previous review of the NO2 NAAQS (EPA, 1993, Table 15-10). The updates to this earlier analysis did not include substantive changes to the approach. As discussed in the final ISA (p. 3-16), the changes made to the analysis were to remove the results of one allergen study and add results from a non-specific responsiveness study, which focused the meta-analysis on non-specific airway responsiveness, and to discuss results for an additional exposure concentration (i.e., 100 ppb). The information needed to reproduce this meta-analysis is provided in the ISA (Tables 3.1-2 and 3.1-3, including footnotes).

While the ISA meta-analysis reports findings on airway responsiveness in asthmatics following exposure to 100 ppb NO2, a concentration not specifically discussed in the findings of the original report by Folinsbee (1992), this does not constitute a substantive change to that original analysis. For exposures at rest, four of the studies included in the analysis by Folinsbee evaluated the effects of exposure to 100 ppb NO2. In that original meta-analysis, these studies were grouped with another study that evaluated exposures to 140 ppb NO2. When analyzed together, exposures to NO2 concentrations of 100 ppb and 140 ppb (grouped together in the manuscript and described as less than 0.2 ppm) increased airway responsiveness in 65% of resting asthmatics (p < 0.01). Therefore, reporting results at 100 ppb NO2 in the ISA meta-analysis reflects a change in the way the data are presented and does not reflect a substantive change to the study. This change in presentation allows specific consideration of the potential for exposures to 100 ppb NO2 to increase airway responsiveness, rather than grouping results at 100 ppb with results at other exposure concentrations.

In addition, the updated meta-analysis was considered by CASAC during their review of the REA (REA, Table 4-5 reports the results of the updated meta-analysis), which based part of the assessment of NO2-associated health risks on the results of the meta-analysis. In their letter to the Administrator on the final REA (Samet, 2008b), CASAC stated that ``[t]he evidence reviewed in the REA indicates that adverse health effects have been documented in clinical studies of persons with asthma at 100 ppb'' and that ``CASAC firmly recommends that the upper end of the range [of standard levels] not exceed 100 ppb, given the findings of the REA.'' In addition, in their comments on the proposal, CASAC reiterated this advice in their statement that ``the level of the one-hour NO2 standard should be within the range of 80-100 ppb and not above 100 ppb.'' These statements indicate that CASAC did specifically consider the results of the updated meta-analysis and that they used those results to inform their recommendations on the range of standard levels supported by the scientific evidence.

In summary, we note the following:

The original meta-analysis was published in a peer-reviewed journal and was reviewed by CASAC in the previous review of the NO2 NAAQS.

The updated meta-analysis does not include substantive changes to the methodology of this original analysis.

The changes that were made are clearly described in the ISA.

CASAC specifically reviewed and considered the ISA meta-analysis in making recommendations regarding the range of standard levels supported by the science.

Many of these same industry groups also referred in their comments to a recent meta-analysis of controlled human exposure studies evaluating the airway response in asthmatics following NO2 exposure (Goodman et al., 2009). These groups generally recommended that EPA rely on this meta-analysis and on the authors' conclusions with regard to NO2 and airway responsiveness. Specific comments based on the manuscript by Goodman et al., as well as EPA's responses, are discussed below in more detail.\9\

\9\ EPA considers the Goodman study to be a ``new study'' on which, as discussed above in section I.B, it would not be appropriate to base a standard in the absence of thorough CASAC and public review of the study and its methodology. However, as discussed below, EPA has considered the study in the context of responding to public comments on the proposal and has concluded it does not provide a basis to materially change any of the broad scientific conclusions regarding the health effects of NO2 made in the air quality criteria.

Industry commenters generally claimed that the meta-analysis by Goodman et al. supports the conclusion that no adverse effects occur following exposures up to 600 ppb NO2. However, Table 4 of the Goodman study reports that 64% (95% Confidence Interval: 58%, 71%) of resting asthmatics exposed to NO2 experienced an increase in airway responsiveness. Furthermore, Figure 2a of this manuscript reports that for exposures < 0.2 ppm, the fraction affected is 0.61 (95% CI: 0.52, 0.70) while for exposures of 0.2 ppm to < 0.3 ppm, the fraction affected is 0.66 (95% CI: 0.59, 0.74). These findings are consistent with those reported in the meta-analysis by Folinsbee and in the updated meta-analysis that was included in the final ISA.

Also based on the meta-analysis by Goodman et al. (2009), several industry commenters concluded that NO2-induced airway hyperresponsiveness is not adverse and, therefore, should not be considered in setting standards. The basis for this comment appears to be the conclusions reached by Goodman et al. that there is no dose-response relationship for NO2 and that the magnitude of any NO2 effect on airway responsiveness is too small to be considered adverse.

Due to differences in study protocols in the NO2-airway response literature (ISA, section 3.1.3), EPA disagrees with the approach taken in the Goodman study to use existing data to attempt to evaluate the presence of a dose-response relationship and to determine the magnitude of the NO2 response. Examples of differences in the study protocols include the NO2 exposure method (i.e., mouthpiece versus chamber), subject activity level (i.e., rest versus exercise) during NO2 exposure, choice of airway challenge agent, and physiological endpoint used to quantify airway responses. Goodman et al. (2009) also recognized heterogeneity among studies as a limitation in their analyses.

As a result of these differences, EPA judged it appropriate in the ISA meta-analysis to assess only the fraction of asthmatics experiencing increased or decreased airway responsiveness

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following NO2 exposure. We have acknowledged in the REA, the proposal, and in this final rulemaking that there is uncertainty with regard to the magnitude and the clinical-significance of NO2-induced increases in airway responsiveness (see sections II.C.3 and II.F.4.a in the proposed rulemaking as well as II.F.3 in this final rulemaking). The REA stated the following (p. 302):

[O]ne of the important uncertainties associated with these [NO2-induced airway hyperresponsiveness] results is that, because the meta-analysis evaluated only the direction of the change in airway responsiveness, it is not possible to discern the magnitude of the change from these data. This limitation makes it particularly difficult to quantify the public health implications of these results.

While we acknowledge this uncertainty, EPA disagrees with the conclusion that the NO2-induced increase in airway responsiveness in asthmatics exposed to NO2 concentrations up to 600 ppb is not adverse and should not be considered in setting standards. Specifically, we note that the ISA concluded that ``[t]ransient increases in airway responsiveness following NO2 exposure have the potential to increase symptoms and worsen asthma control'' (ISA, section 5.4). The uncertainty over the adversity of the response reported in controlled human exposure studies does not mean that the NO2-induced increase in airway responsiveness is not adverse. Rather, it means that there is a risk of adversity, especially for asthmatics with more than mild asthma, but that this risk cannot be fully characterized based on existing studies. The studies of NO2 and airway responsiveness included in the meta-analysis have generally evaluated mild asthmatics, rather than more severely affected asthmatics who could be more susceptible to the NO2-induced increase in airway responsiveness (ISA, section 3.1.3.2). Given that this is the case, and given the large percentage of asthmatics that experienced an NO2-induced increase in airway responsiveness in the studies and the large size of the asthmatic population in the United States, the REA concluded that it is appropriate to consider NO2-induced airway hyperresponsiveness in characterizing NO2-associated health risks (REA, section 10.3.2). As noted above, CASAC endorsed this conclusion in their letters to the Administrator on the final REA and on the proposal (Samet, 2008b; Samet, 2009).

c. Comments on EPA's Characterization of NO2-Associated Exposures and Health Risks

Several commenters discussed the analyses of NO2-associated exposures and health risks presented in the REA. As in past reviews (EPA 2005, 2007c, 2007d), EPA has estimated allowable risks associated with the current standard and potential alternative standards to inform judgments on the public health risks that could exist under different standard options. Some industry commenters (e.g., API, NMA) concluded that the Administrator should consider modeled exposures and risks associated with actual NO2 air quality rather than with NO2 concentrations adjusted to simulate just meeting the current annual standard or potential alternative 1-hour standards. These commenters pointed out that such simulations require large adjustments to air quality and are highly uncertain and that NAAQS are intended to address actual, rather than highly improbable, risks to health.

We disagree with these commenters that exposure- and risk-related considerations in the NAAQS review should rely only on unadjusted air quality. In considering whether the current standard is requisite to protect public health with an adequate margin of safety, air quality adjustments allow estimates of NO2-related exposures and health risks that could exist in areas that just meet that standard. That is, these adjustments allow consideration of exposures and risks that would be permissible under the current standard. Therefore, such adjustments are clearly useful to inform a decision on the issue before EPA (i.e., the adequacy of the level of public health protection associated with allowable NO2 air quality under the standard). Similarly, air quality adjustments to simulate different potential alternative standards provide information on exposures and risks that would be permissible under these alternatives.\10\ As noted above, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC concluded that ``The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure.''

\10\ Once EPA determines whether to retain or revise the current standard, the actual air quality levels in various areas of the country are clearly relevant under the NAAQS implementation provisions for the Act, such as the provision for designation of areas based on whether or not they attain the required NAAQS.

We agree that there are uncertainties inherent in air quality adjustments. These uncertainties are discussed thoroughly in the REA (sections 7.4, 8.12, 9.6, and 10.3.2.1) and in the proposed rule (section II.C.3). For example, the policy assessment chapter of the REA (section 10.3.2.1) noted the following regarding adjustment of NO2 concentrations:

In order to simulate just meeting the current annual standard and many of the alternative 1-h standards analyzed, an upward adjustment of recent ambient NO2 concentrations was required. We note that this adjustment does not reflect a judgment that levels of NO2 are likely to increase under the current standard or any of the potential alternative standards under consideration. Rather, these adjustments reflect the fact that the current standard, as well as some of the alternatives under consideration, could allow for such increases in ambient NO2 concentrations. In adjusting air quality to simulate just meeting these standards, we have assumed that the overall shape of the distribution of NO2 concentrations would not change. While we believe this is a reasonable assumption in the absence of evidence supporting a different distribution and we note that available analyses support this approach (Rizzo, 2008), we recognize this as an important uncertainty. It may be an especially important uncertainty for those scenarios where considerable upward adjustment is required to simulate just meeting one or more of the standards.

These air quality adjustments are not meant to imply an expectation that NO2 concentrations will increase broadly across the United States or in any given area (REA, section 10.3.2.1). Rather, as noted above, they are meant to estimate NO2-related exposures and health risks that would be permitted under the current and potential alternative standards. Such estimates can inform decisions on whether the current standard, or particular potential alternative standards, provide the requisite protection of public health.

3. Conclusions Regarding the Adequacy of the Current Standard

In considering the adequacy of the current standard, the Administrator has considered the scientific evidence assessed in the ISA, the exposure and risk results presented in the REA, the conclusions of the policy assessment chapter of the REA, and comments from CASAC and the public. These considerations are described below.

In considering the scientific evidence as it relates to the adequacy of the current standard, the Administrator notes that the epidemiologic evidence has grown substantially since the last review with the addition of field and panel studies, intervention studies, and time-series studies of effects such as emergency department visits and hospital admissions associated with

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short-term NO2 exposures. No epidemiologic studies were available in 1993 assessing relationships between NO2 and outcomes such as hospital admissions or emergency department visits. In contrast, dozens of epidemiologic studies on such outcomes, conducted at recent and current ambient NO2 concentrations, are now included in this evaluation (ISA, chapter 3).

As an initial consideration with regard to the adequacy of the current standard, the Administrator notes that the evidence relating long-term (weeks to years) NO2 exposures at current ambient concentrations to adverse health effects was judged in the ISA to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). In contrast, the evidence relating short-term (minutes to hours) NO2 exposures to respiratory morbidity was judged to be ``sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1). This conclusion was supported primarily by a large body of recent epidemiologic studies that evaluated associations of short-term NO2 concentrations with respiratory symptoms, emergency department visits, and hospital admissions. Given these conclusions from the ISA, the Administrator judges that, at a minimum, consideration of the adequacy of the current annual standard should take into account the extent to which that standard provides protection against respiratory effects associated with short-term NO2 exposures.

In considering the NO2 epidemiologic studies as they relate to the adequacy of the current standard, the Administrator notes that annual average NO2 concentrations were below the level of the current annual NO2 NAAQS in many of the locations where positive, and often statistically significant, associations with respiratory morbidity endpoints have been reported (ISA, section 5.4). As discussed previously, the ISA characterized that evidence for respiratory effects as consistent and coherent. The evidence is consistent in that associations are reported in studies conducted in numerous locations and with a variety of methodological approaches (ISA, section 5.3.2.1). It is coherent in the sense that the studies report associations with respiratory health outcomes that are logically linked together (ISA, section 5.3.2.1). The ISA noted that when the epidemiologic literature is considered as a whole, there are generally positive associations between NO2 and respiratory symptoms, hospital admissions, and emergency department visits. A number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1).

As discussed in the proposal (II.E.1) and above, the Administrator acknowledges that the interpretation of these NO2 epidemiologic studies is complicated by the fact that on-road vehicle exhaust emissions are a nearly ubiquitous source of combustion pollutant mixtures that include NO2. She notes that, in order to provide some perspective on the uncertainty related to the presence of co-pollutants the ISA evaluated epidemiologic studies that employed multi-pollutant models, epidemiologic studies of indoor NO2 exposure, and experimental studies. Specifically, the ISA noted that a number of NO2 epidemiologic studies have attempted to disentangle the effects of NO2 from those of co-occurring pollutants by employing multi-pollutant models. When evaluated as a whole, NO2 effect estimates in these models generally remained robust when co-pollutants were included. Therefore, despite uncertainties associated with separating the effects of NO2 from those of co-occurring pollutants, the ISA (section 5.4, p. 5-16) concluded that ``the evidence summarized in this assessment indicates that NO2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS.'' With regard to indoor studies, the ISA noted that these studies can test hypotheses related to NO2 specifically (ISA, section 3.1.4.1). Although confounding by indoor combustion sources is a concern, indoor studies are not confounded by the same mix of co-pollutants present in the ambient air or by the contribution of NO2 to the formation of secondary particles or O3 (ISA, section 3.1.4.1). The ISA noted that the findings of indoor NO2 studies are consistent with those of studies using ambient concentrations from central site monitors and concluded that indoor studies provide evidence of coherence for respiratory effects (ISA, section 3.1.4.1). With regard to experimental studies, the REA noted that they have the advantage of providing information on health effects that are specifically associated with exposure to NO2 in the absence of co-pollutants. The ISA concluded that the NO2 epidemiologic literature is supported by (1) evidence from controlled human exposure studies of airway hyperresponsiveness in asthmatics, (2) controlled human exposure and animal toxicological studies of impaired host-defense systems and increased risk of susceptibility to viral and bacterial infection, and (3) controlled human exposure and animal toxicological studies of airway inflammation (ISA, section 5.3.2.1 and 5.4). Given the above consideration of the evidence, particularly the epidemiologic studies reporting NO2-associated health effects in locations that meet the current standard, the Administrator agrees with the conclusion in the policy assessment chapter of the REA that the scientific evidence calls into question the adequacy of the current standard to protect public health.

In addition to the evidence-based considerations described above, the Administrator has considered the extent to which exposure- and risk-based information can inform decisions regarding the adequacy of the current annual NO2 standard. While she acknowledges the uncertainties associated with adjusting air quality in these analyses, she judges that such analyses are appropriate for consideration in this review of the NO2 primary NAAQS. In reaching this conclusion she notes the considerations discussed above, particularly the endorsement by CASAC of the REA and its characterization of NO2-associated exposures and health risks.

In considering the exposure- and risk-based information with regard to the adequacy of the current annual NO2 standard to protect the public health, the Administrator notes the conclusion in the policy assessment chapter of the REA that risks estimated to be associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be concluded to be important from a public health perspective. In particular, a large percentage (8-9%) of respiratory-related ED visits in Atlanta could be associated with short-term NO2 exposures, most asthmatics in Atlanta could be exposed on multiple days per year to NO2 concentrations at or above 300 ppb, and most locations evaluated could experience on-/near-road NO2 concentrations above 100 ppb on more than half of the days in a given year. Therefore, after considering the results of the exposure and risk analyses presented in the REA the Administrator agrees with the conclusion of the policy assessment chapter of the REA that exposure- and risk-based results reinforce the scientific evidence in

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supporting the conclusion that consideration should be given to revising the current standard so as to provide increased public health protection, especially for at-risk groups, from NO2-related adverse health effects associated with short-term, and potential long-term, exposures.

In reaching a conclusion on the adequacy of the current standard, the Administrator has also considered advice received from CASAC. In their comments on the final REA, CASAC agreed that the primary concern in this review is to protect against health effects that have been associated with short-term NO2 exposures. CASAC also agreed that the current annual standard is not sufficient to protect public health against the types of exposures that could lead to these health effects. As noted in their letter to the EPA Administrator, ``CASAC concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised'' (Samet, 2008b).

Based on the considerations discussed above, the Administrator concludes that the current NO2 primary NAAQS alone is not requisite to protect public health with an adequate margin of safety. Accordingly, she concludes that the NO2 primary standard should be revised in order to provide increased public health protection against respiratory effects associated with short-term exposures, particularly for susceptible populations such as asthmatics, children, and older adults. In considering approaches to revising the current standard, the Administrator concludes that it is appropriate to consider setting a new short-term standard (see below). The Administrator notes that such a short-term standard could provide increased public health protection, especially for members of at-risk groups, from effects described in both epidemiologic and controlled human exposure studies to be associated with short-term exposures to NO2.

F. Elements of a New Short-Term Standard

In considering a revised NO2 primary NAAQS, the Administrator notes the need to protect at-risk individuals from short-term exposures to NO2 air quality that could cause the types of respiratory morbidity effects reported in epidemiologic studies and the need to protect at-risk individuals from short-term exposure to NO2 concentrations reported in controlled human exposure studies to increase airway responsiveness in asthmatics. The Administrator's considerations with regard to her decisions are discussed in the following sections in terms of indicator (II.F.1), averaging time (II.F.2), level (II.F.3), and form (II.F.4).

1. Indicator

a. Rationale for Proposed Decision

In past reviews, EPA has focused on NO2 as the most appropriate indicator for ambient NOX. In making a decision in the current review on the most appropriate indicator, the Administrator considered the conclusions of the ISA and the policy assessment chapter of the REA as well as the view expressed by CASAC. The policy assessment chapter of the REA noted that, while the presence of NOX species other than NO2 has been recognized, no alternative to NO2 has been advanced as being a more appropriate surrogate. Controlled human exposure studies and animal toxicology studies assessed in the ISA provide specific evidence for health effects following exposure to NO2. Epidemiologic studies also typically report levels of NO2 though the degree to which monitored NO2 reflects actual NO2 levels, as opposed to NO2 plus other gaseous NOX, can vary (REA, section 2.2.3). In addition, because emissions that lead to the formation of NO2 generally also lead to the formation of other NOX oxidation products, measures leading to reductions in population exposures to NO2 can generally be expected to lead to reductions in population exposures to other gaseous NOX. Therefore, an NO2 standard can also be expected to provide some degree of protection against potential health effects that may be independently associated with other gaseous NOX even though such effects are not discernable from currently available studies indexed by NO2 alone. Given these key points, the policy assessment chapter of the REA concluded that the evidence supports retaining NO2 as the indicator. Consistent with this conclusion, the CASAC Panel stated in its letter to the EPA Administrator that it ``concurs with retention of NO2 as the indicator'' (Samet, 2008b). In light of the above considerations, the Administrator proposed to retain NO2 as the indicator in the current review.

b. Comments on Indicator

A relatively small number of comments directly addressed the issue of the indicator for the standard (CASAC, Dow, API, AAM, and the Missouri Department of Natural Resources Air Pollution Control Program (MODNR)). All of these commenters endorsed the proposal to continue to use NO2 as the indicator for ambient NOX.

c. Conclusions on Indicator

Based on the available information discussed above, and consistent with the views of CASAC and other commenters, the Administrator concludes that it is appropriate to continue to use NO2 as the indicator for a standard that is intended to address effects associated with exposure to NO2, alone or in combination with other gaseous NOX. In so doing, the Administrator recognizes that measures leading to reductions in population exposures to NO2 will also reduce exposures to other nitrogen oxides.

2. Averaging Time

This section discusses considerations related to the averaging time of the NO2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding averaging time (II.F.2.a; see section II.F.2 of the proposal for more detail), discusses comments related to averaging time (II.F.2.b), and presents the Administrator's final conclusions regarding averaging time (II.F.2.c).

a. Rationale for Proposed Decision

In considering the most appropriate averaging time for the NO2 primary NAAQS, the Administrator noted in the proposal the conclusions and judgments made in the ISA about available scientific evidence, air quality correlations discussed in the REA, conclusions of the policy assessment chapter of the REA, and CASAC recommendations (section II.F.2 in the proposal). Specifically, she noted the following:

Experimental studies in humans and animals have reported respiratory effects following NO2 exposures lasting from less than 1-hour up to several hours. Epidemiologic studies have reported associations between respiratory effects and both 1 hour and 24-hour NO2 concentrations. Therefore, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (e.g., 1 hour) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. At a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO2 concentrations.

Air quality correlations presented in the policy assessment chapter of the REA illustrated the relatively high degree of variability in the ratios of annual average to short-term NO2 concentrations (REA, Table 10-2). This

variability suggests that a standard based on annual average NO2 concentrations would not likely be an effective or efficient approach to focus protection on short-term exposures.

These air quality correlations (REA, Table 10-1) suggested that a standard based on 1-hour daily maximum NO2 concentrations could also be effective at protecting against 24-hour NO2 concentrations.

The policy assessment chapter of the REA concluded that the scientific evidence, combined with the air quality correlations, support the appropriateness of a standard based on 1-hour daily maximum NO2 concentrations to protect against health effects associated with short-term exposures.

CASAC concurred ``with having a short-term NAAQS primary standard for oxides of nitrogen and using the one-hour maximum NO2 value'' (Samet, 2008b).

Based on these considerations, the Administrator proposed to set a new standard based on 1-hour daily maximum NO2 concentrations.

b. Comments on averaging time

As discussed above, CASAC endorsed the establishment of a new standard with a 1-hour averaging time. CASAC stated the following in their comments on the proposal (Samet, 2009):

In reviewing the REA, CASAC supported a short-term standard for NO2 and in reviewing the proposal, CASAC supports the proposed one-hour averaging time in EPA's proposed rule.

The supporting rationale offered by CASAC in support of a new 1-hour standard was generally the same as that put forward in the final REA and the proposal. Specifically, that rationale considered the available scientific evidence, which supports a link between 1-hour NO2 concentrations and adverse respiratory effects, and air quality information presented in the REA, which suggests that a 1-hour standard can protect against effects linked to short-term NO2 exposures while an annual standard would not be an effective or efficient approach to protecting against these effects.

A large number of public commenters also endorsed the establishment of a new standard with a 1-hour averaging time. These included a number of State agencies and organizations (e.g., NACAA, NESCAUM and agencies in CA, IL, NM, TX, VA); environmental, medical, and public health organizations (e.g., ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC); and most individual commenters. The supporting rationales offered by these commenters often acknowledged the recommendations of CASAC and the Administrator's rationale as discussed in the proposal.

Though many industry commenters recommended not revising the current annual standard (as discussed above in section II.E.2), several of these groups did conclude that if a short-term standard were to be set, a 1-hour averaging time would be appropriate (e.g., Colorado Petroleum Association (CPA), Dow, NAM, Petroleum Association of Wyoming (PAW), Utah Petroleum Association (UPA)). As discussed above, industry commenters who disagreed with setting a new 1-hour standard generally based this conclusion on their interpretation of the scientific evidence and their conclusion that this evidence does not support the need to revise the current annual standard. These comments, and EPA's responses, are discussed in more detail above (section II.E) and in the Response to Comments document.

c. Conclusions on Averaging Time

In considering the most appropriate averaging time for the NO2 primary NAAQS, the Administrator notes the available scientific evidence as assessed in the ISA, the air quality analyses presented in the REA, the conclusions of the policy assessment chapter of the REA, CASAC recommendations, and public comments received. These considerations are described below.

When considering averaging time, the Administrator notes that the evidence relating short-term (minutes to hours) NO2 exposures to respiratory morbidity was judged in the ISA to be ``sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1) while the evidence relating long-term (weeks to years) NO2 exposures to adverse health effects was judged to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). Thus, the Administrator concludes that these judgments most directly support an averaging time that focuses protection on short-term exposures to NO2.

As in past reviews of the NO2 NAAQS, the Administrator notes that it is instructive to evaluate the potential for a standard based on annual average NO2 concentrations, as is the current standard, to provide protection against short-term NO2 exposures. To this end, the Administrator notes that

Table 10-1 in the REA reported the ratios of short-term to annual average NO2 concentrations. Ratios of 1-hour daily maximum concentrations (98th and 99th percentile \11\) to annual average concentrations across 14 locations ranged from 2.5 to 8.7 while ratios of 24-hour average concentrations to annual average concentrations ranged from 1.6 to 3.8 (see Thompson, 2008 for more details). The policy assessment chapter of the REA concluded that the variability in these ratios across locations, particularly those for 1-hour concentrations, suggested that a standard based on annual average NO2 concentrations would not likely be an effective or efficient approach to focus protection on short-term NO2 exposures. For example, in an area with a relatively high ratio (e.g., 8), the current annual standard (53 ppb) would be expected to allow 1-hour daily maximum NO2 concentrations of about 400 ppb. In contrast, in an area with a relatively low ratio (e.g., 3), the current standard would be expected to allow 1-hour daily maximum NO2 concentrations of about 150 ppb. Thus, for purposes of protecting against the range of 1-hour NO2 exposures, the REA noted that a standard based on annual average concentrations would likely require more control than necessary in some areas and less control than necessary in others, depending on the standard level selected.

\11\ As discussed below, 98th and 99th percentile forms were evaluated in the REA. A 99th percentile form corresponds approximately to the 4th highest 1-hour concentration in a year while a 98th percentile form corresponds approximately to the 7th or 8th highest 1-hour concentration in a year. A 4th highest concentration form has been used previously in the O3 NAAQS while a 98th percentile form has been used previously in the PM2.5 NAAQS.

In considering the level of support available for specific short-term averaging times, the Administrator notes that the policy assessment chapter of the REA considered evidence from both experimental and epidemiologic studies. Controlled human exposure studies and animal toxicological studies provide evidence that NO2 exposures from less than 1-hour up to 3-hours can result in respiratory effects such as increased airway responsiveness and inflammation (ISA, section 5.3.2.7). Specifically, the ISA concluded that NO2 exposures of 100 ppb for 1-hour (or 200 ppb to 300 ppb for 30-min) can result in small but significant increases in nonspecific airway responsiveness (ISA, section 5.3.2.1). In contrast, the epidemiologic literature provides support for short-term averaging times ranging from approximately 1-hour up to 24-hours (ISA, section 5.3.2.7). A

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number of epidemiologic studies have detected positive associations between respiratory morbidity and 1-hour (daily maximum) and/or 24-hour NO2 concentrations. A few epidemiologic studies have considered both 1-hour and 24-hour averaging times, allowing comparisons to be made. The ISA reported that such comparisons in studies that evaluate asthma emergency department visits failed to reveal differences between effect estimates based on a 1-hour averaging time and those based on a 24-hour averaging time (ISA, section 5.3.2.7). Therefore, the ISA concluded that it is not possible, from the available epidemiologic evidence, to discern whether effects observed are attributable to average daily (or multi-day) concentrations (24-hour average) or high, peak exposures (1-hour maximum) (ISA, section 5.3.2.7).

As noted in the policy assessment chapter of the REA, given the above conclusions, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (e.g., 1-h) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. The Administrator concludes that, at a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO2 concentrations. However, she also notes that it is important to consider the ability of a 1-hour averaging time to protect against 24-hour average NO2 concentrations. To this end, the Administrator notes that Table 10-2 in the REA presented correlations between 1-hour daily maximum NO2 concentrations and 24-hour average NO2 concentrations (98th and 99th percentile) across 14 locations (see Thompson, 2008 for more detail). Typical ratios ranged from 1.5 to 2.0, though one ratio (Las Vegas) was 3.1. These ratios were far less variable than those discussed above for annual average concentrations, suggesting that a standard based on 1-hour daily maximum NO2 concentrations could also be effective at protecting against 24-hour NO2 concentrations. The REA concluded that the scientific evidence, combined with the air quality correlations described above, support the appropriateness of a standard based on 1-hour daily maximum NO2 concentrations to protect against health effects associated with short-term exposures.

Based on these considerations, the Administrator concludes that a standard with a 1-hour averaging time can effectively limit short-term (i.e., 1- to 24-hours) exposures that have been linked to adverse respiratory effects. This conclusion is based on the observations summarized above and in more detail in the proposal, particularly that: (1) The 1-hour averaging time has been directly associated with respiratory effects in both epidemiologic and experimental studies and that (2) results from air quality analyses suggest that a 1-hour standard could also effectively control 24-hour NO2 concentrations. In addition, the Administrator notes the support provided for a 1-hour averaging time in comments from CASAC, States, environmental groups, and medical/public health groups. The Administrator notes that arguments offered by some industry groups against setting a 1-hour NO2 standard generally focus on commenters' conclusions regarding uncertainties in the scientific evidence. As discussed in more detail above (section II.E.2), the Administrator disagrees with the conclusions of these commenters regarding the appropriate interpretation of the scientific evidence and associated uncertainties. Given these considerations, the Administrator judges that it is appropriate to set a new NO2 standard with a 1-hour averaging time.

3. Form

This section discusses considerations related to the form of the 1-hour NO2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding form (II.F.4.a; see section II.F.3 of the proposal for more detail), discusses comments related to form (II.F.4.b), and presents the Administrator's final conclusions regarding form (II.F.4.c).

a. Rationale For Proposed Decision

When considering alternative forms in the proposal, the Administrator noted the conclusions in the policy assessment chapter of the REA. Specifically, she noted the conclusion that the adequacy of the public health protection provided by the combination of standard level and form should be the foremost consideration. With regard to this, she noted that concentration-based forms can better reflect pollutant-associated health risks than forms based on expected exceedances. This is the case because concentration-based forms give proportionally greater weight to years when pollutant concentrations are well above the level of the standard than to years when the concentrations are just above the standard, while an expected exceedance form would give the same weight to years with concentrations that just exceed the standard as to years when concentrations greatly exceed the standard. The Administrator also recognized the conclusion in the policy assessment chapter of the REA that it is desirable from a public health perspective to have a form that is reasonably stable and insulated from the impacts of extreme meteorological events. With regard to this, she noted that a form that calls for averaging concentrations over three years would provide greater regulatory stability than a form based on a single year of concentrations. Therefore, consistent with recent reviews of the O3 and PM NAAQS, the proposal focused on concentration-based forms averaged over 3 years, as evaluated in the REA.

In considering specific concentration-based forms, the REA focused on 98th and 99th percentile concentrations averaged over 3 years. This focus on the upper percentiles of the distribution is appropriate given the reliance, in part, on NO2 health evidence from experimental studies, which provide information on specific exposure concentrations that are linked to specific health effects. The REA noted that a 99th percentile form for a 1-hour daily maximum standard would correspond approximately to the 4th highest daily maximum concentration in a year (which is the form of the current O3 NAAQS) while a 98th percentile form (which is the form of the current short-term PM2.5 NAAQS) would correspond approximately to the 7th or 8th highest daily maximum concentration in a year (REA, Table 10-4; see Thompson, 2008 for methods).

Consideration in the REA of an appropriate form for a 1-hour standard was based on analyses of standard levels that reflected the allowable area-wide NO2 concentration, not the maximum allowable concentration. Therefore, in their review of the final REA, CASAC did not have the opportunity to comment on the appropriateness of specific forms in conjunction with a standard level that reflects the maximum allowable NO2 concentration anywhere in an area. Given this, when considering alternative forms for the 1-hour standard in the proposal, the Administrator judged that it was appropriate to consider both forms evaluated in the REA (i.e., 98th and 99th percentiles). Therefore, she proposed to adopt either a 99th percentile or a 4th highest form, averaged over 3 years, and she solicited comment on both 98th percentile and 7th or 8th highest forms.

b. CASAC and Public Comments on Form

In their letter to the Administrator, CASAC discussed the issue of form within the context of the proposed

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approach of setting a 1-hour standard level that reflects the maximum allowable NO2 concentration anywhere in an area. CASAC recommended that, for such a standard, EPA adopt a form based on the 3-year average of the 98th percentile of the distribution of 1-hour daily maximum NO2 concentrations. Specifically, they stated the following in their comments on the proposal (Samet, 2009):

> The 98th percentile is preferred by CASAC for the form, given the likely instability of measurements at the upper range and the absence of data from the proposed two-tier approach.

As indicated in their letter, CASAC concluded that the potential instability in higher percentile NO2 concentrations near major roads argues for a 98th, rather than a 99th, percentile form. Several State organizations and agencies (e.g., NESCAUM and agencies in IN, NC, SD, VA) and industry groups (e.g., AAM, ACC, API, AirQuality Research and Logistics (AQRL), CPA, Dow, ExxonMobil, IPAMS, PAW, UPA) also recommended a 98th percentile form in order to provide regulatory stability. In contrast, a small number of State and local agencies (e.g., in MO and TX), several environmental organizations (e.g., EDF, EJ, GASP, NRDC), and medical/public health organizations (e.g., ALA, ATS) recommended either a 99th percentile form or a more stringent form (e.g., no exceedance) to further limit the occurrence of NO2 concentrations that exceed the standard level in locations that attain the standard.

c. Conclusions On Form

The Administrator recognizes that there is not a clear health basis for selecting one specific form over another. She also recognizes that the analyses of different forms in the REA are most directly relevant to a standard that reflects NO2 concentrations permitted to occur broadly across a community, rather than the maximum concentration that can occur anywhere in the area. In contrast, as discussed below (section II.F.4.c), the Administrator has judged it appropriate to set a new 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area. In light of this, the Administrator places particular emphasis on the comments received on form from CASAC relating to a 1-hour standard level that reflects the maximum allowable NO2 concentration anywhere in an area. In particular, the Administrator notes that CASAC recommended a 98th percentile form averaged over 3 years for such a standard, given the potential for instability in the higher percentile concentrations around major roadways.

In considering this recommendation, the Administrator recognizes that the public health protection provided by the 1-hour NO2 standard is based on the approach used to set the standard and the level of the standard (see below), in conjunction with the form of the standard. Given that the Administrator is setting a standard that reflects the maximum allowable NO2 concentration anywhere in an area, rather than a standard that reflects the allowable area-wide NO2 concentration, she agrees with CASAC that an appropriate consideration with regard to form is the extent to which specific statistics could be unstable at locations where maximum NO2 concentrations are expected, such as near major roads. When considering alternative forms for the standard, the Administrator notes that an unstable form could result in areas shifting in and out of attainment, potentially disrupting ongoing air quality planning without achieving public health goals. Given the limited available information on the variability in peak NO2 concentrations near important sources of NO2 such as major roadways, and given the recommendation from CASAC that the potential for instability in the 99th percentile concentration is cause for supporting a 98th percentile form, the Administrator judges it appropriate to set the form based on the 3-year average of the 98th percentile of the annual distribution of 1-hour daily maximum NO2 concentrations.

4. Level

As discussed below and in more detail in the proposal (section II.F.4), the Administrator has considered two different approaches to setting the 1-hour NO2 primary NAAQS. In the proposal, each of these approaches was linked with a different range of standard levels. Specifically, the Administrator proposed to set a 1-hour standard reflecting the maximum allowable NO2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. The Administrator also solicited comment on the alternative approach of setting a standard that reflects the allowable area-wide NO2 concentration and setting the standard level from 50 to 75 ppb. This section summarizes the rationale for the Administrator's proposed approach and range of standard levels (II.F.3.a), describes the alternative approach and range of standard levels (II.F.3.b), discusses comments related to each approach and range of standard levels (II.F.3.c), and presents the Administrator's final conclusions regarding the approach and level (II.F.3.d).

a. Rationale For Proposed Decisions on Approach and Level

In assessing the most appropriate approach to setting the 1-hour standard and the most appropriate range of standard levels to propose, the Administrator considered the broad body of scientific evidence assessed in the ISA, including epidemiologic and controlled human exposure studies, as well as the results of exposure/risk analyses presented in the REA. In light of the body of available evidence and analyses, as described above, the Administrator concluded in the proposal that it is necessary to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term (i.e., 30 minutes to 24 hours) exposures to NO2. Such health effects have been associated with exposure to the distribution of short-term ambient NO2 concentrations across an area, including higher short-term (i.e., peak) exposure concentrations, such as those that can occur on or near major roadways and near other sources of NO2, as well as the lower short-term exposure concentrations that can occur in areas not near major roadways or other sources of NO2. The Administrator's proposed decisions on approach and level, as discussed in detail in the proposal (section II.F.4), are outlined below.

In considering a standard-setting approach, the Administrator was mindful in the proposal that the available evidence and analyses from the ISA and REA support the public health importance of roadway-associated NO2 exposures. The exposure assessment described in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). The ISA concluded (section 4.3.6) that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level.'' In considering the potential variability in the NO2 concentration gradient, the proposal noted that available monitoring studies suggest that NO2 concentrations could be 30 to 100% higher than those in the same area but away from the road.\12\

\12\ In addition, the air quality analyses presented in the REA estimated that on-road NO2 concentrations are about 80% higher on average than concentrations away from the road (REA, section 7.3.2) and that NO2 monitors within 20 m of roads measure NO2 concentrations that are, on average across locations, 40% higher than concentrations measured by monitors at least 100 m from the road (REA, compare Tables 7-11 and 7-13).

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The Administrator also considered that millions of people in the United States live, work, and/or attend school near important sources of NO2 such as major roadways (ISA, section 4.4), and that ambient NO2 concentrations in these locations vary depending on the distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration) (ISA, section 2.5.4). Therefore, these populations, which likely include a disproportionate number of individuals in groups with higher prevalence of asthma and higher hospitalization rates for asthma (e.g. ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), are likely exposed to NO2 concentrations that are higher than those occurring away from major roadways.

Given the above considerations, the Administrator proposed an approach to setting the 1-hour NO2 primary NAAQS whereby the standard would reflect the maximum allowable NO2 concentration anywhere in an area. In many locations, this concentration is likely to occur on or near a major roadway. EPA proposed to set the level of the standard such that, when available information regarding the concentration gradient around roads is considered, appropriate public health protection would be provided by limiting the higher short-term peak exposure concentrations expected to occur on and near major roadways, as well as the lower short-term exposure concentrations expected to occur away from those roadways. The Administrator concluded that this approach to setting the 1-hour NO2 NAAQS would be expected to protect public health against exposure to the distribution of short-term NO2 concentrations across an area and would provide a relatively high degree of confidence regarding the protection provided against peak exposures to higher NO2 concentrations, such as those that can occur around major roadways. The remainder of this section discusses the proposed range of standard levels.

In considering the appropriate range of levels to propose for a standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator considered the broad body of scientific evidence and exposure/risk information as well as available information on the relationship between NO2 concentrations near roads and those away from roads. Specifically, she considered the extent to which a variety of levels would be expected to protect at-risk individuals against increased airway responsiveness, respiratory symptoms, and respiratory-related emergency department visits and hospital admissions.

After considering the scientific evidence and the exposure/risk information (see sections II.B, II.C, and II.F.4.a.1 through II.F.4.a.3 in the proposal), as well as the available information on the NO2 concentration gradient around roadways (section II.A.2 above and in the proposal), the Administrator concluded that the strongest support is for a standard level at or somewhat below 100 ppb. The Administrator's rationale in reaching this proposed conclusion is provided below.

The Administrator noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to limit short-term NO2 exposures to concentrations that have been reported to increase airway responsiveness in asthmatics (i.e., at or above 100 ppb). While she acknowledged that exposure to NO2 concentrations below 100 ppb could potentially increase airway responsiveness in some asthmatics, the Administrator also noted uncertainties regarding the magnitude and the clinical significance of the NO2-induced increase in airway responsiveness, as discussed in the policy assessment chapter of the REA (section 10.3.2.1, discussed in section II.F.4.e in the proposal). Given these uncertainties, the Administrator concluded in the proposal that controlled human exposure studies provide support for limiting exposures at or somewhat below 100 ppb NO2.

The Administrator also noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to maintain peak area-wide NO2 concentrations considerably below those measured in locations where key U.S. epidemiologic studies have reported associations with more serious respiratory effects, as indicated by increased emergency department visits and hospital admissions. Specifically, the Administrator noted that 5 key U.S. studies provide evidence for such associations in locations where the 99th percentile of the distribution of 1-hour daily maximum NO2 concentrations measured at area-wide monitors ranged from 93 to 112 ppb (Ito et al., 2007; Jaffe et al., 2003; Peel et al., 2005; Tolbert et al., 2007; and a study by the New York State Department of Health, 2006).\13\ The Administrator concluded that these studies provide support for a 1-hour standard that limits the 99th percentile of the distribution of 1-hour daily maximum area-wide NO2 concentrations to below 90 ppb (corresponds to a 98th percentile concentration of 85 ppb), and that limiting area-wide concentrations to considerably below 90 ppb would be appropriate in order to provide an adequate margin of safety. The Administrator noted that, based on available information about the NO2 concentration gradient around roads, a standard level at or somewhat below 100 ppb set in conjunction with the proposed approach would be expected to accomplish this. Specifically, she noted that given available information regarding NO2 concentration gradients around roads (see section II.A.2), a standard level at or below 100 ppb (with either a 99th or 98th percentile form) would be expected to limit peak area-wide NO2 concentrations to approximately 75 ppb or below.\14\ Therefore, the Administrator concluded that a standard level at or somewhat below 100 ppb under the proposed approach would be expected to maintain peak area-wide NO2 concentrations well below 90 ppb across locations despite the expected variation in the NO2 concentration gradient that can exist around roadways in different locations and over time.

\13\ The 98th percentile concentrations in these study locations ranged from 85 to 94 ppb.

\14\ For a standard of 100 ppb, area-wide concentrations would be expected to range from approximately 50 ppb (assuming near-road concentrations are 100% higher than area-wide concentrations) to 75 ppb (assuming near-road concentrations are 30% higher than area-wide concentrations).

The Administrator also noted that a study by Delfino provides mixed evidence for effects in a location with area-wide 98th and 99th percentile 1-hour daily maximum NO2 concentrations of 50 and 53 ppb, respectively. In that study, NO2 effect estimates were positive, but some reported 95% confidence limits for the odds ratio (OR) that included values less than 1.00. Given the mixed results of the Delfino study, the Administrator concluded that it may not be necessary to maintain area-wide NO2 concentrations at or below 50 ppb to provide protection against the effects reported in epidemiologic studies.

In addition to these evidence-based considerations, the Administrator noted that a standard level at or somewhat below 100 ppb under the proposed approach would be consistent with the

results of the exposure and risk analyses presented in the REA. As discussed in section II.C of the proposal, the results of these analyses provide support for setting a standard that limits 1-hour area-wide NO2 concentrations to between 50 and 100 ppb. As described above, a standard level of 100 ppb that reflects the maximum allowable NO2 concentration would be expected to maintain area-wide NO2 concentrations at or below approximately 75 ppb. Given all of these considerations, the Administrator concluded in the proposal that a standard level at or somewhat below 100 ppb (with a 99th percentile form), in conjunction with the proposed approach, would be requisite to protect public health with an adequate margin of safety against the array of NO2-associated health effects.

In addition to the considerations discussed above, which support setting a standard level at or somewhat below 100 ppb, the Administrator also considered the extent to which available evidence could support standard levels below 100 ppb. The Administrator concluded that the evidence could support setting the standard level below 100 ppb to the extent the following were emphasized:

The possibility that an NO2-induced increase in airway responsiveness could occur in asthmatics following exposures to concentrations below 100 ppb and/or the possibility that such an increase could be clinically significant.

The mixed results reported in the study by Delfino et al. (2002) of an association between respiratory symptoms and the relatively low ambient NO2 concentrations measured in the study area.

Specifically, she noted that a standard level of 80 ppb (99th percentile form), in conjunction with the proposed approach, could limit area-wide NO2 concentrations to 50 ppb \15\ and would be expected to limit exposure concentrations to below those that have been reported to increase airway responsiveness in asthmatics. For the reasons stated above, the Administrator proposed to set the level of a new 1-hour standard between 80 ppb and 100 ppb.

\15\ This conclusion assumes that near-road NO2 concentrations are 65% higher than area-wide concentrations, reflecting the mid-point in the range of 30 to 100%. Based on available information suggesting that near-road concentrations can be 30 to 100% higher than area-wide concentrations, a standard level of 80 ppb could limit area-wide concentrations to between 40 and 60 ppb.

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b. Rationale for the Alternative Approach and Range of Levels

As described above, the Administrator proposed to set a 1-hour NO2 NAAQS reflecting the maximum allowable NO2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. However, prior to the proposal, the approach of setting a 1-hour NO2 NAAQS that reflects the maximum allowable NO2 concentration anywhere in an area had not been discussed by EPA in the REA or considered by CASAC. Rather, the potential alternative standards discussed in the REA, and reviewed by CASAC, reflected allowable area-wide NO2 concentrations (i.e., concentrations that occur broadly across communities).

Given this, the Administrator noted in the proposal that comments received on the approach to setting the 1-hour standard (i.e., from CASAC and from members of the public) could provide important new information for consideration. Therefore, the Administrator also solicited comment on the alternative approach of setting a 1-hour NO2 primary NAAQS that would reflect the allowable area-wide NO2 concentration, analogous to the standards evaluated in the REA, and with a level set within the range of 50 to 75 ppb. In discussing this alternative approach with a standard level from 50 to 75 ppb, the Administrator noted the following in the proposal:

Such a standard would be expected to maintain area-wide NO2 concentrations below peak 1-hour area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions.

Standard levels from the lower end of the range would be expected to limit roadway-associated exposures to NO2 concentrations that have been reported in controlled human exposure studies to increase airway responsiveness in asthmatics. Specifically, a standard level of 50 ppb under this approach could limit near-road concentrations to between approximately 65 and 100 ppb, depending on the relationship between near-road NO2 concentrations and area-wide concentrations.

This alternative approach would provide relatively more confidence regarding the degree to which a specific standard level would limit area-wide NO2 concentrations and less confidence regarding the degree to which a specific standard level would limit the peak NO2 concentrations likely to occur near major roadways.

c. Comments on Approach and Level

In the proposal, each approach to setting the 1-hour standard, and each range of standard levels, was linked to different requirements for the design of the NO2 monitoring network. Specifically, in conjunction with the proposed approach (i.e., standard reflects the maximum allowable NO2 concentration anywhere in an area and the level is set within the range of 80 to 100 ppb), the Administrator proposed to establish a 2-tiered monitoring network that would include monitors sited to measure the maximum NO2 concentrations anywhere in an area, including near major roadways, and monitors sited to measure maximum area-wide NO2 concentrations. In conjunction with the alternative approach (i.e., standard reflects the allowable area-wide NO2 concentration and the level is set within the range of 50 to 75 ppb), the Administrator solicited comment on a monitoring network that would only include area-wide NO2 monitors. Because of these linkages in the proposal, most commenters combined their comments on the approach to setting a 1-hour standard and on the standard level with their comments on the monitoring requirements. In this section, we discuss comments from CASAC and public commenters on the approach to setting a 1-hour standard and on the standard level. Comments on the monitoring network are also discussed in this section to the extent they indicate a preference for either the proposed or alternative approach to setting the 1-hour standard. More specific comments on monitor placement and network design are discussed below in section III.B.2 and in the Response to Comments document. EPA responses to technical comments on the scientific evidence and the exposure/response information are discussed above in section II.E.2 and in the Response to Comments document. The Administrator's response to commenters' views on the approach to setting the 1-hour standard and on the standard level is embodied in the discussed in section II.F.4.d.

i. CASAC Comments on the Approach to Setting the Standard

A majority of CASAC and CASAC Panel members \16\ favored the proposed approach of setting a 1-hour standard that reflects the maximum allowable

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NO2 concentration anywhere in an area and linking such a standard with a 2-tiered monitoring network that would include both near-road and area-wide monitors, though CASAC did not reach consensus on this approach. Specifically, in their letter to the Administrator (Samet, 2009), CASAC stated the following:

\16\ CASAC members were also part of the CASAC Panel for the NO2 NAAQS review (i.e., the Oxides of Nitrogen Primary National Ambient Air Quality Standards Panel). Therefore, references to the CASAC Panel include both CASAC members and Panel members.

There was a split view on the two approaches among both CASAC and CASAC panel members with a majority of each favoring the Agency's proposed two-tiered monitoring network because they thought this approach would be more effective in limiting near-roadway exposures that may reach levels in the range at which some individuals with asthma may be adversely affected. Other members acknowledged the need for research and development of near-road monitoring data for criteria pollutants in general but favored retention of EPA's current area-wide monitoring for NO2 regulatory purposes, due to the lack of epidemiological data based on near-roadway exposure measurements and issues related to

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implementing a near-road monitoring system for NO2.

Thus, the recommendation of the majority of CASAC Panel members was based on their conclusion that the proposed approach would be more effective than the alternative at limiting near-roadway exposures to NO2 concentrations that could adversely affect asthmatics.
In addition, these CASAC Panel members noted important uncertainties with the alternative approach. Specifically, they stated the following (Samet, 2009):

Panel members also supported the proposed two-tiered approach because basing regulations on area-wide monitoring alone was problematic. Such an approach would require EPA to embed uncertainties and assumptions about the relationship between area-wide and road-side monitoring into the area-wide standard.

A minority of CASAC Panel members expressed support for the alternative approach of setting a 1-hour standard that reflects the allowable area-wide NO2 concentration. These CASAC Panel members concluded that there would be important uncertainties associated with the proposed approach. Specifically, they noted that the key U.S. NO2 epidemiologic studies relied upon area-wide NO2 concentrations. In their view, the use of area-wide concentrations in these studies introduces uncertainty into the selection of a standard level for a standard that reflects the maximum allowable NO2 concentration anywhere in an area and that is linked with a requirement to place monitors near major roads. As a result of this uncertainty, CASAC Panel members who favored the alternative approach noted that ``it would be better to set the standard on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it [the standard] now relies'' (Samet, 2009). These CASAC Panel members also strongly supported obtaining monitoring data near major roads, while recognizing uncertainties associated with identifying appropriate monitoring sites near roads (see section III.B.2 and the Response to Comments document for more discussion of CASAC's monitoring comments).

ii. Public Comments on the Approach to Setting the Standard

Consistent with the views expressed by the majority of CASAC members, a number of commenters concluded that the most appropriate approach would be to set a 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area and to couple that standard with a requirement that monitors be placed in locations where maximum concentrations are expected, including near major roads. This view was expressed by some State and local agencies (e.g., in CA, IA, NY, TX, WA, WI), by a number of environmental organizations (e.g., CAC, EDF, EJ, GASP, NRDC), by the ALA, and individual commenters. Several additional medical and public health organizations (ACCP, AMA, ATS, NADRC, NACPR) did not explicitly express a recommendation regarding the approach though these organizations did recommend that, in setting a 1-hour standard, particular attention should be paid to NOX concentrations around major roadways.

In support of their recommendation to adopt the proposed approach and to focus monitoring around major roads, these commenters generally concluded that a primary consideration should be the extent to which the NO2 NAAQS protects at-risk populations that live and/or attend school near important sources of NO2 such as major roads. As such, these comments supported the rationale in the proposal for setting a 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area.

A number of State commenters expressed the view that area-wide monitors should be used for attainment/non-attainment determinations (e.g., NACAA, NESCAUM and agencies in IL, IN, MI, MS, NC, NM, SC). One State commenter (NESCAUM) agreed with EPA concerns about near-road exposures but concluded that it is premature to establish a large near-road monitoring network at this time due to uncertainty regarding the relationship between near-road and area-wide NO2 concentrations and the variability in that relationship. NESCAUM recommended that EPA work with States to establish a targeted monitoring program in select urban areas to gather data that would inform future modifications to the monitoring network, but that ``[t]he existing area-wide monitoring network should be used to identify initial nonattainment areas.'' Other State commenters also concluded that the most appropriate approach would be to base non-attainment determinations only on area-wide monitors. Based on their monitoring comments, many of these commenters appeared to support setting a 1-hour standard that reflects the allowable area-wide NO2 concentration. State concerns with the proposed approach often included uncertainties associated with identifying and accessing appropriate monitor sites near major roads, as well as concerns related to implementation and cost to States (as discussed further in the Response to Comments document, the Administrator may not consider cost of implementation in decisions on a NAAQS).

One commenter (AAM) concluded that the focus of the proposed approach on NO2 concentrations around major roadways is not justified because the REA and the proposal overstate the extent to which NO2 concentrations near roads are higher than NO2 concentrations farther away from the road. This conclusion is based on an analysis of 42 existing NO2 monitors in 6 locations. Comparing NO2 concentrations measured by these monitors, some of which are closer to roads and others of which are farther from roads, AAM concluded that ``roadside monitors are not measuring high NO2 concentrations.''

We agree that there is uncertainty associated with estimates of roadway-associated NO2 concentrations (see REA, sections 7.4.6 and 8.4.8.3 for detailed discussion of these uncertainties) and in identifying locations where maximum concentrations are expected to occur. However, we note that the Administrator's conclusions regarding the relationship between NO2 concentrations near roads and those away from roads rely on multiple lines of scientific evidence and information. Specifically, the Administrator relied in the proposal on the following in drawing conclusions regarding the distribution of NO2 concentrations across areas:

Monitoring studies discussed in the ISA and REA that were designed to characterize the NO2 concentration gradient around roads, which indicated that NO2 concentrations near roads can

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be approximately 30 to 100% higher than concentrations away from the road in the same area.

Air quality and exposure analyses presented in the REA which estimate that, on average across locations, NO2 concentrations on roads could be 80% higher than those away from roads and that roadway-associated exposures account for the majority of exposures to NO2 concentrations at or above 100 ppb.

In contrast, the existing NO2 monitoring network, which was the basis for the analysis submitted by AAM, was not designed to characterize the spatial gradients in NO2 concentrations surrounding roadways. Rather, concentrations of NO2 measured by existing monitors are likely to reflect contributions from a combination of mobile and stationary sources, with one or the other dominating depending on the proximity of these sources to the monitors. Therefore, we conclude that the analysis submitted by AAM, which does not consider other relevant lines of evidence and information, does not appropriately characterize the relationship between NO2 concentrations near roads and those away from roads. (See the Response to Comments document for a more detailed discussion of AAM comments.)

In addition, we note that, although the Administrator concluded in the proposal that maximum NO2 concentrations in many areas are likely to occur around major roads, she also recognized that maximum concentrations can occur elsewhere in an area. For this reason, she proposed to set a 1-hour NO2 standard that reflects the maximum allowable NO2 concentration anywhere in an area, regardless of where that maximum concentration occurs.\17\ Therefore, the proposed approach to setting the standard would be expected to limit the maximum NO2 concentrations anywhere in an area even if in some areas, as is contended by AAM, those maximum NO2 concentrations do not occur near roads.

\17\ To measure maximum concentrations, the Administrator proposed monitoring provisions that would require monitors within 50 meters of major roads and to allow the Regional Administrator to require additional monitors in situations where maximum concentrations would be expected to occur in locations other than near major roads (e.g., due to the influence of multiple smaller roads and/or stationary sources).

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iii. CASAC Comments on Standard Level

In commenting on the proposal, CASAC discussed both the proposed range of standard levels (i.e., 80-100 ppb) and the alternative range of standard levels (i.e., 50-75 ppb). CASAC did express the consensus conclusion that if the Agency finalizes a 1-hour standard in accordance with the proposed approach (i.e., standard level reflects the maximum allowable NO2 concentration anywhere in an area), then it is appropriate to consider the proposed range of standard levels from 80 to 100 ppb. Specifically, the CASAC letter to the Administrator on the proposal (Samet, 2009) stated the following with regard to the proposed approach:

[T]he level of the one-hour NO2 standard should be within the range of 80-100 ppb and not above 100 ppb. In its letter of December 2, 2008, CASAC strongly voiced a consensus view that the upper end of the range should not exceed 100 ppb, based on evidence of risk at that concentration. The lower limit of 80 ppb was viewed as reasonable by CASAC; selection of a value lower than 80 ppb would represent a policy judgment based on uncertainty and the degree of public health protection sought, given the limited health-based evidence at concentrations below 100 ppb.

CASAC also recommended that this level be employed with a 98th percentile form, in order to promote the stability of the standard (see above for discussion of form).

iv. Public Comments on Standard Level

A number of State and local agencies and organizations expressed support for setting the level of the 1-hour NO2 standard within the proposed range of 80 to 100 ppb. While some State and local agencies (e.g., in CA, IA, MI, NY, TX) made this recommendation in conjunction with a recommendation to focus monitoring near major roads and other important sources of NO2, a number of State commenters (e.g., NACAA, NESCAUM and agencies in IL, NC, NM, TX, VA) recommended a standard level from 80 to 100 ppb in conjunction with a recommendation that only area-wide monitors be deployed for purposes of determining attainment with the standard. Based on these monitoring comments, these State commenters appear to favor an approach where a standard level from 80 to 100 ppb would reflect the allowable area-wide NO2 concentration. As discussed above (and in more detail in section III.B.2 and the Response to Comments document), State commenters often based these recommendations on uncertainties associated with designing an appropriate national near-road monitoring network.

A number of environmental organizations (e.g., CAC, EDF, EJ, GASP, NRDC) and medical/public health organizations (e.g., ACCP, ALA, AMA, ATS, NACPR, NAMDRC) supported setting a standard level below 80 ppb for a standard that reflects the maximum allowable NO2 concentration anywhere in an area. Several of these groups recommended a standard level of 50 ppb. This recommendation was typically based on the commenters' interpretation of the epidemiologic and controlled human exposure evidence, as described below.

Some of these commenters noted that the 98th percentile area-wide NO2 concentration was below 80 ppb in the location of a single key U.S. epidemiologic study (i.e., 50 ppb in study by Delfino). Given this, commenters concluded that the standard level should be set at 50 ppb. Their comments on the monitoring network generally favored a requirement to place monitors near major roads and, therefore, these commenters appeared to favor a standard level as low as 50 ppb and to recommend that such a standard level reflect the maximum allowable NO2 concentration anywhere in an area. In their comments, the ALA, EDF, EJ, and NRDC stated the following:

Considering the Delfino study alone on EPA's terms, that is, focusing on the 98th percentile of the 1-hour daily maximum concentrations, EPA reports a concentration of 50 ppb where asthma symptoms were observed. Based primarily on this study, EPA concluded in the REA that it was appropriate to set the lower end of the range at 50 ppb, which corresponded to the lowest-observed effects level of airway hyperresponsiveness in asthmatics. To provide the strongest public health protection, we therefore urge the level of the standard be set at 50 ppb.

In some cases, the same commenters also appeared to recommend setting a standard level below 50 ppb because mean area-wide NO2 concentrations reported in locations of key U.S. epidemiologic studies are below this concentration. Specifically, with regard to the key U.S. epidemiologic studies, these commenters (e.g., ALA, EDF, EJ, NRDC) stated the following:

These studies clearly identify adverse health effects such as emergency room visits and hospital admissions for respiratory causes at concentrations currently occurring in the United States. Mean concentrations for all but two of these studies are about or below 50 ppb, suggesting that the standard must be set below this level to allow for a margin of safety.

The Administrator's consideration of the Delfino study as it relates to a decision on standard level is discussed below (section II.F.4.d). Regarding the recommendation to set the level below 50 ppb based on mean area-wide NO2 concentrations in epidemiologic study

locations, we note that the Administrator proposed to set a standard that reflects the maximum allowable NO2 concentration anywhere in an area and to set the form of that standard at the upper end of the distribution of 1-hour daily maximum NO2 concentrations.\18\ As described in the proposal, such a standard, with a level from the proposed range of 80 to 100 ppb, would be expected to maintain peak area-wide NO2 concentrations below the peak area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Because reducing NOX emissions to meet a 98th percentile NO2 standard should lower the distribution of NO2 concentrations, including the mean, a standard that limits the 98th percentile of the distribution of 1-hour daily maximum concentrations would also be expected to limit mean concentrations. Therefore, although we acknowledge that the relationship between peak and mean NO2 concentrations will likely vary across locations and over time, if peak area-wide NO2 concentrations are maintained below those in key epidemiologic study locations, mean area-wide NO2 concentrations would also be expected to be maintained below the mean area-wide concentrations in those locations (see ISA, figure 2.4-13 for information on the relationship between peak and mean NO2 concentrations).

\18\ As discussed above, the Administrator has selected the 98th percentile as the form for the new 1-hour NO2 standard.

As discussed above (section, II.E.2), a number of industry groups did not support setting a new 1-hour NO2 standard. However, several of these groups (e.g., AAM, Dow, NAM, NPRA) also concluded that, if EPA does choose to set a new 1-hour standard, the level of that standard should be above 100 ppb. As a basis for this recommendation, these groups emphasized uncertainties in the scientific evidence. Specifically, as discussed in more detail above (section II.E.2), these commenters typically concluded that available epidemiologic studies do not support the conclusion that NO2 causes reported health effects. This was based on their assertion that the presence of co-pollutants in the ambient air precludes the identification of a specific NO2 contribution to reported effects. As a result, these commenters recommended that a 1-hour standard should be based on the controlled human exposure evidence and that, in considering that evidence, EPA should rely on the meta-analysis of NO2 airway responsiveness studies conducted by Goodman et al., (2009) rather than the meta-analysis included in the final ISA. As described above, they concluded that in relying on the ISA meta-analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. EPA recognizes the uncertainties in the scientific evidence that are discussed by these industry commenters; however, we strongly disagree with their conclusions regarding the implications of these uncertainties for decisions on the NO2 NAAQS. These comments, and EPA's responses, are discussed in detail above (section II.E.2) and in the Response to Comments document and are summarized briefly below.

As noted in section II.E.2, we agree that the presence of co-pollutants in the ambient air complicates the interpretation of epidemiologic studies; however, our conclusions regarding causality are based on consideration of the broad body of epidemiologic studies (including those employing multi-pollutant models) as well as animal toxicological and controlled human exposure studies. The ISA concluded that this body of evidence ``supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS level'' (ISA, p. 5-16). In addition, the ISA (p. 5-15) concluded the following:

[T]he strongest evidence for an association between NO2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED visits and hospital admissions. These new findings were based on numerous studies, including panel and field studies, multipollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-h avg NO2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average).

Given that epidemiologic studies provide the strongest support for an association between NO2 and respiratory morbidity, and that a number of these studies controlled for the presence of other pollutants with multi-pollutant models (in which NO2 effect estimates remained robust), we disagree that NO2 epidemiologic studies should not be used to inform a decision on the level of the 1-hour NO2 standard.

In addition, we agree that uncertainty exists regarding the extent to which the NO2-induced increase in airway responsiveness is adverse (REA, section 10.3.2.1); however, as discussed in detail above (section II.E.2), we disagree with the conclusion by many industry commenters that this effect is not adverse in asthmatics following exposures from 100 to 600 ppb NO2. Specifically, we do not agree that the approach taken in the study by Goodman et al.

(2009), which was used by many industry commenters to support their conclusions, was appropriate. The authors of the Goodman study used data from existing NO2 studies to characterize the dose-response relationship of NO2 and airway responsiveness and to calculate the magnitude of the NO2 effect. Given the protocol differences in existing studies of NO2 and airway responsiveness, we do not agree that it is appropriate to base such an analysis on these studies.

The Administrator's consideration of these uncertainties, within the context of setting a standard level, is discussed in the next section.

d. Conclusions on Approach and Standard Level

Having carefully considered the public comments on the appropriate approach and level for a 1-hour NO2 standard, as discussed above, the Administrator believes the fundamental conclusions reached in the ISA and REA remain valid. In considering the approach, the Administrator continues to place primary emphasis on the conclusions of the ISA and the analyses of the REA, both of which focus attention on the importance of roadways in contributing to peak NO2 exposures, given that roadway-associated exposures can dominate personal exposures to NO2. In considering the level at which the 1-hour primary NO2 standard should be set, the Administrator continues to place primary emphasis on the body of scientific evidence assessed in the ISA, as summarized above in section II.B, while viewing the results of exposure and risk analyses, discussed above in section II.C, as providing information in support of her decision.

With regard to her decision on the approach to setting the 1-hour standard, the Administrator continues to judge it appropriate to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term exposures to NO2, where such health effects have been associated with exposure to the distribution of short-term ambient NO2 concentrations across

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an area. In protecting public health against exposure to the distribution of short-term NO2 concentrations across an area, the Administrator is placing emphasis on providing a relatively high degree of confidence regarding the protection provided against exposures to peak concentrations of NO2, such as those that can occur around major roadways. Available evidence and information suggest that roadways account for the majority of exposures to peak NO2 concentrations and, therefore, are important contributors to NO2-associated public health risks. In reaching this conclusion, the Administrator notes the following:

Mobile sources account for the majority of NOX emissions (ISA, Table 2.2-1).

The ISA stated that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level,'' that ``exposure in traffic can dominate personal exposure to NO2,'' and that ``NO2 levels are strongly associated with distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration)'' (ISA, sections 2.5.4, 4.3.6).

The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18).

Monitoring studies suggest that NO2 concentrations near roads can be considerably higher than those in the same area but away from roads (e.g., by 30-100%, see section II.A.2).

In their comments on the approach to setting the 1-hour NO2 standard, the majority of CASAC Panel members emphasized the importance of setting a standard that limits roadway-associated exposures to NO2 concentrations that could adversely affect asthmatics. These CASAC Panel members favored the proposed approach, including its focus on roads.

In addition, the Administrator notes that a considerable fraction of the population resides, works, or attends school near major roadways or other sources of NO2 and that these populations are likely to have increased exposure to NO2 (ISA, section 4.4). Based on data from the 2003 American Housing Survey, approximately 36 million individuals live within 300 feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).\19\ Furthermore, in California, 2.3% of schools with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads (ISA, section 4.4). Of this population, which likely includes a disproportionate number of individuals in groups with a higher prevalence of asthma and higher hospitalization rates for asthma (e.g., ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), asthmatics and members of other susceptible groups (e.g., children, elderly) will have the greatest risks of experiencing health effects related to NO2 exposure. In the United States, approximately 10% of adults and 13% of children have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4).

\19\ The most current American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs.html) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary. According to Table 1A-6 from that report (http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf), out of 128.2 million total housing units in the United States, about 20 million were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.6% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306.3 million, that means that there would be 47.8 million people meeting the 300 foot criteria.

In considering the approach to setting the 1-hour standard, the Administrator also notes that concerns with the proposed approach expressed by the minority of CASAC Panel members included concern with the uncertainty in the relationship between near-road and area-wide NO2 concentrations, given that U.S. epidemiologic studies have been based on concentrations measured at area-wide monitors. However, as discussed by the majority of CASAC Panel members, a similar uncertainty would be involved in setting a standard with the alternative approach (Samet, 2009). The Administrator agrees with the majority of CASAC Panel members and concludes that uncertainty in the relationship between near-road and area-wide NO2 concentrations should be considered regardless of the approach selected to set the standard. She recognizes that this uncertainty can and should be taken into consideration when considering the level of the standard.

In drawing conclusions on the approach, the Administrator has considered the extent to which each approach, in conjunction with the ranges of standard levels discussed in the proposal, would be expected to limit the distribution of NO2 concentrations across an area and, therefore, would be expected to protect against risks associated with NO2 exposures. Specifically, she has considered the extent to which a standard set with each approach would be expected to limit maximum NO2 concentrations and area-wide NO2 concentrations.

With regard to expected maximum concentrations, the Administrator notes the following:

A standard reflecting the maximum allowable NO2 concentration anywhere in an area would provide a relatively high degree of confidence regarding the level of protection provided against peak exposures, such as those that can occur on or near major roadways. A standard level from anywhere within the proposed range (i.e., 80 to 100 ppb) would be expected to limit exposures to NO2 concentrations reported to increase airway responsiveness in asthmatics.

A standard reflecting the allowable area-wide NO2 concentration would not provide a high degree of confidence regarding the extent to which maximum NO2 concentrations would be limited. Maximum NO2 concentrations would be expected to be controlled to varying degrees across locations and over time depending on the NO2 concentration gradient around roads. Given the expected variability in gradients across locations and over time, most standard levels within the range considered in the proposal with this option (i.e., 50 to 75 ppb) would not be expected to consistently limit the occurrence of NO2 concentrations that have been reported to increase airway responsiveness in asthmatics.

With regard to expected area-wide concentrations, the Administrator notes the following:

The extent to which a standard reflecting the maximum allowable NO2 concentration anywhere in an area would be expected to limit area-wide NO2 concentrations would vary across locations, e.g., depending on the NO2 concentration gradient around roads. However, in conjunction with a standard level from anywhere within the proposed range (i.e., 80-100 ppb), such an approach would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits (based on available information regarding the NO2 concentration gradient around roads as discussed below).

A standard reflecting the maximum allowable area-wide NO2 concentration would provide a relatively high degree of certainty regarding the extent to which area-wide NO2 concentrations are limited. In conjunction with a standard level from anywhere within the range of

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levels discussed in the proposal (i.e., 50-75 ppb) with this alternative approach, such a standard would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits.

Given the above considerations, the Administrator concludes that both approaches, in conjunction with appropriate standard levels, would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits. In contrast, the Administrator concludes that only a standard reflecting the maximum allowable NO2 concentration anywhere in an area, in conjunction with an appropriate standard level, would be expected to consistently limit exposures, across locations and over time, to NO2 concentrations reported to increase airway responsiveness in asthmatics. After considering the evidence and uncertainties, and the advice of the CASAC Panel, the Administrator judges that the most appropriate approach to setting a 1-hour standard to protect against the distribution of short-term NO2 concentrations across an area, including the higher concentrations that can occur around roads and result in elevated exposure concentrations, is to set a standard that reflects the maximum allowable NO2 concentration anywhere in an area.

In considering the level of a 1-hour NO2 standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator notes that there is no bright line clearly directing the choice of level. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. Specifically, the Administrator notes the following:

Controlled human exposure studies have reported that various NO2 exposure concentrations increased airway responsiveness in mostly mild asthmatics (section II above and II.B.1.d in proposal). These studies can inform an evaluation of the risks associated with exposure to specific NO2 concentrations, regardless of where those exposures occur in an area. Because concentrations evaluated in controlled human exposure studies are at the high end of the distribution of ambient NO2 concentrations (ISA, section 5.3.2.1), these studies most directly inform consideration of the risks associated with exposure to peak short-term NO2 concentrations.

Epidemiologic studies (section II.B.1.a and b) conducted in the United States have reported associations between ambient NO2 concentrations measured at area-wide monitors in the current network and increased respiratory symptoms, emergency department visits, and hospital admissions. Area-wide monitors in the urban areas in which these epidemiologic studies were conducted are not sited in locations where localized peak concentrations are likely to occur. Thus, they do not measure the full range of ambient NO2 concentrations across the area. Rather, the area-wide NO2 concentrations measured by these monitors are used as surrogates for the distribution of ambient NO2 concentrations across the area, a distribution that includes NO2 concentrations both higher than (e.g., around major roadways) and lower than the area-wide concentrations measured in study locations. Epidemiologic studies evaluate whether area-wide NO2 concentrations are associated with the risk of respiratory morbidity. Available information on NO2 concentration gradients around roadways can inform estimates of the relationship between the area-wide NO2 concentrations measured in epidemiologic study locations and the higher NO2 concentrations likely to have occurred around roads in those locations, which can then inform the decision on the level of a standard reflecting the maximum allowable NO2 concentration anywhere in an area.

The risk and exposure analyses presented in the REA provide information on the potential public health implications of setting standards that limit area-wide NO2 concentrations to specific levels. While the Administrator acknowledges the uncertainties associated with these analyses which, as discussed in the REA, could result in either over- or underestimates of NO2-associated health risks, she judges that these analyses are informative for considering the relative levels of public health protection that could be provided by different standards.

The Administrator's consideration of the controlled human exposure evidence, epidemiologic evidence, and exposure/risk information are discussed below specifically with regard to a decision on the level of a standard that reflects the maximum allowable NO2 concentration anywhere in an area.

In considering the potential for controlled human exposure studies of NO2 and airway responsiveness to inform a decision on standard level, the Administrator notes the following:

NO2-induced increases in airway responsiveness, as reported in controlled human exposure studies, are logically linked to the adverse respiratory effects that have been reported in NO2 epidemiologic studies.

The meta-analysis of controlled human exposure data in the ISA reported increased airway responsiveness in a large percentage of asthmatics at rest following exposures at and above 100 ppb NO2, the lowest NO2 concentration for which airway responsiveness data are available in humans.

This meta-analysis does not provide any evidence of a threshold below which effects do not occur. The studies included in the meta-analysis evaluated primarily mild asthmatics while more severely affected individuals could respond to lower concentrations. Therefore, it is possible that exposure to NO2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics.

In considering the evidence, the Administrator recognizes that the NO2-induced increases in airway responsiveness reported for exposures to NO2 concentrations at or above 100 ppb could be adverse for some asthmatics. However, she also notes that important uncertainties exist with regard to the extent to which NO2-induced increases in airway responsiveness are adverse. Specifically, she notes the following with regard to these uncertainties:

The magnitude of the NO2-induced increase in airway responsiveness, and the extent to which it is adverse, cannot be quantified from the ISA meta-analysis (REA, section 10.3.2.1).

The NO2-induced increase in airway responsiveness in resting asthmatics was typically not accompanied by increased respiratory symptoms, even following exposures to NO2 concentrations well above 100 ppb (ISA, section 3.1.3.3).

The increase in airway responsiveness that was reported for resting asthmatics was not present in exercising asthmatics (ISA, Table 3.1-3).

Taking into consideration all of the above, the Administrator concludes that existing evidence supports the conclusion that the NO2-induced increase in airway responsiveness at or above 100 ppb presents a risk of adverse

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effects for some asthmatics, especially those with more serious (i.e., more than mild) asthma. The Administrator notes that the risks associated with increased airway responsiveness cannot be fully characterized by these studies, and thus she is not able to determine whether the increased airway responsiveness experienced by asthmatics in these studies is an adverse health effect. However, based on these studies the Administrator concludes that asthmatics, particularly those suffering from more severe asthma, warrant protection from the risk of adverse effects associated with the NO2-induced increase in airway responsiveness. Therefore, the Administrator concludes that the controlled human exposure evidence supports setting a standard level no higher than 100 ppb to reflect a cautious approach to the uncertainty regarding the adversity of the effect. However, those uncertainties lead her to also conclude that this evidence does not support setting a standard level lower than 100 ppb.

In considering the more serious health effects reported in NO2 epidemiologic studies, as they relate to the level of a standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator notes the following:

A cluster of 5 key U.S. epidemiologic studies (Ito et al., 2007; Jaffe et al., 2003; Peel et al., 2005; Tolbert et al., 2007; and a study by the New York State Department of Health, 2006) provide evidence for associations between NO2 and respiratory-related emergency department visits and hospital admissions in locations where 98th percentile 1-hour daily maximum NO2 concentrations measured at area-wide monitors ranged from 85 to 94 ppb. The Administrator judges it appropriate to place substantial weight on this cluster of key U.S. epidemiologic studies in selecting a standard level, as they are a group of studies that reported positive, and often statistically significant, associations between NO2 and respiratory morbidity in multiple cities across the United States.\20\

\20\ Some of these studies also included susceptible and vulnerable populations (e.g., children in Peel et al. (2005); poor and minority populations in Ito et al., 2007).

A single study (Delfino et al., 2002) provides mixed evidence for NO2 effects (i.e., respiratory symptoms) in a location with a 98th percentile 1-hour daily maximum NO2 concentration, as measured by an area-wide monitor, of 50 ppb. In that study, most of the reported NO2 effect estimates were positive, but not statistically significant. Given the variability in the NO2 effect estimates in this study, as well as the lack of studies in other locations with similarly low NO2 concentrations, the Administrator judges it appropriate to place limited weight on this study, compared to the cluster of 5 studies as noted above.

Given these considerations, the Administrator concludes that the epidemiologic evidence provides strong support for setting a standard that limits the 98th percentile of the distribution of 1-hour daily maximum area-wide NO2 concentrations to below 85 ppb. This judgment takes into account the determinations in the ISA, based on a much broader body of evidence, that there is a likely causal association between exposure to NO2 and the types of respiratory morbidity effects reported in these studies. Given the considerations discussed above, the Administrator judges that it is not necessary, based on existing evidence, to set a standard that maintains peak area-wide NO2 concentrations to below 50 ppb.

In considering specific standard levels supported by the epidemiologic evidence, the Administrator notes that a level of 100 ppb, for a standard reflecting the maximum allowable NO2 concentration anywhere in the area, would be expected to maintain area-wide NO2 concentrations well below 85 ppb, which is the lowest 98th percentile concentration in the cluster of 5 studies. With regard to this, she specifically notes the following:

If NO2 concentrations near roads are 100% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 50 ppb.

If NO2 concentrations near roads are 30% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 75 ppb.

The Administrator has also considered the NO2 exposure and risk information within the context of the above conclusions on standard level. Specifically, she notes that the results of exposure and risk analyses were interpreted as providing support for limiting area-wide NO2 concentrations to no higher than 100 ppb. Specifically, these analyses estimated that a standard that limits area-wide NO2 concentrations to approximately 100 ppb or below would be expected to result in important reductions in respiratory risks, relative to the level of risk permitted by the current annual standard alone. As discussed above, a standard reflecting the maximum allowable NO2 concentration with a level of 100 ppb would be expected to maintain area-wide NO2 concentrations to within a range of approximately 50 to 75 ppb. Given this, the Administrator concludes that a standard level of 100 ppb is consistent with conclusions based on the NO2 exposure and risk information.

Finally, the Administrator notes that a standard level of 100 ppb is consistent with the consensus recommendation of CASAC.

Given the above considerations and the comments received on the proposal, the Administrator determines that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties, is a standard level of 100 ppb (for a standard that reflects the maximum allowable NO2 concentration anywhere in an area). She concludes that such a standard, with the averaging time and form discussed above, will provide a significant increase in public health protection compared to that provided by the current annual standard alone and would be expected to protect against the respiratory effects that have been linked with NO2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concludes that such a standard will limit exposures at and above 100 ppb for the vast majority of people, including those in at-risk groups, and will maintain maximum area-wide NO2 concentrations well below those in locations where key U.S. epidemiologic studies have reported that ambient NO2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits.

In setting the standard level at 100 ppb rather than a lower level, the Administrator notes that a 1-hour standard with a level lower than 100 ppb would only result in significant further public health protection if, in fact, there is a continuum of serious, adverse health risks caused by exposure to NO2 concentrations below 100 ppb and/or associated with area-wide NO2 concentrations well-below those in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Based on the available evidence, the Administrator does not believe that such assumptions are warranted. Taking into account the uncertainties that remain in interpreting the evidence from available controlled human exposure and epidemiologic studies, the Administrator notes that the likelihood of obtaining benefits to public health with a standard set below

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100 ppb decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases.

Therefore, the Administrator judges that a standard reflecting the maximum allowable NO2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO2 and for which the evidence supports a likely causal relationship with NO2 exposures. The Administrator does not believe that a lower standard level is needed to provide this degree of protection. These conclusions by the Administrator appropriately consider the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that reduces risk sufficiently so as to protect the public health with an adequate margin of safety.

G. Annual Standard

In the proposal, the Administrator noted that some evidence supports a link between long-term exposures to NO2 and adverse respiratory effects and that CASAC recommended in their comments prior to the proposal that, in addition to setting a new 1-hour standard to increase public health protection, the current annual standard be retained. CASAC's recommendation was based on the scientific evidence and on their conclusion that a 1-hour standard might not provide adequate protection against exposure to long-term NO2 concentrations (Samet, 2008b).

With regard to an annual standard, CASAC and a large number of public commenters (e.g., NACAA, NESCAUM; agencies from States including CA, IN, MO, NC, NY, SC, TX, VA; Tribal organizations including Fon du Lac and the National Tribal Air Organization; environmental/medical/ public health groups including ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC) agreed with the proposed decision to maintain an annual standard, though their recommendations with regard to the level of that annual standard differed (see below).

As noted above, CASAC recommended ``retaining the current standard based on the annual average'' based on the ``limited evidence related to potential long-term effects of NO2 exposure and the lack of strong evidence of no effect'' and that ``the findings of the REA do not provide assurance that a short-term standard based on the one-hour maximum will necessarily protect the population from long-term exposures at levels potentially leading to adverse health effects'' (Samet, 2008b). A number of State agencies and organizations also recommended maintaining the current level of the annual standard (i.e., 53 ppb). This recommendation was based on the conclusion that, while some evidence supports a link between long-term NO2 exposures and adverse respiratory effects, that evidence is not sufficient to support a standard level either higher or lower than the current level. In addition, a number of industry groups (e.g., AAM, API, Dow, INGAA, UARG) recommended retaining the level of the current annual standard but, as described above, did so within the context of a recommendation that EPA should not set a new 1-hour standard.

In contrast, some environmental organizations and medical/public health organizations as well as a small number of States (e.g., ALA, EDF, EJ, NRDC, and organizations in CA) recommended setting a lower level for the annual standard. These commenters generally supported their recommendation by pointing to the State of California's annual standard of 30 ppb and to studies where long-term ambient NO2 concentrations have been associated with adverse respiratory effects such as impairments in lung function growth.

As discussed above (II.B.3), the evidence relating long-term NO2 exposures to adverse health effects was judged in the ISA to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). In the case of respiratory morbidity, the ISA (section 5.3.2.4) concluded that ``The high correlation among traffic-related pollutants made it difficult to accurately estimate the independent effects in these long-term exposure studies.'' Given these uncertainties associated with the role of long-term NO2 exposures in causing the reported effects, the Administrator concluded in the proposal that, consistent with the CASAC recommendation, existing evidence is not sufficient to justify setting an annual standard with either a higher or lower level than the current standard. Commenters have not submitted any new analyses or information that would change this conclusion. Therefore, the Administrator does not agree with the commenters who recommended a lower level for the annual standard.

The Administrator judges that her conclusions in the proposal regarding the annual standard remain appropriate. Specifically, she continues to agree with the conclusion that, though some evidence does support the need to limit long-term exposures to NO2, the existing evidence for adverse health effects following long-term NO2 exposures does not support either increasing or decreasing the level of the annual standard. In light of this and considering the recommendation from CASAC to retain the current level of the annual standard, the Administrator judges it appropriate to maintain the level of the annual standard at 53 ppb.

H. Summary of Final Decisions on the Primary NO2 Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA, the advice and recommendations of the CASAC, and public comments, the Administrator has decided to revise the existing primary NO2 standard. Specifically, the Administrator has determined that the current annual standard by itself is not requisite to protect public health with an adequate margin of safety. In order to provide protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO2 exposure, the Administrator is establishing a short-term NO2 standard defined by the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum NO2 concentrations. She is setting the level of this standard at 100 ppb, which is to reflect the maximum allowable NO2 concentration anywhere in an area. In addition to setting a new 1-hour standard, the Administrator retains the current annual standard with a level of 53 ppb. The new 1-hour standard, in combination with the annual standard, will provide protection for susceptible groups against adverse respiratory health effects associated with short-term exposures to NO2 and effects potentially associated with long-term exposures to NO2.

III. Amendments to Ambient Monitoring and Reporting Requirements

The EPA is finalizing several changes to the ambient air monitoring, reporting, and network design requirements for the NO2 NAAQS. This section discusses the changes we are finalizing which are intended to support the proposed 1-

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hour NAAQS and retention of the current annual NAAQS as discussed in Section II. Ambient NO2 monitoring data are used to determine whether an area is in violation of the NO2 NAAQS. Ambient NO2 monitoring data are collected by State, local, and Tribal monitoring agencies (``monitoring agencies'') in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58.

A. Monitoring Methods

We are finalizing the proposed changes regarding the NO2 Federal Reference Method (FRM) or Federal Equivalent Method (FEM) analyzers. Specifically, we are continuing to use the NO2 chemiluminescence FRM and are finalizing the requirement that any NO2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data. The following paragraphs provide background and rationale for the continued use of the chemiluminescence FRM and the decision to finalize the proposed changes.

1. Chemiluminescence FRM and Alternative Methods

The current monitoring method in use by most State and local monitoring agencies is the gas-phase chemiluminescence FRM (40 CFR Part 50, Appendix F), which was implemented into the NO2 monitoring network in the early 1980s. EPA did not propose to discontinue using the chemiluminescence FRM, although we received some comments from industry (Alliance of Automobile Manufacturers, Edison Electric, and the National Petrochemical and Refiners Association) raising concerns about using a method that is subject to known interferences from certain species of oxides of nitrogen known as NOZ. Important components of ambient NOZ include nitrous acid (HNO2), nitric acid (HNO3), and the peroxyacetyl nitrates (PANs).

The issue of concern in public comments is that the reduction of NO2 to NO on the MoOX converter substrate used in chemiluminescence FRMs is not specific to NO2; hence, chemiluminescence method analyzers are subject to varying interferences produced by the presence in the air sample of the NOZ species listed above and others occurring in trace amounts in ambient air. This interference is often termed a ``positive artifact'' in the reported NO2 concentration since the presence of NOZ results in an over-estimate in the reported measurement of the actual ambient NO2 concentration. This interference by NOZ compounds has long been known and evaluated (Fehsenfeld et al., 1987; Nunnermacker et al., 1998; Parrish and Fehsenfeld, 2000; McClenny et al., 2002; U.S. Environmental Protection Agency, 1993, 2006a). Further, as noted in the ISA (ISA Section 2.3), it appears that interference by NOZ on chemiluminescence FRMs is not more than 10 percent of the reported NO2 concentration during most or all of the day during winter (cold temperatures), but larger interference ranging up to 70 percent can be found during summer (warm temperatures) in the afternoon at sites away

and downwind from strong emission sources.
The EPA acknowledges that the NOZ interference in the reported NO2 concentrations collected well downwind of NOX source areas and in relatively remote areas away from concentrated point, area, or mobile sources is significantly larger than the NOZ interference in NO2 measurements taken in urban cores or other areas with fresh NOX emissions. To meet the primary objective of monitoring maximum NO2 concentrations in an area, the EPA is requiring NO2 monitors to be placed in locations of the expected highest concentrations, not in relatively remote areas away from NOX sources. The required monitors resulting from the network design discussed below in Section III.B will require monitors to be placed near fresh NOX sources or in areas of dense NOX emissions, where NO2 concentrations are expected to be at a maximum, and interference from NOZ species is at a minimum. Therefore, EPA believes that the positive artifact issue, although present, is small, relative to the actual NO2 being measured. As a result EPA believes the chemiluminescence FRM is suitable for continued use in the ambient NO2 monitoring network, as the potential positive bias from NOZ species is not significant enough to discontinue using the chemiluminescence FRM.

EPA also received support from some industry groups (e.g. Savannah River Nuclear Solutions, Teledyne API, and the Utility Air Regulatory Groups) and States (e.g., MODEQ and NCDENR) to further the development of alternative methods in determining NO2 concentrations. Such alternative methods include the photolytic- chemiluminescence method and cavity ring-down spectroscopy. As a result, EPA will continue working with commercial and industrial vendors, to identify and evaluate such new technologies. These efforts may include field testing instruments and further characterizing methods in a laboratory setting to assess their potential as future reference or equivalent methods, and their role in more directly measuring NO2.

2. Allowable FRM and FEMs for Comparison to the NAAQS

The current CFR language does not prohibit the use of any particular NO2 FRM or FEM to be used in comparison to the standard.\21\ There are designated wet chemical methods that are only able to report ambient concentration values averaged across multiple hours. With the establishment of a 1-hour NAAQS, any FRM or FEM which is a wet chemical based method would not be appropriate for use in determining compliance of the 1-hour NAAQS because they are unable to report hourly data. EPA addressed this issue by proposing and finalizing that only those methods capable of providing 1-hour measurements will be comparable to the NAAQS.

\21\ A list of approved FRM and FEMs is maintained by EPA's Office of Research and Development, and can be found at: http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-li

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a. Proposed Changes to FRM and FEMs That May Be Compared to the NAAQS

EPA proposed that only those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to the NAAQS.

b. Comments

EPA received comments from some State and industry groups (e.g. Missouri, North Carolina, and Air Quality Research and Logistics) supporting the proposed approach to only allowing those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to both the annual and 1-hour NAAQS, and did not receive any public comments that objected to the proposed approach.

c. Decisions on Allowable FRM and FEMs for Comparison to the NAAQS

Accordingly, EPA is finalizing the proposed changes to 40 CFR Part 58 Appendix C to allow only data from FRM or FEMs that are capable of providing hourly data to be used for comparison to both the annual and 1-hour NAAQS.

B. Network Design

With the establishment of a 1-hour NO2 NAAQS intended to limit exposure to maximum concentrations that may occur anywhere in an area, EPA recognizes that the data from the current NO2 network is inadequate to fully assess compliance with the revised

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NAAQS. As a result, EPA is promulgating new NO2 network design requirements. The following sections provide background, rationale, and details for the final changes to the NO2 network design requirements.

1. Two-Tiered Network Design

A two-tiered monitoring network is appropriate for the NO2 NAAQS because one tier (the near-road network) reflects the much higher NO2 concentrations that occur near-road and the second-tier (area-wide) characterizes the NO2 concentrations that occur in a larger area such as neighborhood or urban areas. The ISA (Section 2.5.4 and 4.3.6) stated that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level,'' that ``exposure in traffic can dominate personal exposure to NO2,'' and that ``NO2 levels are strongly associated with distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration).'' The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). Monitoring studies suggest that NO2 concentrations near roads can be considerably higher than those in the same area but away from the road (e.g., by 30-100%, see section II.A.2), where pollutants typically display peak concentrations on or immediately adjacent to roads, producing a gradient in pollutant concentrations where concentrations decrease with increasing distance from roads. Since the intent of the revised NAAQS is to limit exposure to peak NO2 concentrations that occur anywhere in an area, monitors intended to measure the maximum allowable NO2 concentration in an area should include measurements of the peak concentrations that occur on and near roads due to on-road mobile sources. The first tier of the network design, which focuses monitoring near highly trafficked roads in urban areas where peak NO2 concentrations are likely to occur, is intended to measure maximum concentrations anywhere in an area, particularly those due to on-road mobile sources since roadway-associated exposures account for the majority of exposures to peak NO2 concentrations. The basis for the second tier of the network design is to measure the highest area-wide concentrations to characterize the wider area impact of a variety of NO2 sources on urban populations. Area-wide monitoring of NO2 also serves to maintain continuity in collecting data to inform long-term pollutant concentration trends analysis and support ongoing health and scientific research.

This section discusses the two-tier network design approach compared to the alternative network design which was also presented for comment in conjunction with a solicitation for comment on an alternative NAAQS. The alternative network design concept was based entirely on requiring only monitors that would be considered area-wide, while not requiring any near-road monitoring sites. The details of the two-tier network design, including how many monitors are required, where they are to be located, and the related siting criteria are discussed in subsequent sections.

a. Proposed Two-Tier Network Design

EPA proposed a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the highest expected NO2 concentrations at the neighborhood and larger spatial scales (also referred to as ``area-wide'' monitors). As an alternative, and in conjunction with a solicitation for comment on an alternative NAAQS, EPA solicited comment on a network comprised of only area-wide monitors.

b. Comments

EPA received many comments on the overall two-tier network design, with those who made statements with a relatively clear position on the issue generally falling into four categories: (1) Those who support the adoption of the proposed two-tier design approach, (2) those who support the adoption of the two-tier concept, but with modifications, (3) those who only supported the adoption of the alternative network design, and (4) those who encourage EPA to commit to further research of the near-road environment by monitoring near-roads, but not to use near-road data for regulatory purposes, and therefore support the alternative network design in which EPA solicited comment on a network design composed only of area-wide monitors.

Those commenters who generally supported the proposed two-tier network, included CASAC (while there was not a consensus, a majority were in support of the proposed network design), public health organizations (e.g., AACPR, ACCP, AMA, ATA, and NAMDRC), several State groups (e.g., the New York City Law Department and the Metropolitan Washington Air Quality Committee), and some industry commenters (e.g., American Chemistry Council, The Clean Energy Group, and Dow Chemical).

Those commenters who supported the adoption of the two-tier network design concept, but suggested modifications to the actual design included some health and environmental organizations (e.g., ALA, EDF, EJ, and the NRDC), some States (e.g., California, the Central Pennsylvania Clean Air Board, Harris County (Texas), Iowa, New York, San Joaquin Air Pollution Control District, Spokane Regional Clean Air Agency (SRCAA), the Texas Commission on Environmental Quality, and Wisconsin), and some industry commenters, including the American Petroleum Institute and the Utility Air Regulatory Group, who are cited by other industry commenters. We believe that although these commenters made suggestions to modify the proposed two-tier network design, they are indicating that it is an acceptable approach. Their comments and suggestions are discussed in greater detail in the following sections.

Those commenters who only supported the adoption of the alternative network design included State and industry groups (e.g., Indiana Department of Environmental Management, the New York Department of Transportation (NYSDOT), Alliance of Automobile Manufacturers, and the Engine Manufacturers Association). These commenters typically made comments on the two-tier network design, but did not do so in a way that clearly supported near-road research.

EPA received comments from some States or State organizations (e.g., National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and 10 other individual States or State groups) and industry commenters (e.g., Consumers Energy, Edison Electric, and the National Association of Manufacturers) that encouraged EPA to further research the near-road environment, opposing use of near-road monitoring data for regulatory purposes, and supported the adoption of the alternative network design for regulatory purposes. For example, with regard to implementing the two-tier network design that includes near-road regulatory monitoring, NACAA stated that ``* * *a major new network--particularly one that is inherently complicated and untried--should not be rolled out without the benefit of an effective near-road monitoring research program that can address many of the relevant data questions, and inform the specific siting requirements of the rule.'' The NAM stated that ``conducting such

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a near road [research] monitoring program would allow EPA to collect necessary data that can be used to better understand the health impacts associated with short term NO2 exposures.''

The EPA notes that the existing scientific research referenced in the proposal and throughout this final rule show that there are on- and near-road peaks of NO2 concentrations, relative to upwind or background levels, which exist due to on-road mobile source emissions. This research, as a body of evidence, also identifies the multiple local factors that affect how, where, and when peak NO2 concentrations occur on or near a particular road segment. These factors include traffic volume, fleet mix, roadway design, congestion patterns, terrain, and meteorology. The EPA and States have access to such data typically through Federal, State, and/or local departments of transportation or other government organizations, and, as a result, are in a position to implement a near-roar monitoring network that is intended to measure maximum expected NO2 concentrations resulting from on-road mobile source emissions. Further, EPA notes that near-road monitoring is not a new objective for the ambient air monitoring community as near-road carbon monoxide monitoring has been a part of ongoing, long-term, routine networks for nearly three decades. As a result, there is experience within EPA (both OAR and ORD) and State and local agencies on conducting ambient monitoring near-roads. In addition, EPA intends to develop guidance with input from all stakeholders to assist with implementation of the monitoring requirements, which is discussed in section III.B.5. EPA believes that the existing science and research provide a sufficient base of information to require a near-road monitoring network and that the collective experience that exists in the ambient monitoring community will allow for successful implementation of that network. EPA also believes that through adherence of requirements for near-road site selection and siting criteria discussed in sections III.B.6 and III.B.7, respectively, that the two-tier network design will provide a network that has a reasonable degree of similarity across the country where the required near-road monitors are targeting the maximum NO2 concentrations in an area attributable to on-road mobile sources.

Some industry commenters (e.g., Engine Manufacturers Association, the South Carolina Chamber of Commerce, and the South Carolina Manufacturers Alliance) who supported the adoption of the alternative network design suggested that monitoring in the near-road environment would not be indicative of exposure for general populations, and that EPA should not focus on the near-road environment when requiring monitoring. For example, the South Carolina Chamber of Commerce and the South Carolina Manufacturers Alliance both state that ``it appears the proposed monitoring network will result in a collection of microscale data, which is not at all representative of air quality relevant to population exposure.''

The EPA notes that the intent of a near-road monitoring is to support the revised NAAQS by assessing peak NO2 concentrations that may occur anywhere in an area. EPA recognizes that there is variability in the properties (such as traffic counts, fleet mix, and localized features) among the road segments that may exist in an area, but on the whole, roads are ubiquitous, particularly in urban environments. Consequently, a substantial fraction of the population is potentially exposed to relatively higher concentrations of NO2 that can occur in the near-road environment. The 2007 American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs07/ahs07.html) estimates that over 20 million housing units are within 300 feet (91 meters) of a 4-lane highway, airport, or railroad. Using the same survey, and considering that the average number of residential occupants in a housing unit is approximately 2.25, it is estimated that at least 45 million American citizens live near 4-lane highways, airports, or railroads. Although that survey includes airports and railroads, roads are the most pervasive of the three, indicating that a significant amount of the general population live near roads. Furthermore, the 2008 American Time Use Survey (http://www.bls.gov/tus/) reported that the average U.S. civilian spent over 70 minutes traveling per day. Accordingly, EPA concludes that monitors near major roads will address a component of exposure for a significant portion of the general population that would otherwise not be addressed.

The majority of State commenters, regardless of their position on the proposed network design, along with some industry commenters, observed that there was a need for funding the monitoring network. These comments urged EPA to provide the resources needed to implement and operate the required monitoring network. EPA notes that it has historically funded part of the cost of the installation and operation of monitors used to satisfy Federal monitoring requirements. EPA understands these concerns, although the CAA requirements from which this final rule derives (CAA sections 110, 310(a) and 319) are not contingent on EPA providing funding to States to assist in meeting monitoring requirements. However, EPA intends to work with NACAA and the State and local air agencies in identifying available State and Tribal Air Grant (STAG) funds and consider the increased resource needs that may be needed to plan, implement, and operate this revised set of minimum requirements.

c. Conclusions Regarding the Two-Tier Network Design

The EPA believes that requiring near-road monitors in urban areas as part of the network design are necessary to protect against risks associated with exposures to peak concentrations of NO2 anywhere in an area. The combination of increased mobile source emissions and increased urban population densities can lead to increased exposures and associated risks, therefore urban areas are the appropriate areas to concentrate required near-road monitoring efforts. The EPA also recognizes the need to have monitors in neighborhood and larger spatial scale locations away from roads that represent area-wide concentrations. These types of monitors serve multiple important monitoring objectives including comparison to the NAAQS, photochemical pollutant assessment, ozone forecasting, characterization of point and area source impacts, and by providing historical trends data for current and future epidemiological health research. In some situations, when coupled with data from near-road monitors, area-wide monitors may also assist in the determination of spatial variation of NO2 concentrations across a given area and provide insight to the gradients that exist between near-road or stationary source oriented

concentrations and area-wide concentration levels.
After considering the scientific data and the public comments regarding the proposed network design, the Administrator concludes that a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the maximum expected NO2 concentrations at the neighborhood and larger spatial scales (also referred to as ``area-wide'' monitors) are needed to implement the 1-hour NO2 NAAQS and

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support the annual NAAQS. The details of this two-tier network design are discussed in the following eight sections.

2. First Tier (Near-Road Monitoring Component) of the NO2 Network Design

This section provides background, rationale, and details for the final changes to the first tier of the two-tier NO2 network design. In particular, this section will focus on the thresholds that trigger monitoring requirements. Near-road site selection and siting criteria details will be discussed in subsequent sections.

a. Proposed First Tier (Near-Road Monitoring Component) of the Network Design

EPA proposed that the first tier of the two-tier NO2 monitoring network design focus monitors in locations of expected maximum 1-hour concentrations near major roads in urban areas. As noted in the previous section, the exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). Since the combination of increased mobile source emissions and increased urban population densities leads to increased exposures and associated risks, the Administrator judges that urban areas are the appropriate areas in which to concentrate required near-road monitoring efforts. Therefore, we proposed that a minimum of one near-road NO2 monitor be required in Core Based Statistical Areas (CBSAs) with a population greater than or equal to 350,000 persons. Based on 2008 Census Bureau statistics, EPA estimated this would result in approximately 143 monitoring sites in as many CBSAs.

We also proposed that a second near-road monitor be required in CBSAs with a population greater than or equal to 2,500,000 persons, or in any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000. Based on 2008 Census Bureau statistics and data from the 2007 Highway Performance Monitoring System (HPMS) maintained by the U.S. Department of Transportation (DOT) Federal Highway Administration (FHWA), this particular element of the minimum monitoring requirements would have added approximately 24 \22\ sites to the approximate 143 near-road sites in CBSAs that already would have had one near-road monitor required due to the 350,000 population threshold. Overall, the first tier of the proposed network design was estimated to require 167 near-road sites in 143 CBSAs.

\22\ Of the 24 additional sites, 22 are estimated to be triggered due to a population of 2,500,000 while 2 (Las Vegas, NV and Sacramento, CA) are estimated to be triggered by the presence of one or more road segments with 250,000 AADT since they do not have a population of 2,500,000 people.

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b. Comments

The EPA received comments from some industry and public health organizations (e.g. Dow Chemical, ATS, and the AMA) supporting the proposed approach to use population thresholds for triggering minimum near-road monitoring requirements. For example, Dow Chemical Company stated that ``Dow comments that the proposed population thresholds are reasonable for implementation of the new network design and that we don't see a need to establish a threshold lower than 350,000 people for the lower bound.''

The EPA received comments from some States and State groups suggesting that a combination of population and AADT counts or just AADT counts should be used to trigger minimum near-road monitoring requirements. For example, the San Joaquin Air Pollution Control District in California suggested that we modify minimum monitoring requirements so that one near-road NO2 monitor is required for any CBSA with a population of 350,000 people which also had one or more road segments with AADT counts of 125,000 or more. In another example, Harris County Public Health and Environmental Services (HCPHES) suggested that ``* * * rather than specifying population limits for the monitoring, HCPHES supports a metric like the Annual Average Daily Traffic (AADT) as a threshold for requiring a near-road monitor. An initial focus on an AADT in excess of 250,000 is acceptable as a starting point but EPA should revisit that level and consider lowering it to 100,000 in five years.'' AASHTO \23\ and NYDOT \23\ suggested that EPA could set a threshold at 140,000 AADT for requiring near-road monitors rather than using population thresholds.

\23\ AASHTO, NESCAUM, and NYDOT did not support the two-tier network design; however they provided suggestions on how the network design might be modified if the EPA were to finalize requirements for near-road monitors. In the case of AASHTO and NYDOT, their suggestions were made with the suggestion that EPA use a separate rulemaking process to require monitors.

EPA is finalizing the population-only threshold approach to trigger near-road monitoring, as the first step in the process of establishing the first-tier of near-road monitors, and for identifying the appropriate number and locations for siting these monitors. EPA believes that the uncertainty in defining specific national AADT counts is too great to support use in this first step of the alternative approaches suggested by the commenters. EPA notes that, in general, roads with higher AADT counts have relatively higher amounts of mobile source emissions, leading to an increased potential for relatively higher on-road and roadside NO2 concentrations. This concept is supported, for example, by Gilbert et al., 2007, who state that the NO2 concentrations analyzed in their study are significantly associated with traffic counts. In part, these suggestions by commenters to include AADT counts as part of, or independently as, a threshold for requiring monitors appears to be aimed at increasing the focus of the near-road network to locations where NO2 concentrations are expected to be highest. However these suggestions would also, in effect, reduce the size of the required network compared to the network that EPA had proposed. The differences in fleet mix, roadway design, congestion patterns, terrain, and local meteorology amongst road segments that may have identical AADTs are quite variable and affect the NO2 concentrations on and near those segments. The available data and related technical and scientific quantification of what particular AADT count might be expected to contribute to some specific NO2 concentration is insufficient to establish a specific, nationally applicable AADT count threshold that could be used as part of a population-AADT combination, or a distinct AADT count, to require all near-road monitors. Therefore, EPA chose not to utilize a population-AADT or an AADT-only threshold to trigger all minimally required near-road monitoring because of the lack of a quantitative, nationally applicable relationship between a certain AADT threshold and an expected NO2 concentration. Instead, EPA is finalizing the proposed population-only threshold approach to trigger a minimum of one monitor in a CBSA. In larger CBSAs, EPA does require, at a minimum, a second monitor based on either an AADT count of 250,000 or a population threshold of 2,500,00 or more persons in a CBSA as described more fully below. EPA believes this approach for siting near-road monitoring provides a greater degree of certainty in covering a large segment of the total population (66%, which is explained below) and will provide data on exposure from geographically and spatially diverse areas where a larger number of people

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are likely to be exposed to peak NO2 concentrations.

Some commenters (e.g., AASHTO,\23\ NESCAUM,\23\ NYDEC, NYDOT \23\) suggested focusing multiple near-road monitors only in relatively larger CBSAs than those which were proposed. For example, NYDEC suggested that EPA require, at minimum, two near-road monitors in any CBSA of 2,500,000 people or more, but not in CBSAs below that population threshold. In their comments, they point out the variety of near-road environments that exist in the larger CBSAs such as New York City.

EPA notes that the larger CBSAs, such as those with a population of 2,500,000 or more persons, are more likely to have a greater number of major roads across a potentially larger geographic area, and a corresponding increase in potential for exposure in different settings (evidenced in the U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) ``Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance'' document which is discussed below). This is the primary reasoning behind the requirement for two monitors in CBSAs with more than 2,500,000 people. EPA also believes that having multiple monitors in the largest CBSAs will allow better understanding of the differences that may exist between roads in the same CBSA due to fleet mix, congestion patterns, terrain, or geographic locations. However, EPA believes that a network with substantially fewer monitors in correspondingly fewer CBSAs, as the commenters suggested, would lead to an insufficient monitoring network lacking a balanced approach needed for a regulatory network intended to support the revised NAAQS on a national basis.

On a related note to those comments that suggested focusing more near-road monitors only in the larger CBSAs, EPA proposed that any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000 must have a second monitor if they do not already have two near-road monitors because of the population threshold. Such an AADT-triggered monitor would account for situations where a relatively less populated area has a very highly trafficked road. In this case, EPA notes that because those road segments with 250,000 AADT have been identified by U.S. DOT FHWA (http://www.fhwa.dot.gov/policyinformation/tables/02.cfm) as being the top 0.03 percent of the most traveled public road segments, that they are the most heavily trafficked roads in the country. Again noting that NO2 concentrations are significantly associated with traffic counts (Gilbert et al. 2007), these roads segments likely have the greatest potential for high exposures directly connected to motor vehicle emissions in the entire country. Typically, these very highly trafficked roads are in the largest populated CBSAs, such as those with 2,500,000 people or more, and are somewhat atypical for CBSAs with less than 2,500,000 people. As a result, EPA believes it is appropriate to require a second monitor in a CBSA that has one or more road segments with 250,000 AADT counts or more if they do not already have two near-road monitors required due their population.

EPA received comments requesting that EPA explain the rationale for the selection of the population thresholds that trigger minimum monitoring requirements and also to reconsider the size of the network. For example, NYDOT suggested that this final rule explain the basis for the 350,000 and 2,500,000 population thresholds that will establish near-road monitors. In another comment, the Clean Air Council (CAC) questioned the selected population thresholds, noting that they believe that the population thresholds that were proposed were too high. Specifically, CAC stated that ``at 350,000 persons, numerous metro areas in the mid-Atlantic and Northeastern States with urban cores and highways running through will likely be exempted from the new monitors.'' The Spokane Regional Clean Air Agency stated that they ``do not believe it is necessary to require air quality monitoring for NO2 near major roadways in every metropolitan area. It is our [SRCAA's] view that EPA could establish a statistically significant number of air quality monitoring stations near roadways and develop a correlation between traffic density and ambient NO2 levels.'' Further, the EPA received many State comments suggesting reductions to the overall size of the near-road network; however the commenters did not provide very specific suggestions on how EPA should accomplish that reduction in size. For example, the Regional Air Pollution Control Agency, which represents a portion of Ohio, stated ``given the fairly standard fleet of vehicles on the nation's major highways, we urge EPA to consider the need for 142 near-roadway monitors. Perhaps a limited number of monitors across the country would suffice to sufficiently characterize near-roadway NO2 levels.'' These State commenters provided various reasons which are discussed throughout this document suggesting that the network be reduced in size, including funding concerns (section III.B.1.b), the perceived need to implement a smaller near-road research network in lieu of a regulatory network (section III.B.1.b), safety issues (section III.B.7.b), and problems with State implementation plans (section VI. D) and designation issues (section V).

EPA notes that the intent of the first tier of the network design is to support the revised NAAQS in measuring peak NO2 exposures in an area by including a minimum number of monitors resulting in a sufficiently sized national near-road monitoring network that will provide data from a geographically and spatially diverse array of areas, in terms of population, potential fleet mixes, geographic extent, and geographic setting, from across the country. The U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) ``Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance'' document (http://www.fhwa.dot.gov/policy/2006cpr/es02h.htm) states that ``while urban mileage constitutes only 24.9 percent of total (U.S.) mileage, these roads carried 64.1 percent of the 3 trillion vehicles miles (VMT) travelled in the United States in 2004.'' The document also states that ``urban interstate highways made up only 0.4 percent of total (U.S.) mileage but carried 15.5 percent of total VMT.'' These statements indicate how much more traffic volume exists on roads in urban areas versus the more rural areas that have significant amounts mileage of the total public road inventory. The basis for the selection of the proposed CBSA population level of 350,000 to trigger the requirement of one near-road monitor was chosen in an attempt to provide near-road monitoring data from a diverse array of areas, as noted above. However, in response to the significant number of comments discussed above, which in various ways encouraged at least a reduction of the size of the required near-road network or the implementation of a relatively smaller research network, EPA reconsidered the population threshold that will require one near-road NO2 monitor in a CBSA.

EPA reviewed the data, such as population, geographic, and spatial distribution, associated with particular CBSA areas that would and would not be included in particular CBSA population thresholds. According to the 2008 U.S. Census Bureau estimates (http://www.census.gov) there are 143 CBSAs with 350,000 or more persons (including territories) which contain approximately 71% of the total population (excluding territories). These

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CBSAs collectively represent territory in 44 States, the District of Columbia, and Puerto Rico. For comparison, there are 391 CBSAs with 100,000 or more persons, which contain approximately 86% of the total population (excluding territories). These particular CBSAs collectively represent territory in 49 States, the District of Columbia, and Puerto Rico. Further, there are 102 CBSAs with 500,000 or more persons, which contain approximately 66% of the total population (excluding territories). These 102 CBSAs collectively represent territory in 43 States, the District of Columbia, and Puerto Rico. Finally, there are 22 CBSAs with 2,500,000 or more persons, which contain approximately 39% of the total population, collectively representing territory in 19 States, the District of Columbia, and Puerto Rico. In comparison to the CBSA population threshold of 350,000, the 500,000 population threshold has 41 less CBSAs. However, the percentage of the total U.S. population residing in these two sets of CBSAs differs by only approximately 5 percent of the total population (e.g., 71% in CBSAs of 350,000 or more versus 66% in CBSAs of 500,000 or more persons). Also, when comparing the number of States that have some amount of their territory included in these CBSAs, the difference between the two sets of CBSAs differs by only 1 State (Alaska).

Further, EPA notes that the REA Air Quality Analysis, (REA, section 7.3.2) estimated the exceedences of health benchmark levels across the United States, including explicit consideration of on- or near- roadway exceedances in 17 urban areas associated with CBSA populations ranging from approximately 19,000,000 to 540,000. The analysis indicated that all 17 of the areas under explicit consideration were estimated to experience NO2 concentrations on or near roads that exceeded health benchmark levels.

c. Conclusions Regarding the First Tier (Near-Road Monitoring Component) of the Network Design

After consideration of public comments, and in light of the information discussed above, the Administrator has chosen to finalize the CBSA population threshold for requiring a minimum of one near-road monitor in CBSAs with a population of 500,000 or more persons. The Administrator is finalizing the other thresholds that will trigger a second near-road monitor as proposed. Accordingly, one near-road NO2 monitor is required in CBSAs with a population greater than or equal to 500,000 persons and a second near-road monitor is required in CBSAs with a population greater than or equal to 2,500,000 persons, or in any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000.

The Administrator has concluded that using a population threshold of 500,000 to require a minimum of one near-road monitor in a CBSA provides a sufficiently sized, national network of near-road monitors that will provide data from a geographically and spatially diverse set of CBSAs that supports the intent of the revised NAAQS and continues to meet the monitoring objectives of the network. Combined with the forty additional monitors that the Regional Administrators are required to site, discussed below, the monitoring network would cover an additional percentage of the total population.

EPA believes that selecting a lower population threshold, such as 100,000 or, to a lesser degree, 350,000, as discussed in the above examples, would create a much larger network of required near-road monitors but would provide diminished population coverage per monitor, compared to that provided by the 500,000 threshold. EPA notes that if a particular area, such as one with a population less than 500,000 people, might warrant a near-road monitor, the Regional Administrator has the authority to require additional monitors. The Regional Administrators' authority is discussed in section III.B.4. Further, States have the right to conduct additional monitoring above the minimum requirements on their own initiative. In the Administrator's judgment, selecting a higher threshold, such as 2,500,000, as was suggested by some commenters, does not provide a sufficient geographical and spatially diverse near-road network, compared to that provided by the 500,000 threshold. The selection of the 2,500,000 population threshold to trigger a second near-road monitor, as noted earlier in this section, is based on the fact that the larger urban areas in the country are likely to have a greater number of major roads across a potentially larger geographic area, and have a corresponding increase in potential for population exposure to elevated levels in different settings.

Changing the CBSA population threshold 350,000 to 500,000 results in a near-road monitoring network requiring approximately 126 monitors distributed within 102 CBSAs. Compared to the total number of required near-road monitors that would have resulted from the proposed CBSA population threshold of 350,000 (167 monitors), an estimated 41 fewer monitors are required. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site forty monitors in appropriate locations, focusing primarily on protecting such susceptible and vulnerable communities. This decision is discussed in detail in section III.B.4.

3. Second Tier (Area-Wide Monitoring Component) of the Network Design

The following paragraphs provide background, rationale, and details for the final changes to the second tier of the two-tier NO2 network design. In particular, this section will focus on the threshold that triggers area-wide monitoring requirements. Area-wide site selection and siting criteria details will be discussed in a subsequent section.

a. Proposed Second Tier (Area-Wide Monitoring Component) of the Network Design

As the second tier of the proposed two-tier network design, EPA proposed to require monitors to characterize the expected maximum NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in an area. This component of the two-tier network design provides information on area-wide exposures that may occur due to an individual or a group of point, area, on-road, and/or non-road sources. Further, area-wide sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, aiding in ozone forecasting, aiding in particulate matter precursor analysis and particulate matter forecasting. We proposed to require one area-wide monitoring site in each CBSA with a population greater than or equal to 1,000,000. We proposed that these area-wide sites were to be sited to represent an area of highest concentration at the neighborhood or larger spatial scales. Based on 2008 Census Bureau statistics, there are 52 CBSAs with 1,000,000 people or more, which would result in an estimated 52 area-wide monitors in as many CBSAs being minimally required. EPA also proposed to allow any current photochemical assessment monitoring station (PAMS) sites that are sited where the highest NO2 concentrations occur in an urban area

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and represent a neighborhood or urban scale to satisfy the area-wide monitoring requirement.

b. Comments

Most commenters who commented on area-wide monitoring supported the adoption of the alternative area-wide network design and did not specifically comment on the area-wide monitoring component of the proposed two-tier network design. However, EPA did receive comments from public health organizations on area-wide monitoring in the context of the proposed network design. The public health group commenters, including the ALA, EJ, EDF, and the NRDC, stated they ``oppose the proposed requirement to retain only 52 air monitors to measure area-wide concentrations of NO2.''

EPA understands the perceived concern to be that with this provision, EPA is actively reducing the number of required area-wide monitors. Prior to this rulemaking, the Ambient Air Monitoring Regulations, 71 FR 61236 (Oct. 17, 2006) (2006 monitoring rule) removed minimum monitoring requirements for NO2, and the rationale for that action is explained in that rule; however, the 2006 Monitoring rule has had a limited impact to date, evidenced by the fact that the size of the NO2 network has remained relatively steady at around 400 monitors, a majority of which are area-wide monitors, that were operating in 2008 (Watkins and Thompson, 2008). The stability of the NO2 network is due in large part to the fact that area-wide monitors serve multiple monitoring objectives, including photochemical pollutant assessment, pollutant forecasting, and in some cases, support to ongoing health research. However, considering the objective of this two-tier network design, particularly the first tier, of supporting the revised NAAQS to protect against peak NO2 exposures, some shrinkage in the area-wide network is appropriate and likely. EPA believes that the actual number of area-wide monitors that will operate in the NO2 network will be greater than the minimally required 52 sites, but likely less than the current number. States and Regional Administrators will work together on which area-wide sites may warrant retention above the minimum required if States request existing area-wide sites to be shut down or relocated.

c. Conclusions on the Second Tier (Area-Wide Monitoring Component) of the Network Design

Area-wide monitoring sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, ozone forecasting, particulate matter precursor analysis and particulate matter forecasting. EPA recognizes that a significant portion of the existing NO2 monitoring network can be characterized as area-wide monitors and that these monitoring sites serve multiple monitoring objectives, as noted above. In order to ensure that a minimum number of area-wide monitors continue operating into the future, we are finalizing the proposed minimum monitoring requirements for area-wide monitors, where one area-wide monitor is required in any CBSA with 1,000,000 people or more. Since there were no adverse comments received with regard to allowing PAMS stations that meet siting criteria to satisfy minimum monitoring requirements for area-wide monitors, we are finalizing that allowance as proposed. EPA encourages States to use the upcoming 2010 network assessment process to review existing area-wide NO2 sites to help determine what monitors might meet minimum monitoring requirements and whether or not other existing monitors warrant continued operation.

4. Regional Administrator Authority

The following paragraphs provide background, rationale, and details for the final changes to Regional Administrator authority to use discretion in requiring additional NO2 monitors beyond the minimum network requirements. The proposed rule estimated that approximately 167 near-road monitors would be required within CBSAs having populations of 350,000 or more persons. As discussed above in section III.B.2, in response to public comments, particularly from States, EPA is changing the population threshold for siting a minimum of one near-road NO2 monitor from CBSAs with 350,000 or more persons to CBSAs with 500,000 or more persons. EPA estimates that this change in the population threshold will result in a reduction in the number of minimally required near-road NO2 monitors by approximately forty monitors. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site these forty monitors in appropriate locations, focusing primarily on protecting susceptible and vulnerable communities. In addition, the Regional Administrators, working with States, may take into account other considerations described below in using their discretion to require additional monitors.

a. Proposed Regional Administrator Authority

EPA proposed that Regional Administrators have the authority to require monitoring at their discretion in particular instances. First, EPA proposed that the Regional Administrator have discretion to require monitoring above the minimum requirements as necessary to address situations where the required near-road monitors do not represent a location or locations where the expected maximum hourly NO2 concentrations exist in a CBSA. Second, EPA proposed to allow Regional Administrators the discretion to require additional near-road monitoring sites to address circumstances where minimum monitoring requirements are not sufficient to meet monitoring objectives, such as where exposures to NO2 concentrations vary across an area because of varied fleet mixes, congestion patterns, terrain, or geographic areas within a CBSA. And third, EPA proposed that Regional Administrators have the discretion to require additional area-wide NO2 monitoring sites above the minimum requirements for area-wide monitors where the minimum requirements are not sufficient to meet monitoring objectives.

b. Comments

EPA received comments from the Center on Race, Poverty and Environment expressing concern that the proposed monitoring provisions fail to consider ``disproportionately impacted communities'' which include people of color and of lower socioeconomic status. The commenter argues that this is ``a gaping hole'' in the proposed monitoring system and disproportionately impacts minority and low income populations in rural communities. In addition, the National Tribal Air Association stated that ``Indian Tribes and Alaska Natives are highly susceptible to health impacts as a result of NO2 exposure'' and ``the prevalence and severity of asthma is higher among certain ethnic or racial groups such as Indian Tribes and Alaska Natives,'' which is also discussed in section II.B.4 and the ISA (ISA, section 4.4).

The proposed rule provided the Regional Administrators with the authority to use their discretion and

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consider certain factors to require monitors above the minimum number in a CBSA. The proposal described one example where a Regional Administrator might require an additional near-road monitor where ``a particular community or neighborhood is significantly or uniquely affected by road emissions.'' EPA recognizes that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, as noted in section II.F.4.d, are at particular risk of NO2-related health effects, both because of increased exposure and because these groups have a higher prevalence of asthma and higher hospitalization rates for asthma. As noted above, in conjunction with raising the threshold for requiring one near-road NO2 monitor in CBSAs with 500,000 persons or more, EPA is requiring the Regional Administrators, under their discretionary authority, to work with States to site an additional forty monitors, nationally, focusing primarily on communities where susceptible and vulnerable populations are located. To address the risks of increased exposure to these populations, the Administrator has determined that it is appropriate and necessary, under this provision, to ensure these additional forty monitors are sited primarily in communities where susceptible and vulnerable populations are exposed to NO2 concentrations that have the potential to exceed the NAAQS (due to emissions from motor vehicles, point sources, or area sources). As a result of this action, the total number of monitors required through this rulemaking is generally equivalent to the proposed number of minimally required monitors.

EPA received comments from public health groups (e.g., ALA, Center on Race, Poverty, and the Environment, EDF, EJ, NRDC) and the Swinomish Tribe, who suggested that EPA expand monitoring coverage to address impacts from stationary sources outside of urban areas. For example, ALA, EDF, EJ, and NRDC, stated that ``EPA should require States and local offices to review inventory data to identify any potential NO2 hotspots outside of those large metropolitan areas. For instance, if a large power plant or any other source is creating elevated NO2 levels in proximity to homes, schools or other sensitive sites, in an area of less than one million people, EPA should consider requiring a monitor.''

EPA recognizes that there are major NO2 sources outside of CBSAs that have the potential to contribute to NO2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. While the proposal did not specifically state that Regional Administrators could require non-area-wide monitors outside of CBSAs, EPA believes that it is important that Regional Administrators have the authority to require NO2 monitoring in locations where NO2 concentrations may be approaching or exceeding the NAAQS, whether located inside or outside of CBSAs. Therefore, in the final rule, EPA is not limiting the Regional Administrators' discretionary authority to require NO2 monitoring only inside CBSAs; instead, the EPA is providing Regional Administrators the authority to site monitors in locations where NO2 concentrations may be approaching or exceeding the NAAQS, both inside or outside of CBSAs.

The EPA also received comments from some State groups (e.g. the New York Department of Environmental Conservation (NYSDEC), New York Department of Transportation (NYSDOT), and the New York City Law Department) and an industry group (the Council of Industrial Boiler Operators) requesting greater clarification on the way in which Regional Administrators may use their authority to require additional monitors above the minimum requirements. For example, the Council of Industrial Boiler Operators stated that ``this [Regional Administrator authority] unreasonably vests an unbounded amount of discretion in EPA to determine when ``minimum monitoring requirements are not sufficient'' and which neighborhoods are ``uniquely affected,'' and impose additional monitoring requirements where all applicable monitoring requirements are already met by the State and local agency.''

The authority of Regional Administrators to require additional monitoring above the minimum required is not unique to NO2. For example, Regional Administrators have or are proposed to have the authority to use their discretion to require additional Pb monitors (40 CFR Part 58 Appendix D section 4.5), and have the discretion to work with States or local agencies in designing and/or maintaining an appropriate ozone network, per 40 CFR Part 58 Appendix D section 4.1. EPA believes that while the NO2 monitoring network is sufficiently sized and focused, a nationally applicable network design may not account for all locations in which potentially high concentrations approaching or exceeding the NAAQS exist. Therefore, EPA believes it is important for Regional Administrators to have the ability to address possible gaps in the minimally required monitoring network, by granting them authority to require monitoring above the minimum requirements.

One case in which the Regional Administrator may exercise discretion in requiring a monitor might be a location or community affected by a stationary source where the required near-road NO2 monitor site is not the location of the maximum hourly concentration in a CBSA. For any given CBSA, there is the possibility that the maximum NO2 concentrations could be attributed to impacts from one, or a combination of, multiple sources that could include point, area, and non-road source emissions in addition to on-road mobile source emissions. As a result, the Regional Administrator may choose to require monitoring in such a location. In addition, there is the possibility that a single source or group of sources exists which may contribute to concentrations approaching or exceeding the NAAQS at locations inside or outside CBSAs, including rural communities. In such cases, Regional Administrators, working with States, may require a monitor in these locations. Further, if there are NO2 sources responsible for producing more widespread impacts on a community or relatively larger area, Regional Administrators may require an area-wide monitor to assess wider population exposures, or to support other monitor objectives served by area-wide monitors such as photochemical pollutant assessment or pollutant forecasting.

Regional Administrators may also require additional monitoring where a State or local agency is fulfilling its minimum monitoring requirements with an appropriate number of near-road monitors, but an additional location is identified where near-road population exposure exists at concentrations approaching or exceeding the NAAQS. In this case, the exposure may be due to differences in fleet mix, congestion patterns, terrain, or geographic area, relative to any minimally required monitoring site(s) in that area. We note

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that such areas might exist in CBSAs with populations less than 500,000 persons.

EPA recognizes that high concentrations of NO2 that approach or exceed the NAAQS could potentially occur in a variety of locations in an area, and we believe that Regional Administrators should have the discretion to require additional monitoring when a location is identified based on the factors discussed in the paragraph above. In such situations, State or EPA Regional staff is likely to have identified these locations through data analysis, such as the evaluation of existing ambient data and/or emissions data, or through air quality modeling. Such information may indicate that an area has NO2 concentrations that may approach or exceed the NAAQS, and that there is potential for population exposure to those high concentrations.

The Regional Administrator would use this authority in collaboration with State agencies. We expect Regional Administrators to work with State and local agencies to design and/or maintain the most appropriate NO2 network to meet the needs of a given area.

For all the situations where a Regional Administrator may require additional monitoring, including the forty additional monitors the Regional Administrators are required to site, EPA expects Regional Administrators to work on a case-by-case basis with States. Further, for the forty additional monitors that will focus primarily on protecting susceptible and vulnerable communities, EPA intends to work with States to develop criteria to guide site selection for those monitors.

c. Conclusions on Regional Administrator Authority

EPA is requiring Regional Administrators to work with States to site forty NO2 monitors, above the minimum number required in the two-tier network design, focused primarily in susceptible and vulnerable communities exposed to NO2 concentrations that have the potential to approach or exceed NAAQS. In addition, recognizing that a nationally applicable monitoring network design will not include all sites with potentially high concentrations due to variations across locations, and in response to public comments, the Administrator is providing Regional Administrators with the discretion to require additional monitors above the minimum requirements.

Regional Administrators may also use their discretionary authority to require monitoring above the minimum requirements as necessary to address situations inside or outside of CBSAs in which (1) The required near-road monitors do not represent all locations of expected maximum hourly NO2 concentrations in an area and NO2 concentrations may be approaching or exceeding the NAAQS in that area; (2) areas that are not required to have a monitor in accordance with the monitoring requirements and NO2 concentrations may be approaching or exceeding the NAAQS; or (3) the minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives. In all cases in which a Regional Administrator may consider the need for additional monitoring, EPA expects that Regional Administrators will work with the State or local agencies to evaluate evidence that suggests an area may warrant additional monitoring. EPA also notes that if additional monitoring should be required, as negotiated between the Regional Administrator and the State, the State will modify the information in its Annual Monitoring Network Plan to include any potential new sites prior to approval by the EPA Regional Administrator.

5. Monitoring Network Implementation

The following paragraphs provide background, rationale, and details for the final changes to the approach for the monitoring network implementation.

a. Proposed Monitoring Network Implementation Approach

EPA proposed that State and, when appropriate, local air monitoring agencies provide a plan for deploying monitors in accordance with the proposed network design by July 1, 2011. EPA also proposed that the proposed NO2 network be physically established no later than January 1, 2013.

b. Comments

Most environmental and public health group commenters suggested that EPA change the implementation date from the proposed January 1, 2013 to a date that would require the minimum required NO2 network to be deployed sooner than proposed. Most States and State group commenters, along with industry group commenters, recommended that EPA keep the network implementation date as January 1, 2013, or move it later than proposed. Those commenters who suggested moving it later noted that issues with monitoring site identification, site development, and overall lack of experience working in the near-road environment would make implementation difficult under the proposed implementation deadline.

EPA recognizes the challenges involved with deploying the two-tier network design by the January 1, 2013 date. We recognize the need for additional information and plan to aid State agencies in the network implementation process, particularly by developing guidance in partnership with affected stakeholders, ideally including at a minimum NACAA and the States. EPA agrees with NACAA's suggestion that the CASAC Ambient Air Monitoring and Methods subcommittee should be consulted as part of developing any guidance developed for near-road monitoring, and has already begun the process by scheduling meetings with them regarding near-road monitoring. Further, EPA believes that collaboration with the States and State groups in developing guidance will be highly beneficial to the implementation process. This would allow for those States that do have increased experience in near-road monitoring to support the guidance development process and provide a conduit for sharing experiences amongst all stakeholders.

In perspective, EPA believes that the approximate 2 years and 11 months between promulgation of this rulemaking and the mandated January 1, 2013 network implementation date includes extra time relative to what is traditionally allowed for network implementation following rulemakings. We are also cognizant of the time needed to collect complete data that would allow data from the two-tier network to be considered for designations and for use in the next NO2 NAAQS review data from the 2013, 2014, and 2015 years would provide critical information in the next NAAQS review, intended to occur on a 5-year cycle, and for use in subsequent designations. Even with complete data from 2013, 2014, and 2015 years designations would not occur until 2017, at the earliest.

c. Conclusions on Monitoring Network Implementation

EPA is finalizing the date by which State and, when appropriate, local air monitoring agencies shall establish the required NO2 monitoring network as January 1, 2013, as was proposed. We believe that the allotted time for implementation will allow for the development of guidance documentation, particularly allowing for interactions with CASAC and NACAA/States, and for the processes that will be involved in deploying this network. However, EPA recognizes that the network implementation process,

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particularly for near-road monitors, will include the assessment of road segments in CBSAs to identify locations of maximum expected hourly NO2 concentrations, identifying and working with other State and local agencies, such as transportation officials, as needed on issues regarding access and safety, and the exchange of information and feedback on potential sites with EPA, prior to any commitment to selecting and presenting new sites in an annual monitoring plan. As a result, based on feedback received through public comments, and to allow for more time to process guidance information, to carry out the deployment processes, and to allow for information exchanges to occur, we are changing the date by which State and, when appropriate, local air monitoring agencies shall provide a plan for deploying monitors in accordance with required network design, including the monitors required under the Regional Administrators' discretional authority which are to be primarily focused on providing protection to susceptible and vulnerable populations, as discussed in section III.B.4, from July 1, 2011 to July 1, 2012. EPA strongly encourages State and local air agencies to supply as much information as possible on the NO2 sites they may be considering, including possible site coordinates if available, or have possibly selected, to satisfy the minimum NO2 network monitoring requirements in their Annual Monitoring Network Plan submitted July 1, 2011.

6. Near-Road Site Selection

The following paragraphs provide background, rationale, and details for the final changes to the approach and criteria by which required near-road sites shall be selected.

a. Proposed Near-Road Site Selection Criterion

EPA proposed that the required near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments where maximum hourly NO2 concentrations are expected to be highest and siting criteria can be met in accordance with that proposed for 40 CFR Part 58 Appendix E (discussed in III.B.7). Where a State or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO2 concentrations are expected to occur, the monitoring agency should consider taking into account the potential for population exposure in the criteria utilized to select the final site location. Where one CBSA is required to have two near-road NO2 monitoring stations, we proposed that the sites shall be differentiated from each other by one or more of the following factors: Fleet mix; congestion patterns; terrain; geographic area within the CBSA; or different route, interstate, or freeway designation.

b. Comments

EPA received many comments from CASAC, public health groups, States and State groups, and industry groups on the proposed process by which States will select near-road sites. CASAC, along with some health group and State commenters questioned how States should select a site near the road with the highest ranked AADT possible, noting that EPA did not appear to require States to account for other factors. For example, one CASAC panel member noted that siting monitors based on traffic counts alone might miss locations where maximum NO2 concentrations would occur. They proceeded to recommend the use of modeling to assist in the site selection process. In another example, the ALA, EDJ, EJ, and NRDC, stated that ``Near-road monitor placement should be determined not only by the highest AADT volumes in a given CBSA, but also by the highest heavy-duty truck volumes.'' NACAA also expressed concerns on ``* * * basing monitor locations on the annual average daily traffic (AADT) without regard to vehicle mix or dispersion characteristics * * *''.

EPA does not intend for AADT counts to be the sole basis for choosing a near-road site. As noted earlier in section III.B.2, there is a general relationship between AADT and mobile source pollution, where higher traffic counts correspond to higher mobile source emissions. The use of AADT counts is intended to be a mechanism for focusing on identifying the locations of expected maximum NO2 concentrations due to mobile sources. There are other factors that can influence which road segment in a CBSA may be the actual location where the maximum NO2 concentrations could occur. These factors include vehicle fleet mix, roadway design, congestion patterns, terrain, and meteorology. When States identify their top-ranked road segments by AADT, EPA intends for States to evaluate all of the factors listed above in their site selection process, due to their influence on where the location of expected maximum NO2 concentration may occur. As a result of the comments indicating a need for clarification, EPA will specifically list the factors that must be considered by States in their site selection process once a State has identified the most heavily trafficked roads in a CBSA based on AADT counts. In addition, EPA proposed that States consider these factors when they are required to place two near-road monitors in a CBSA, i.e., CBSAs with a population of 2,500,000 persons or more. EPA notes that these factors will be used in differentiating the two monitoring sites from each other, providing further characterization of near-road environments in larger urban areas that are more likely to have a greater number of major roads across a potentially larger geographic area, and a corresponding increase in potential for exposure in different settings. Finally, EPA notes that air quality models, which were noted by the CASAC panel member to be considered for use in near-road site selection, are tools that EPA believes will be useful, and likely used by some States to inform where near-road sites need to be placed.

EPA received comments from some State and industry commenters (e.g. Iowa, NY DEC, Edison Electric Institute, and Savannah River Nuclear Solutions) who suggested that potential population exposure should be a first-level metric in the near-road monitoring site selection process, instead of a second-level metric as EPA had proposed.

EPA notes that the intent of the revised primary NO2 NAAQS is to protect against the maximum allowable NO2 concentration anywhere in an area, which includes ambient air on and around roads. This would limit exposures to peak NO2 concentrations, including those due to mobile source emissions, across locations (including those locations where population exposure near roads is greatest) in a given CBSA or area, with a relatively high degree of confidence. We also note the agency's historical practice has been to site ambient air monitors in locations of maximum concentration, at the appropriate spatial scale. If EPA were to allow population, population density, or another population weighted metric to be a primary factor in the decision on where required near-road NO2 monitors are to be located, it is possible that the required near-road monitors in a CBSA would not be located at a site of expected maximum hourly near-road NO2 concentration. By monitoring in the location of expected maximum 1-hour concentrations, near-road monitoring sites will likely represent the highest NO2 concentrations in an area directly attributable to mobile sources or a group of sources that includes mobile sources. The proposed rule did permit, and the final rule states, that States are to

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consider population in the site selection process in situations when a State identifies multiple candidate sites where maximum hourly NO2 concentrations are expected to occur.

EPA received a comment from HCPHES suggesting that required monitoring should take into consideration the location of other major mobile sources for NO2 emissions such as airports and seaports. EPA also received a comment from the South Carolina Department of Health and Environmental Control stating that a near-road network does not address ``widespread pollutants from numerous and diverse sources.''

EPA recognizes that there are major NO2 sources outside of CBSAs that have the potential to contribute to NO2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. Providing the Regional Administrators with the discretion to require additional monitors allows them to effectively address such situations, even if that area is satisfying minimum monitoring requirements. This Regional Administrator authority is discussed above in section III.B.4. EPA also notes that State and local agencies may also monitor such locations on their own initiative.

One State commenter, the Wisconsin Department of Natural Resources, requested that the term ``major road'' be defined and also requested clarification on what ``top-ranked'' means with regard to AADT counts on road segments. While the term ``major road'' is widely used in literature and can be found to be defined differently from one scientific study to another, here, EPA is using it in its commonly understood meaning as a road that is relatively heavily trafficked. EPA also does not believe it is appropriate to provide a bright-line definition for ``top-ranked''. Each CBSA will have a different distribution of total road segments and corresponding AADT counts on those segments. Further, since required near-road monitors are to be sited in locations of expected maximum concentrations, a percentile restriction on ``top ranked'' roads is unnecessary. The intent of the requirement to rank all road segments by AADT counts and select a site, considering the other local factors noted above, near a ``top-ranked'' road segment is to focus attention on the most heavily trafficked roads, around which there is higher potential for maximum NO2 concentrations to occur.

c. Conclusions on Near-Road Site Selection

We are finalizing the near-road site selection criteria as proposed, and are clarifying that the proposal intended the selection criteria to include consideration of localized factors when identifying locations of expected maximum concentrations. As a result, required near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO2 concentrations are expected to occur and siting criteria can be met in accordance with 40 CFR Part 58 Appendix E. As was noted in section III.B.5 above, EPA will work with States to assist with the near-road site selection process through the development of guidance material and through information exchanges amongst the air monitoring community.

We are also finalizing the requirement, as proposed, that when one CBSA is required to have two near-road NO2 monitoring stations, the sites shall be differentiated from each other by one or more of the following factors: fleet mix; congestion patterns; terrain; geographic area within the CBSA; or different route, interstate, or freeway designation, as was proposed.

7. Near-Road Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the siting criteria for required near-road monitoring sites.

a. Proposed Near-Road Siting Criteria

EPA proposed that near-road NO2 monitoring stations must be sited so that the NO2 monitor probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, and shall have no obstructions in the fetch between the monitor probe and roadway traffic such as noise barriers or vegetation higher than the monitor probe height. We solicited comment on, but did not propose, having near-road sites located on the predominantly downwind side of the target roadways. EPA proposed that the monitor probe shall be located within 2 to 7 meters above the ground, as is required for microscale PM2.5 and PM10 sites. We also proposed that monitor probe placement on noise barriers or buildings, where the inlet probe height is no less than 2 meters and no more than 7 meters above the target road, will be acceptable, so long as the inlet probe is at least 1 meter vertically or horizontally away (in the direction of the target road) from any supporting wall or structure, and the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer does not exceed 20 seconds.

b. Comments

EPA received comments from a number of States (e.g. Michigan, Mississippi, and Tennessee) indicating that the near-road network poses significant safety issues and a related need for increased logistical flexibility for installing a monitoring site. For example, the Mississippi Department of Environmental Quality states that ``Given the fact that these NO2 sites will be required to be housed in shelters that are within 50 meters of the road, we believe that these buildings could be large and pose a serious risk to drivers on the road.''

EPA notes that in all instances of field work, safety is a top priority. In this instance of near-road monitoring, we are dealing with the safety of the public driving on roads and the monitoring staff who may operate the near-road monitoring station as well. There are various ways to install near-road sites while ensuring worker and traffic safety, and safety is an important part of the logistical considerations that States should consider when selecting and installing near-road sites. In many cases, State and local monitoring agencies may be able to work with their State or local transportation officials during the site selection process to deal with access and safety issues. In public comments, AASHTO recommended that ``* * * State and local air monitoring agencies be required to coordinate with State and local DOTs for near-road monitoring during the establishment of the monitoring plan.'' Although EPA cannot require States to coordinate with other State or local entities, EPA believes that transportation officials would likely be able to assist in finding solutions to ensure safety while working with monitoring agencies in accommodating a new near-road monitoring station. An

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example of a step that could be taken to alleviate safety concerns might be purposefully placing a monitoring site behind existing barriers like guardrails and fencing, or possibly by installing a short distance of such barriers to protect the site workers, site infrastructure, and nearby traffic. In addition, EPA notes that the 50m distance proposed is wide enough to accommodate a site that would satisfy many setback provisions that exist for private or commercial building permits near roads, and may be viewed as a confirmation that our proposed siting criteria are safely attainable.

Some State commenters (e.g. AASHTO, NYSDOT, and Wisconsin) suggested that the allowable maximum distance a near-road monitoring probe can be from the target road be increased from 50 meters to something wider, such as 200 meters. Conversely, there were some State, environmental, and industry commenters (e.g. NESCAUM,\24\ Group Against Smog and Pollution, and Air Quality Research and Logistics) who suggested that the proposed range was appropriate, or, as suggested by both NESCAUM and the Group Against Smog and Pollution, the allowable distance should be reduced to as close as 30 or 20 meters to the nearest edge of the traffic lanes of the target road segment, respectively.

\24\ NESCAUM officially supported the alternative network design; however, they made suggestions regarding the near-road network in the event EPA finalized the proposed two-tier network design.

EPA believes that increasing the allowable distance above 50 meters would compromise the intent of near-road monitoring. As was noted in the proposal and this document, the ISA (2.5.4 and 4.3.6) and REA (7.3.2) indicate that on-road, mobile source derived NO2 exhibits a peak concentration on or very near the source road, and those concentrations decay over a variable but relatively short distance back to near area-wide or background (upwind of the target road) concentrations. Literature values indicate that the distance required for NO2 concentrations to return to near area-wide or background concentrations away from major roadways can range up to 500 meters, but the peak concentrations are occurring on or very near the source roadway. The behavior of NO2 concentrations and the actual distance over which concentrations return to near area-wide or background levels is variable, and highly dependent on topography, roadside features, meteorology, and the related photochemical reactivity conditions (Baldauf et al., 2008; Beckerman et al., 2007; Clements et al., 2008; Gilbert et al., 2003; Hagler et al., 2009; Rodes and Holland, 1980; Singer et al., 2003; Zhou and Levy, 2007). Therefore, monitor probe placement at increasing distances from a road, such as 200 meters, will correspondingly decrease the potential for sampling maximum concentrations of NO2 due to the traffic on the target road. Baldauf et al. (2009) indicate that monitoring probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

Regarding the comments suggesting required monitor probes be closer than 50 meters, EPA believes the allowable distance of 50 meters that a near-road NO2 probe can be from the target road provides enough flexibility for the logistical issues that can occur on a case-by-case basis, which is inherent in monitoring site placement, while not sacrificing the potential to monitor the peak NO2 concentrations. However, in light of the information provided here on how NO2 peak concentrations can decay over relatively short distances away from roads, EPA strongly encourages States to place near-road sites, or at least monitor probes, as close as safely possible to target roads to increase the probability of measuring the peak NO2 concentrations that occur in the near-road environment, again noting that Baldauf et al. (2009) indicate that monitor probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

EPA also proposed that required near-road NO2 monitor probes shall have no obstructions in the fetch between the monitor probe and roadway traffic such as noise barriers or vegetation higher than the monitor probe height. EPA expects that when a State makes a measurement in determining whether an NO2 inlet probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, that the measurement would likely represent a path to the monitor probe that is normal to the target road. However, EPA notes that the monitor probe will likely be influenced by various parts of the target road segment that are at a relative angle compared to the normal transect between the road and the monitor probe. EPA is not adjusting the wording of this requirement, but does intend for States to consider more than one linear pathway between the target road and the monitor probe being clear of obstructions when considering candidate site locations.

EPA received comments on the solicitation for comment on requiring near-road monitoring sites to be placed on the downwind side of the target road where the commenters (e.g. NACAA,\25\ NESCAUM, and the Clean Air Council) encouraged such a requirement. Conversely, other commenters (e.g., Air Quality and Logistics and NYSDEC suggested that such a requirement may be overly restrictive and not necessary. For example, NYSDEC stated that ``It is important to avoid making the monitor siting criteria too restrictive. It is very likely that in some CBSAs, finding suitable locations near the busiest road segments will not be possible. It is also important to remember that the NO2 monitoring instrumentation provides data continuously. Sites located downwind of sources will likely be impacted more frequently than the sites located upwind particularly when the sites are more than 50 meters from the source, and are preferred, but either side of the road will be downwind some of the time. Many of the highest NO2 concentrations are also likely to occur during inversion periods and during calm meteorological conditions when the upwind-downwind designations have little meaning.''

\25\ NACAA made a statement containing many concerns about the near-road monitoring component proposal which included a passage regarding the lack of requiring sites to be downwind. They expressed concern in ``* * * allowing upwind siting of monitors over a wide range of horizontal and vertical distances from the road * * *''.

EPA noted in its proposal that research literature indicates that in certain cases, mobile source derived pollutant concentrations, including NO2, can be detected upwind of roads, above background levels, due to a phenomenon called upwind meandering. Kalthoff et al. (2007) indicates that mobile source derived pollutants can meander upwind on the order of tens of meters, mainly due to vehicle induced turbulence. Further, Beckerman et al. (2008) note that near-road pollutant concentrations on the predominantly upwind side of their study sites dropped off to near background levels within the first 50 meters, but were above background in this short and variable upwind range, which could be due, at least in part, to vehicle induced turbulence. This upwind meandering characteristic of pollutants in the near-road environment provides an additional basis for locating near-road sites within 50 meters of target road segments, but also reduces the absolute need to be downwind of the road. EPA believes that very few, if any, near-road sites would be able to be situated in a location that was always downwind. For example, a hypothetical

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site may have winds routinely out of several different cardinal directions throughout the year, without one being a dominant direction. As a result, given variable meteorology, for some period of a year, a given near-road site may not be downwind of the target road, no matter which side of the road it is on. Therefore, EPA is not finalizing a requirement that near-road sites must be climatologically downwind of the target road segment because of the additional limitations this introduces to finding potential site candidates in exchange for what may be a small increase in the opportunity to monitor peak NO2 concentrations. However, EPA encourages States to place monitors in the climatologically downwind direction whenever possible, in an attempt to measure the peak NO2 concentrations more often than not. One way States may identify where the predominantly downwind location might be for candidate sites could be to use portable meteorolcgical devices to characterize meteorological tendencies, in addition to evaluating other available meteorological data sources.

EPA proposed that required near-road NO2 monitor probes be located within 2 to 7 meters above the ground, as is required for microscale PM2.5 and PM10 sites. EPA also proposed that monitor probe placement on noise barriers or buildings, where the inlet probe height is no less than 2 meters and no more than 7 meters above the target road, will be acceptable, so long as the inlet probe is at least 1 meter vertically or horizontally away (in tbe direction of the target road) from any supporting wall or structure. NESCAUM commented that ``EPA needs to reconcile near-roadway NO2 probe height requirements with the existing micro-scale near-roadway CO probe height requirement of 2.5 to 3.5 meters above prevailing terrain. NESCAUM supports using this existing height for all near-roadway pollution monitors, as it minimizes probe height effects on measurements, and allows for proper measurement of collocated particle number concentration (which requires a very short inlet, i.e., on the order of inches) and CO.'' NYSDEC commented that ``The height requirement may not be practical for road segments in dense urban areas where existing buildings heights may exceed 7 meters. The requirement to maintain a 1 meter clearance from a supporting wall or structure may not be adequate for taller walls often found in urban areas. These walls can create down washing and street canyon effects which will make the resulting data less representative of nearby areas and will make interpretation of the resulting data difficult. However, there will need to be consistency between similar site settings.'' Finally, EPA received comments from some health groups (e.g., ALA, EJ, EDF, and NRDC) who commented that ``the lower end of the proposed height of 2 to 7 meters appears to capture the highest NO2 concentrations, and more accurately represents human exposure at the breathing zone.''

In the proposal, EPA noted that near-road monitoring sites will be adjacent to a variety of road types, where some target roads will be on an even plane with the monitoring station, while others may be cut roads (i.e., below the plane of the monitoring station) or fill and open elevated roads (i.e., where the road plane is above the monitoring station). EPA recognizes that consistency across sites with regard to probe height is desirable, and consistency with microscale, urban canyon CO sites might also be desirable. However, as was noted in the earlier discussion on ``downwind'' site placements, it is important to avoid making the monitor siting criteria too restrictive. An allowable range between 2 and 7 meters provides more flexibility in site installation, which EPA considers important because of the variety of siting situations each State may have to deal with for each individual site. While EPA agrees that a tighter allowable range such as 2.5 to 3.5 meters would reduce site to site variability and keep probes nearer the microscale siting requirements of CO, the wider range of 2 to 7 meters still provides an adequate amount of site to site consistency. EPA may also address this issue through forthcoming guidance, where an increased consistency for probe heights in similar situations such as urban canyons may be a site implementation goal, within the required 2 to 7 meter probe height range. Further, EPA believes that although certain situations, as noted by NYSDEC, may exist where the 1 meter clearance from walls or structures may be problematic near taller buildings or walls, this requirement is consistent with similar such clearance requirements for microscale CO sites in similar such situations that exist in urban canyons.

In the proposed rule, EPA proposed in the siting criteria language that the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer cannot exceed 20 seconds. EPA received comments from Air Quality Research and Logistics regarding guidelines for maximum allowable inlet length and sample residence time, where they stated that ``* * * the fast photodynamic O3-NOX equilibrium may occur in darkened sample lines at residence times of 10-20 seconds (Butcher et al. 1971; Ridley et al. 1988; Parrish et al. 1990). EPA should correct this apparent error by specifying much lower maximum residence times (e.g., 1-2 seconds) or accounting for this effect by reporting `corrected' values in error by no more than the allowed rounding convention (e.g., 1 ppb).''

EPA notes that in 40 CFR Part 58 Appendix E, paragraph (9)(c), states that sample probes for reactive gas analyzers, particularly NOY monitors, at NCore monitoring sites must have a sample residence time less than 20 seconds. EPA believes this rule is also appropriate for NO2 monitors, particularly if a monitor inlet manifold is extended away from the main monitoring shelter. EPA does agree that shorter sample residence time in the inlet manifold is desirable. Although we do not believe it appropriate to require residence times on the order of 1 to 2 seconds, and do not believe correcting values is appropriate (which was not a concept which was proposed), we do encourage States to use best practices in selecting non-reactive manifold materials, and to install sampling manifolds in an efficient manner that minimizes sample residence time. While EPA proposed this concept in the preamble to the proposed rule, we did not include it in the proposed regulatory text. The final rule includes regulatory text on this subject at 40 CFR Part 58 Appendix E, paragraph (9)(c).

c. Conclusions on Near-Road Siting Criteria

We are finalizing the near-road NO2 monitor siting criteria, as proposed, where (1) required near-road NO2 monitor probes shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment, (2) required near-road NO2 monitor probes shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment, (3) required near-road NO2 monitors are required to have sampler inlets between 2 and 7 meters above ground level, and (4) residence time of NO2 in the sample line between the

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inlet probe and the analyzer does not exceed 20 seconds.

8. Area-Wide Monitor Site Selection and Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the site selection and monitor siting criteria for required area-wide monitoring sites.

a. Proposed Area-Wide Monitor Site Selection and Siting Criteria

EPA proposed that sites required as part of the second tier of the NO2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

b. Comments

While most commenters who supported area-wide monitoring did so with regard to the adoption of the alternative area-wide network design rather than as part of the proposed approach, only a few commented on the actual sites and siting criteria. The Dow Chemical Company suggested that area-wide sites should be located at least 1,000 meters away from any major roads or intersections to ensure that the concentration of NO2 measured is representative of an area-wide concentration instead of peak near-road concentrations.

EPA notes that in order for an NO2 monitoring site to be classified as a neighborhood (or larger) spatial scale site, it must meet the roadway set-back requirements in Table E-1 of 40 CFR Part 58 Appendix E. EPA believes that this existing set-back table is appropriate to use to ensure that any NO2 site that may be intended as an area-wide site will be sufficiently distanced from any major road. For example, an NO2 monitoring site may be considered neighborhood scale if it is 10 or more meters from the edge of the nearest traffic lane of a road with 10,000 or less AADT counts.

c. Conclusions on Area-Wide Monitor Site Selection and Siting Criteria

We are finalizing the requirement that any sites required as part of the second tier of the NO2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

9. Meteorological Measurements

The following paragraphs provide background, rationale, and details for the final changes to the requirement of meteorological monitoring at near-road monitoring sites.

a. Proposed Meteorological Measurements

In further support of characterizing the peak NO2 concentrations occurring in the near-road environment, EPA proposed to require three-dimensional anemometry, providing wind vector data in the horizontal and vertical planes, along with temperature and relative humidity measurements, at all required near-road monitoring sites.

b. Comments

EPA received comments from the South Carolina Department of Health and Environmental Control commented that the recording of air turbulence data at near-road monitoring stations should be encouraged but not required. Other States (e.g., Alaska, North Carolina, and Wisconsin) provided comments that did not support the proposed meteorological measurement requirements, noting issues with costs, problems siting the probe nearer to structures and to the ground than is typically done, and that the averaging period required to better understand turbulence (through anemometry data) in the near-road environment requires a much higher frequency than what is typically reported.

EPA is removing the proposed requirements that would have required meteorological monitoring at near-road NO2 monitoring stations. However, EPA strongly encourages States to do some meteorological monitoring to better characterize the conditions under which they are acquiring NO2 data. The near-road microscale environment is complex, and understanding the turbulent dispersion that may be affecting NO2 measurements, along with having a basic understanding of from which direction the measured NO2 concentrations are coming from, which are very informative in the effort to fully understand the data being collected. At a minimum, basic anemometry data would be useful in identifying whether the site is upwind, downwind, or otherwise oriented, relative to the target road.

c. Conclusions on Meteorological Measurements

We are not finalizing the proposal to require three-dimensional anemometry, providing wind vector data in the horizontal and vertical planes, along with temperature and relative humidity measurements, at all required near-road monitoring sites.

C. Data Reporting

The following paragraphs provide background, rationale, and details for the final changes to the data reporting requirements, data quality objectives, and measurement uncertainty.

1. Proposed Data Quality Objectives and Measurement Uncertainty

In the proposal, EPA noted that State and local monitoring agencies are required to report hourly NO, NO2, and NOX data to AQS within 90 days of the end of each calendar quarter. We also noted that many agencies also voluntarily report their pre-validated data on an hourly basis to EPA's real time AIRNow data system, where the data may be used by air quality forecasters to assist in ozone forecasting. We believe these data reporting procedures are appropriate to support the revised primary NO2 NAAQS.

EPA proposed to develop data quality objectives (DQOs) for the proposed NO2 network. We proposed a goal for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

2. Comments

EPA received comments from the State of Missouri, supporting the proposed DQOs and goals for measurement uncertainty, and from North Carolina, suggesting that measurement uncertainty goals match those of the NCore multi-pollutant network.

EPA agrees that it is desirable to have measurement uncertainty goals that match that of other pollutants. EPA originally proposed the goals for precision and bias under consideration that there may be a need to account for potential increased uncertainty in 1-hour near-road NO2 data. However, we agree with the suggestion from the State of North Carolina, and are changing the goals for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent. These goals match the existing goals for NO2 and are consistent with historical measurement uncertainty goals.

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3. Conclusions on Data Quality Objectives and Measurement Uncertainty

We are finalizing the approach to develop data quality objectives, and are changing the proposed goal for measurement uncertainty, where the goals for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

IV. Appendix S--Interpretation of the Primary NAAQS for Oxides of Nitrogen and Revisions to the Exceptional Events Rule

The EPA proposed to add Appendix S, Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, to 40 CFR part 50 in order to provide data handling procedures for the proposed NO2 1-hour primary standard and for the existing NO2 annual primary standard. The proposed Appendix S detailed the computations necessary for determining when the proposed 1-hour and existing annual primary NO2 NAAQS are met. The proposed Appendix S also addressed data reporting, data completeness considerations, and rounding conventions.

Two versions of Appendix S were proposed. The first applied to a 1-hour primary standard based on the annual 4th high value form, while the second applied to a 1-hour primary standard based on the 99th percentile daily value form.

The final version of Appendix S is printed at the end of this notice and applies to an annual primary standard and a 1-hour primary standard based on the 98th percentile daily value form. Appendix S is based on the near-roadway approach to the setting the level of the 1-hour standard and to siting monitors. As such, these versions place no geographical restrictions on which monitoring sites' concentration data can and will be compared to the 1-hour standard when making nonattainment determinations and other findings related to attainment or violation of the standard.

The EPA is amending and moving the provisions of 40 CFR 50.11 related to data completeness for the existing annual primary standard to the new Appendix S, and adding provisions for the proposed 1-hour primary standard. Substantively, the data handling procedures for the annual primary standard in Appendix S are the same as the existing provisions in 40 CFR 50.11 for that standard, except for an addition of a cross-reference to the Exceptional Events Rule, the addition of Administrator discretion to consider otherwise incomplete data complete, and the addition of a provision addressing the possibility of there being multiple NO2 monitors at one site. The procedures for the 1-hour primary standard are entirely new.

The EPA is also making NO2-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines now contained in 40 CFR 50.14 are generic, and are not always appropriate for NO2 given the anticipated schedule for the designations of areas under the final NO2 NAAQS.

The purpose of a data interpretation appendix in general is to provide the practical details on how to make a comparison between multi-day and possibly multi-monitor ambient air concentration data and the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. The regulatory language for the pre-existing annual NO2 NAAQS, originally adopted in 1977, contained data interpretation instructions only for the issue of data completeness. This situation contrasts with the situations for ozone, PM2.5, PM10, and most recently Pb for which there are detailed data interpretation appendices in 40 CFR part 50 addressing more issues that can arise in comparing monitoring data to the NAAQS.

A. Interpretation of the Primary NAAQS for Oxides of Nitrogen for the Annual Primary Standard

The purpose of a data interpretation rule for the NO2 NAAQS is to give effect to the form, level, averaging time, and indicator specified in the regulatory text at 40 CFR 50.11, anticipating and resolving in advance various future situations that could occur. Appendix S provides common definitions and requirements that apply to both the annual and the 1-hour primary standards for NO2. The common requirements concern how ambient data are to be reported, what ambient data are to be considered (including the issue of which of multiple monitors' data sets will be used when more than one monitor has operated at a site), and the applicability of the Exceptional Events Rule to the primary NO2 NAAQS.

The proposed Appendix S also addressed several issues in ways which are specific to the individual primary NO2 standards, as described below.

1. Proposed Interpretation of the Annual Standard

The proposed data interpretation provisions for the annual standard are consistent with the pre-existing instructions included along with the statement of the level and form of the standard in 40 CFR 50.11. These are the following: (1) At least 75% of the hours in the year must have reported concentration data. (2) The available hourly data are arithmetically averaged, and then rounded (not truncated) to whole parts per billion. (3) The design value is this rounded annual average concentration. (4) The design value is compared with the level of the annual primary standard (expressed in parts per billion).

In the proposal, EPA noted that it would be possible to introduce additional steps for the annual primary standard which in principle could make the design value a more reliable indicator of actual annual average concentration in cases where some monitoring data have been lost. For example, averaging within a calendar quarter first and then averaging across quarters could help compensate for uneven data capture across the year. For some aspects of the data interpretation procedures for some other pollutants, the current data interpretation appendices do contain such additional steps. The proposed provisions for the proposed 1-hour NO2 standard also incorporated some such features.

2. Comments on Interpretation of the Annual Standard

We received four comments, all from State agencies, on data interpretation for the annual NO2 standard. Of the four commenters, two recommended the use of a weighted annual mean to appropriately implement the annual primary standard. Two other commenters asserted that there is no strong seasonality in NO2 concentrations, and that therefore there is no need to use a weighted annual mean or to require data completeness quarter-by-quarter.

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3. Conclusions on Interpretation of the Annual Standard

Upon investigating the issue of NO2 seasonality using data from AQS as part of considering the comments, we have found that there are notable variations in quarterly mean NO2 concentrations. It is therefore quite possible that an unweighted annual mean calculated without a quarter-by-quarter data completeness requirement might not represent the true annual mean as well as a weighted annual mean calculated with a quarter-by-quarter completeness requirement. However, the current practice of requiring 75% completeness of all of the hours in the year and calculating the annual mean without weighting has been retained in the final rule, because of its simplicity and because we believe it will not interfere with effective implementation of the annual NAAQS. No area presently is nonattainment for or comes close to violating the annual standard. Therefore, the choice between the two approaches can only have a practical effect, if any, on whether at some time in the future an area is determined to be newly violating the annual standard. If a monitor has a complete and valid design value below the standard using the unweighted mean approach (with only an annual data completeness requirement) but the design value would be considered incomplete and invalid under a hypothetical weighted mean approach (with a quarterly completeness requirement), the monitor would in either case be considered not to be violating and its data would not be the basis for a nonattainment designation. If a monitor has a design value above the standard using the unweighted annual mean approach but is incomplete with respect to a hypothetical quarterly completeness requirement, then the two approaches would have different implications for the determination of a violation. A quarterly completeness requirement would make a finding of violation impossible, unless the Administrator chose to treat the data as if complete under another provision of the final rule. The unweighted annual mean approach would allow but not force a finding of violation, because the Administrator will have discretion to make any such findings because there will be no mandatory round of designations for the annual standard given that the annual standard has not been revised in this review. The Administrator will be able to consider the representativeness of the unweighted annual mean when deciding whether to make a discretionary nonattainment redesignation. Given that the annual standard requires only one year of monitoring data for the calculation of a design value, little time will be lost if the Administrator chooses to work with a State to obtain a new design value based on more complete and/or seasonally balanced monitoring data.

B. Interpretation of the Primary NAAQS for Oxides of Nitrogen 1-Hour Primary Standard

1. Proposed Interpretation of the 1-Hour Standard

With regard to data completeness for the 1-hour primary standard with a 4th highest daily value form, the proposed Appendix followed past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the 1-hour primary NO2 NAAQS, the key air quality statistics are the daily maximum 1-hour concentrations in three successive years. It is important that sampling within a day encompass the period when concentrations are likely to be highest and that all seasons of the year are well represented. Hence, the 75% requirement was proposed to be applied at the daily and quarterly levels.

Recognizing that there may be years with incomplete data, the proposed text provided that a design value derived from incomplete data would nevertheless be considered valid in either of two situations.

First, if the design value calculated from at least four days of monitoring observations in each of these years exceeds the level of the 1-hour primary standard, it would be valid. This situation could arise if monitoring was intermittent but high NO2 levels were measured on enough hours and days for the mean of the three annual 4th high values to exceed the standard. In this situation, more complete monitoring could not possibly have indicated that the standard was actually met.

Second, we proposed a diagnostic data substitution test which was intended to identify those cases with incomplete data in which it nevertheless is very likely, if not virtually certain, that the daily 1-hour design value would have been observed to be below the level of the NAAQS if monitoring data had been minimally complete.

It should be noted that one possible outcome of applying the proposed substitution test is that a year with incomplete data may nevertheless be determined to not have a valid design value and thus to be unusable in making 1-hour primary NAAQS compliance determinations for that 3-year period.

Also, we proposed that the Administrator have general discretion to use incomplete data based on case-specific factors, either at the request of a State or at her own initiative. Similar provisions exist already for some other NAAQS.

The second version of the proposed Appendix S contained proposed interpretation procedures for a 1-hour primary standard based on the 99th percentile daily value form. The 4th high daily value form and the 99th percentile daily value form would yield the same design value in a situation in which every hour and day of the year has reported monitoring data, since the 99th percentile of 365 daily values is the 4th highest value. However, the two forms diverge if data completeness is 82% or less, because in that case the 99th percentile value is the 3rd highest (or higher) value, to compensate for the lack of monitoring data on days when concentrations could also have been high.

Logically, provisions to address possible data incompleteness under the 99th percentile daily value form should be somewhat different from those for the 4th highest form. With a 4th highest form, incompleteness should not invalidate a design value that exceeds the standard, for reasons explained above. With the 99th percentile form, however, a design value exceeding the standard stemming from incomplete data should not automatically be considered valid, because concentrations on the unmonitored days could have been relatively low, such that the actual 99th percentile value for the year could have been lower, and the design value could have been below the standard. The second proposed version of Appendix S accordingly had somewhat different provisions for dealing with data incompleteness. One difference was the addition of another diagnostic test based on data substitution, which in some cases can validate a design value based on incomplete data that exceeds the standard.

The second version of the proposed Appendix S provided a table for determining which day's maximum 1-hour concentration will be used as the 99th percentile concentration for the year. The proposed table is similar to one used now for the 24-hour PM2.5 NAAQS, which is based on a 98th percentile form, but adjusted to reflect

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a 99th percentile form for the 1-hour primary NO2 standard. The proposed Appendix S also provided instructions for rounding (not truncating) the average of three annual 99th percentile hourly concentrations before comparison to the level of the primary NAAQS.

2. Comments on Interpretation of the 1-Hour Standard

Three commenters expressed the view that the 75% completion per quarter requirement should apply with respect to the 1-hour standard. A fourth commenter recommended that the requirement be increased to 82%. Another person commented that the requirement of 75% of the hours in a day is too stringent. The commenter noted that it would be inappropriate not to count the day if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS. A comment was received that the substitution test should not be included, on the grounds that nonattainment should not be declared without irrefutable proof. This commenter also said that the same completeness requirement as used for nonattainment should be used for attainment. We received one comment that the computation of design values where multiple monitors are present at a site should be averaged and not taken from a designated primary monitor.

3. Conclusions on Interpretation of the 1-Hour Standard

Consistent with the Administrator's decision to adopt a 98th percentile form for the 1-hour NAAQS, the final version of Appendix S is based on that form. Table 1 has been revised from the version that was proposed, so that it results in the selection of the 98th percentile value rather than the 99th percentile value.

We agree with the three comments expressing the view that the requirement for 75% data completeness per quarter should apply with respect to the 1-hour standard. A fourth comment recommended that the requirement be increased to 82%. We believe 82% is too stringent because of the number of monitors that would not achieve such a requirement and we believe that 75% captures the season. We agree that an incomplete day should be counted if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS, and we have accounted for that in section 3.2.c.i by validating the design value if it is above the level of the primary 1-hour standard when at least 75 percent of the days in each quarter have at least one reported hourly value. We agree that substitution should not be used for the establishment of attainment/nonattainment. The commenter who remarked on this issue appears not to have understood that the specific proposed substitution tests have essentially zero probability of making a clean area fail the NAAQS, or vice versa, because the substituted values are chosen to be conservative against such an outcome. As noted in section 3.2(c)(i), when substitution is used, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

In the course of considering the above comment regarding data substitution tests to be used in cases of data incompleteness, EPA has realized that there could be some cases of data incompleteness in which the proposed procedure for calculating the 1-hour design value might result in an in appropriately low design value. As proposed, only days with measurements for at least 75% of the hours in the day would be considered in any way when identifying the 99th percentile value (99th for purposes of the adopted NAAQS). However, there could be individual hours in other, incompletely monitored days that had measured concentrations higher than the identified 98th percentile value from the complete days. It would be inappropriate not to consider those hours and days in some way. However, if all days with at least one hourly concentration were used to identify the 99th percentile value without any regard to their incompleteness, this could also result in a design value that is biased low because the extra days could increase the number of ``annual number of days with valid data'' enough to affect which row of Table 1 of Appendix S is used. It could, for example, result in the 8th highest ranked daily maximum concentration being identified as the 98th percentile value (based on Table 1 of Appendix S) rather than a higher ranked concentration; this would also be inappropriate because days which were not monitored intensively enough to give a reasonable likelihood of catching the maximum hourly concentration would in effect be treated as if they had such a likelihood. For example, 50 days with only one hourly measurement during a time of day with lower concentrations would ``earn'' the State the right to drop one notch lower in the ranking of days when identifying the 98th percentile day, inappropriately. The final version of Appendix S solves this problem by providing that two procedures be used to identifying the 98th percentile value, the first based only on days with 75% data completeness and the second based on all days with at least one hourly measurement. The final design value is the higher of the two values that result from these two procedures.

With regard to situations with multiple monitors operating at one site, we think as discussed in the proposal, that designation of a primary monitor is preferable to averaging the data from multiple monitors based on administrative simplicity and transparency for the public, and is unbiased with respect to compliance outcome provided the State is able to make the designation only before any data has been collected.

Finally, as proposed, the final version of Appendix S has a cross reference to the Exceptional Events Rule (40 CFR 50.14) with regard to the exclusion of data affected by exceptional events. In addition, the specific steps for including such data in completeness calculations while excluding such data from actual design value calculations is clarified in Appendix S.

C. Exceptional Events Information Submission Schedule

The Exceptional Events Rule at 40 CFR 50.14 contains generic deadlines for a State to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A State must initially notify EPA that data has been affected by an event by July 1 of the year after the data are collected; this is done by flagging the data in AQS and providing an initial event description. The State must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review is foreshortened, and all information must be submitted to EPA no later than one year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a newly revised NAAQS. One problem is

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that some of the deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the revised NAAQS is promulgated. Until the level and form of the NAAQS have been promulgated a State does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day. The only way a State could guard against this possibility is to flag all data that could possibly be eligible for exclusion under a future NAAQS. This could result in flagging far more data than will eventually be eligible for exclusion. EPA believes this is an inefficient use of State and EPA resources, and is potentially confusing and misleading to the public and regulated entities. Another problem is that it may not be feasible for information on some exceptional events that may affect final designations to be collected and submitted to EPA at least one year in advance of the final designation decision. This could have the unintended consequence of EPA designating an area nonattainment as a result of uncontrollable natural

or other qualified exceptional events.
When Section 50.14 was revised in March 2007, EPA was mindful that designations were needed under the recently revised PM2.5 NAAQS, so exceptions to the generic deadline were included for PM2.5. The EPA was also mindful that similar issues would arise for subsequent new or revised NAAQS. The Exceptional Events Rule at section 50.14(c)(2)(v) indicates ``when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those NAAQS.''

EPA proposed revised exceptional event data flagging and documentation deadlines in FR 34404 [Federal Register/Vol. 74, No. 134/ Wednesday, July 15, 2009/Proposed Rules] and invited comments from the public. The Agency received no comments related to the revised proposed schedule for NO2 exceptional event data flagging and documentation deadlines.

For the specific case of NO2, EPA anticipates that initial designations under the revised NAAQS may be made by January 22, 2012 based on air quality data from the years 2008-2010. (See Section VI below for more detailed discussion of the designation schedule and what data EPA intends to use.) If final designations are made by January 22, 2012, all events to be considered during the designations process must be flagged and fully documented by States one year prior to designations, by January 22, 2011. This date also coincides with the Clean Air Act deadline for Governors to submit to EPA their recommendations for designating all areas of their States.

The final rule text at the end of this notice shows the changes that will apply if a revised NO2 NAAQS is promulgated by January 22, 2010, and designations are made two years after promulgation of a NO2 NAAQS revision.

Table 1 below summarizes the data flagging and documentation deadlines corresponding to the two year designation schedule discussed in this section. If the promulgation date for a revised NO2 NAAQS occurs on a different date than January 22, 2010, EPA will revise the final NO2 exceptional event flagging and documentation submission deadlines accordingly to provide States with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS.

Table 1--Schedule for Exceptional Event Flagging and Documentation Submission for Data To Be Used in Designations Decisions for New or Revised NAAQS

NAAQS pollutant/standard/(level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
NO2/1-Hour Standard (100 PPB)........	2008	July 1, 2010 \a\........	January 22, 2011.
	2009	July 1, 2010............	January 22, 2011.
	2010	April 1, 2011\a\........	July 1, 2011.\a\

\a\ Indicates change from general schedule in 40 CFR 50.14.
Note: EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

V. Designation of Areas

A. Proposed Process

The CAA requires EPA and the States to take steps to ensure that the new or revised NAAQS are met following promulgation. The first step is to identify areas of the country that do not meet the new or revised NAAQS. Section 107(d)(1) provides that, ``By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under section 109, the Governor of each State shall * * * submit to the Administrator a list of all areas (or portions thereof) in the State'' that should be designated as nonattainment, attainment, or unclassifiable for the new NAAQS. Section 107(d)(1)(B)(i) further provides, ``Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation.''

No later than 120 days prior to promulgating designations, EPA is required to notify States of any intended modifications to their designations as EPA may deem necessary. States then have an opportunity to comment on EPA's tentative decision. Whether or not a State provides a recommendation, the EPA must promulgate the designation that it deems appropriate.

Accordingly, Governors must submit their initial NO2 designation recommendations to EPA no later than January 2011. If the Administrator intends to modify any State's recommendation, the EPA will notify the Governor no later than 120 days prior to designations in January 2012. States that believe the Administrator's modification is inappropriate will have an opportunity to demonstrate why they believe their recommendation is more appropriate before designations are finalized.

B. Public Comments

Several industry commenters requested that EPA slow the timeline for implementing a near-roadway monitoring network and designating roadway areas because they believe EPA lacks significant information about the implementation and performance of a national, near-roadway monitoring network. Two commenters also requested that if a near-roadway monitoring network is deployed, that 1-hour NO2 standards be made more

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lenient until the next review period so that more information will be available about near-roadway NO_2 concentrations before a stringent standard is selected.

A response to commenters' requests that EPA slow the monitoring implementation schedule and the request that EPA make the 1-hour NO_2 standard more lenient until the next review period are addressed in sections III.B.5 and II.F.4.D, respectively.

Section 110(d)(1)(B) requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS (i.e., by January 2012). While the CAA provides the Agency an additional third year from promulgation of a NAAQS to complete designations in the event that there is insufficient information to make NAAQS compliance determinations, we anticipate that delaying designations for an additional year would not result in significant new data to inform the initial designations. A near-roadway monitoring network is not expected to be fully deployed until January 2013 therefore, EPA must proceed with initial designations using air quality data from the existing NO_2 monitoring network. Because none of the current NO_2 monitors are sited to measure near-roadway ambient air, we expect that most areas in the country with current NO_2 monitors will not violate the new NO_2 NAAQS. In the event that a current NO_2 monitor indicates a violation of the revised standards, EPA intends to designate such areas ``nonattainment'' no later than 2 years following promulgation of the revised standards. We intend to designate the rest of the country as ``unclassifiable'' for the revised NO_2 NAAQS until sufficient air quality data is collected from a near-roadway monitoring network. Once the near-roadway network is fully deployed and 3 years of air quality data are available, the EPA has authority under the CAA to redesignate areas as appropriate from ``unclassifiable'' to ``attainment'' or ``nonattainment.'' We anticipate that sufficient data to conduct designations would be available after 2015.

A number of commenters, largely from industry groups, focused on the concern that a near-roadway monitoring network would lead to regional nonattainment on the basis of high NO_2 concentrations found near roadways. These commenters requested that any future nonattainment areas be limited to the area directly surrounding roadways found to have above-standard NO_2 concentrations.

The CAA requires that any area that does not meet a NAAQS or that contributes to a violation in a nearby area that does not meet the NAAQS be designated ``nonattainment.'' States and EPA will need to determine which sources and activities contribute to a NAAQS violation in each area. Depending on the circumstances in each area this may include sources and activities in areas beyond the area directly surrounding a major roadway. EPA intends to issue nonattainment area boundary guidance after additional information is gathered on the probable contributors to violating near-roadway NO_2 monitors.

C. Final Designations Process

The EPA intends to promulgate initial NO_2 designations by January 2012 (2 years after promulgation of the revised NAAQS). Along with today's action EPA is also promulgating new monitoring rules that focus on roadways. As noted in section III, States must site required NO_2 near-roadway monitors and have them operational by January 1, 2013. States will need an additional 3 years thereafter to collect air quality data in order to determine compliance with the revised NAAQS. This means that a full set of air quality data from the new network will not be available until after 2015. Since we anticipate that data from the new network will not be available prior to the CAA designation deadlines discussed above, the EPA intends to complete initial NO_2 designations by January 2012 using the 3 most recent years of quality-assured air quality data from the current monitoring network, which would be for the years 2008-2010. The EPA will designate as ``nonattainment'' any areas with $NO_2$ monitors recording violations of the revised $NO_2$ NAAQS. We intend to designate all other areas of the country as ``unclassifiable'' to indicate that there is insufficient data to determine whether or not they are attaining the revised NO_2 NAAQS.

Once the NO_2 monitors are positioned in locations meeting the near-roadway siting requirements and monitoring data become available, the Agency has authority under section 107(d)(3) of the CAA to redesignate areas as appropriate from ``unclassifiable'' to ``attainment'' or ``nonattainment.'' The EPA intends to issue guidance on the factors that States should consider when determining nonattainment boundaries after additional information is gathered on the probable contributors to violating near-roadway NO_2 monitors.

VI. Clean Air Act Implementation Requirements

This section of the preamble discusses the Clean Air Act (CAA) requirements that States and emissions sources must address when implementing new or revised NO_2 NAAQS based on the structure outlined in the CAA and existing rules.\26\ EPA may provide additional guidance in the future, as necessary, to assist States and emissions sources to comply with the CAA requirements for implementing new or revised NO_2 NAAQS.

\26\ Since EPA is retaining the annual standard without revision, the discussion in this section relates to implementation of the proposed 1-hour standard, rather than the annual standard.

The CAA assigns important roles to EPA, States, and, in specified circumstances, Tribal governments to achieve the NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain State measures necessary to achieve the air quality standards in each area. EPA provides assistance to States by providing technical tools, assistance, and guidance, including information on the potential control measures that may help areas meet the standards.

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once they have been established by EPA. Under section 110 of the CAA, 42 U.S.C. 7410, and related provisions, States are required to submit, for EPA approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed at sources of NO2 emissions. If a State fails to adopt and implement the required SIPs by the time periods provided in the CAA, the EPA has responsibility under the CAA to adopt a Federal Implementation Plan (FIP) to assure that areas attain the NAAQS in an expeditious manner.

The States, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program for NO2 and nonattainment new source review (NSR). See sections 160-169 of the CAA. In addition, Federal programs provide for nationwide reductions in emissions of NO2 and other air pollutants under Title II of the Act, 42 U.S.C. 7521-7574, which involves controls for automobiles, trucks, buses, motorcycles, nonroad engines, and aircraft emissions; the new source performance standards (NSPS) for stationary sources under section 111 of the CAA, 42 U.S.C. 7411.

CAA Section 301(d) authorizes EPA to treat eligible Indian Tribes in the same manner as States (TAS) under the CAA and requires EPA to promulgate regulations specifying the provisions of the statute for which such treatment is appropriate. EPA has promulgated these

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regulations--known as the Tribal Authority Rule or TAR--at 40 CFR Part 49. See 63 FR 7254 (February 12, 1998). The TAR establishes the process for Indian Tribes to seek TAS eligibility and sets forth the CAA functions for which TAS will be available. Under the TAR, eligible Tribes may seek approval for all CAA and regulatory purposes other than a small number of functions enumerated at section 49.4. Implementation plans under section 110 are included within the scope of CAA functions for which eligible Tribes may obtain approval. Section 110(o) also specifically describes Tribal roles in submitting implementation plans. Eligible Indian Tribes may thus submit implementation plans covering their reservations and other areas under their jurisdiction.

Under the CAA and TAR, Tribes are not, however, required to apply for TAS or implement any CAA program. In promulgating the TAR EPA explicitly determined that it was not appropriate to treat Tribes similarly to States for purposes of, among other things, specific plan submittal and implementation deadlines for NAAQS-related requirements. 40 CFR 49.4(a). In addition, where Tribes do seek approval of CAA programs, including section 110 implementation plans, the TAR provides flexibility and allows them to submit partial program elements, so long as such elements are reasonably severable--i.e., ``not integrally related to program elements that are not included in the plan submittal, and are consistent with applicable statutory and regulatory requirements.'' 40 CFR 49.7.

To date, very few Tribes have sought TAS for purposes of section 110 implementation plans. However, some Tribes may be interested in pursuing such plans to implement today's proposed standard. As noted above, such Tribes may seek approval of partial, reasonably severable plan elements, or they may seek to implement all relevant components of an air quality program for purposes of meeting the requirements of the Act. In several sections of this preamble, EPA describes the various roles and requirements States will address in implementing today's proposed standard. Such references to States are generally intended to include eligible Indian Tribes to the extent consistent with the flexibility provided to Tribes under the TAR. Where Tribes do not seek TAS for section 110 implementation plans, EPA will promulgate Federal implementation plans as ``necessary or appropriate to protect air quality.'' 40 CFR 49.11(a). EPA also notes that some Tribes operate air quality monitoring networks in their areas. For such monitors to be used to measure attainment with this primary NAAQS for NO2, the criteria and procedures identified in this rule would apply.

A. Classifications

1. Proposal

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purpose of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify NO2 nonattainment areas, but is not required to do so. The primary reason to establish classifications is to set different deadlines for each class of nonattainment area to complete the planning process and to provide for different attainment dates based upon the severity of the nonattainment problem for the affected area. However, the CAA separately establishes specific planning and attainment deadlines for certain pollutants including NO2 in sections 191 and 192: 18 months from nonattainment designation for the submittal of an attainment plan, and as expeditiously as possible, but no later than 5 years from nonattainment designation for areas to attain the standard. In the proposal, EPA stated its belief that classifications are unnecessary in light of these relatively short deadlines.

2. Public Comments

One commenter stated that they disagree with EPA's decision not to impose non-attainment classifications on areas with measured near-road NO2 concentrations in excess of the new NO2 standard, and urged EPA to provide a graduated non-attainment classification system for the new standard. According to the commenter, ``a classification system defining higher levels of non-attainment with increasingly stringent requirements at those levels is one that allows for finer calibration of air quality regulatory response defined at the Federal level.''

As stated in the proposed rule, Section 192(a), of part D, of the CAA specifically provides an attainment date for areas designated as nonattainment for the NO2 NAAQS. Therefore, EPA has legal authority to classify NO2 nonattainment areas, but the 5-year attainment date addressed under section 192(a) cannot be extended pursuant to section 172(a)(2)(D). Based on this limitation, EPA proposed not to establish classifications within the 5- year interval for attaining any new or revised NO2 NAAQS. It is also EPA's belief that given the short deadlines that States have to develop and submit SIP's and for areas to achieve emissions reductions in order to attain the standard within the 5 year attainment period, a graduated classifications system would not be appropriate. Therefore, EPA is using it's discretion under the CAA not to establish classifications.

3. Final

EPA is not making any changes to the discussion on classifications in the proposed rule. Therefore, there will be no classifications for the revised NO2 NAAQS.

B. Attainment Dates

The maximum deadline by which an area is required to attain the NO2 NAAQS is determined from the effective date of the nonattainment designation for the affected area. For areas designated nonattainment for the revised NO2 NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). The EPA will determine whether an area has demonstrated attainment of the NO2 NAAQS by evaluating air quality monitoring data consistent with the form of the NAAQS for NO2 if revised, which will be codified at 40 CFR part 50, Appendix F.

1. Attaining the NAAQS

a. Proposal

In order for an area to be redesignated as attainment, the State must comply with the five requirements as provided under section 107(d)(3)(E) of the CAA. This section requires that:

--EPA must have determined that the area has met the NO2 NAAQS;
--EPA has fully approved the State's implementation plan;
--The improvement in air quality in the affected area is due to permanent and enforceable reductions in emissions;
--EPA has fully approved a maintenance plan for the area; and
--The State(s) containing the area have met all applicable requirements under section 110 and part D.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the

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discussion on attaining the NAAQS in the proposed rule.

2. Consequences of Failing To Attain by the Statutory Attainment Date

a. Proposal

Any NO2 nonattainment area that fails to attain by its statutory attainment date would be subject to the requirements of sections 179(c) and (d) of the CAA. EPA is required to make a finding of failure to attain no later than 6 months after the specified attainment date and publish a notice in the Federal Register. The State would be required to submit an implementation plan revision, no later than one year following the effective date of the Federal Register notice making the determination of the area's failure to attain, which demonstrates that the standard will be attained as expeditiously as practicable, but no later than 5 years from the effective date of EPA's finding that the area failed to attain. In addition, section 179(d)(2) provides that the SIP revision must include any specific additional measures as may be reasonably prescribed by EPA, including ``all measures that can be feasibly implemented in the area in light of technological achievability, costs, and any nonair quality and other air quality-related health and environmental impacts.''

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on consequences of failing to attain by the statutory attainment date in the proposed rule.

C. Section 110(a)(2) NAAQS Infrastructure Requirements

1. Proposal

Section 110(a)(2) of the CAA requires all States to develop and maintain a solid air quality management infrastructure, including enforceable emission limitations, an ambient monitoring program, an enforcement program, air quality modeling, and adequate personnel, resources, and legal authority. Section 110(a)(2)(D) also requires State plans to prohibit emissions from within the State which contribute significantly to nonattainment or maintenance areas in any other State, or which interfere with programs under part C to prevent significant deterioration of air quality or to achieve reasonable progress toward the national visibility goal for Federal class I areas (national parks and wilderness areas).

Under section 110(a)(1) and (2) of the CAA, all States are required to submit SIPs to EPA which demonstrate that basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) listed below, set forth the elements that a State's program must contain in the SIP.\27\ The list of section 110(a)(2) NAAQS implementation requirements are the following:

\27\ Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.

Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation and permitting of new/modified sources.

Interstate transport: Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in the State from contributing significantly to nonattainment in another State or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.

Adequate resources: Section 110(a)(2)(E) requires States to provide assurances of adequate funding, personnel and legal authority for implementation of their SIPs.

Stationary source monitoring system: Section 110(a)(2)(F) requires States to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.

Emergency power: Section 110(a)(2)(G) requires States to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.

Provisions for SIP revision due to NAAQS changes or findings of inadequacies: Section 110(a)(2)(H) requires States to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.

Consultation with local and Federal government officials: Section 110(a)(2)(J) requires States to meet applicable local and Federal government consultation requirements when developing SIP and reviewing preconstruction permits.

Public notification of NAAQS exceedances: Section 110(a)(2)(J) requires States to adopt measures to notify the public of instances or areas in which a NAAQS is exceeded.

PSD and visibility protection: Section 110(a)(2)(J) also requires States to adopt emissions limitations, and such other measures, as may be necessary to prevent significant deterioration of air quality in attainment areas and protect visibility in Federal Class I areas in accordance with the requirements of CAA Title I, part C.

Air quality modeling/data: Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.

Permitting fees: Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.

Consultation and participation by affected local government: Section 110(a)(2)(M) requires States to provide for consultation and participation by local political subdivisions affected by the SIP.

2. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on section 110(a)(2) NAAQS infrastructure requirements in the proposed rule.

D. Attainment Planning Requirements

1. Nonattainment Area SIPs

a. Proposal

Any State containing an area designated as nonattainment with respect to the NO2 NAAQS must develop for submission a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable statutory attainment date (see sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the NO2 part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment.

Section 172 of the CAA includes general requirements for all designated nonattainment areas. Section 172(c)(1)

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requires that each nonattainment area plan ``provide for the implementation of all reasonably available control measures (RACM) as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of Reasonably Available Control Technology (RACT)), and shall provide for attainment of the national primary ambient air quality standards.'' States are required to implement RACM and RACT in order to attain ``as expeditiously as practicable''.

Section 172(c) requires States with nonattainment areas to submit a SIP for these areas which contains an attainment demonstration that shows that the affected area will attain the standard by the applicable statutory attainment date. The State must also show that the area will attain the standards as expeditiously as practicable, and it must include an analysis of whether implementation of reasonably available measures will advance the attainment date for the area.

Part D SIPs must also provide for reasonable further progress (RFP) (see section 172(c)(2) of the CAA). The CAA defines RFP as ``such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date.'' (See section 171 of the CAA.) Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions sufficient to maintain generally linear progress toward attainment by the applicable attainment date.

All NO2 nonattainment area SIPs must include contingency measures which must be implemented in the event that an area fails to meet RFP or fails to attain the standards by its attainment date. (See section 172(c)(9).) These contingency measures must be fully adopted rules or control measures that take effect without further action by the State or the Administrator. The EPA interprets this requirement to mean that the contingency measures must be implemented with only minimal further action by the State or the affected sources with no additional rulemaking actions such as public hearings or legislative review.

Emission inventories are also critical for the efforts of State, local, and Federal agencies to attain and maintain the NAAQS that EPA has established for criteria pollutants including NO2. Section 191(a) in conjunction with section 172(c) requires that areas designated as nonattainment for NO2 submit an emission inventory to EPA no later than 18 months after designation as nonattainment. In the case of NO2, sections 191(a) and 172(c) also require that States submit periodic emission inventories for nonattainment areas. The periodic inventory must include emissions of NO2 for point, nonpoint, mobile (on-road and non-road), and area sources.

b. Public Comments

Several commenters indicated that EPA should take steps to ensure that States actually require mobile source emissions reductions in order to attain the NO2 NAAQS as opposed to controlling point sources. Another commenter went further and stated that States be required to control on-road emissions as opposed to emissions from stationary sources and in particular EGUs. This commenter also indicated that EPA should delay nonattainment designations until States had a cost effective means of reducing on-road emissions of NO2.

EPA cannot require States to develop a SIP that only addresses one type of source, in this case on-road mobile sources. States may select appropriate control measures to attain the NAAQS and EPA must approve them if they otherwise meet all applicable requirements of the Act. See CAA 116. EPA expects that States will evaluate a range of control measures that will reduce NO2 emissions within the time allowed to attain the standard. This would include the emissions reductions attributable to Federal controls on on-road and non-road mobile sources, and controls that they have put in place to reduce NOX emissions in order to attain the 8-hour ozone NAAQS and/ or the PM2.5 NAAQS. If these existing controls are not sufficient for an area to reach attainment with the NO2 NAAQS, EPA would expect the State to implement additional control measures that would bring the area into attainment by the deadline. For a designation based on data from a near roadway monitor EPA would expect the States to give primary consideration to controlling emissions from on-road sources; however, it is likely that other types of sources contribute to the concentrations that are measured at a near roadway monitor and a State may decide to implement controls on these other contributing sources.

The Clean Air Act requires that EPA finalize designations within two years after a NAAQS is revised unless the available air quality data is insufficient to make designations by that time. In that case, EPA must finalize designations within three years after the NAAQS is revised. As discussed elsewhere in today's final rule, EPA believes that it has sufficient data to make designations within two years and that most areas will be designated as unclassifiable at that time. Taking the additional year provided by the CAA would not allow additional data from the new near roadway monitors to be factored into the designations process in any event. Therefore, it is EPA's intention to designate areas within two years as required by the Act. EPA intends to redesignate areas once it has sufficient data from the new monitoring network to designate areas as clearly attaining or not attaining the standard.

c. Final

The EPA is not making any changes to the discussion on nonattainment area SIPs in the proposed rule.

2. New Source Review and Prevention of Significant Deterioration Requirements

a. Proposal

The Prevention of Significant Deterioration (PSD) and nonattainment New Source Review (NSR) programs contained in parts C and D of Title I of the CAA govern preconstruction review of any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator.\28\ The EPA rules addressing these programs can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S. States which have areas designated as nonattainment for the NO2 NAAQS must submit, as a part of the SIP due 18 months after an area is designated as nonattainment, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area. SIPs that address the PSD requirements related to attainment areas are due no later than 3 years after the promulgation of a revised NAAQS for NO2.

\28\ The terms ``major'' and ``minor'' define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not ``major.'' ``Major'' is defined by the applicable regulations--PSD or nonattainment NSR.

The NSR program is composed of three different permit programs:
Prevention of Significant Deterioration (PSD).
Nonattainment NSR (NA NSR).
Minor NSR.
The PSD program applies when a major source, that is located in an area that is designated as attainment or

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unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.\29\ The nonattainment NSR program applies on a pollutant-specific basis when a major source constructs or modifies in an area that is designated as nonattainment for that pollutant. The minor source NSR program addresses both major and minor sources which undergo construction or modification activities that do not qualify as major, and it applies, as necessary to assure attainment, regardless of the designation of the area in which a source is located.

\29\ In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

The PSD requirements include but are not limited to the following:
Installation of Best Available Control Technology (BACT);
Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
Notification of Federal Land Manager of nearby Class I areas; and
Public comment on permit.
Nonattainment NSR requirements include but are not limited to:
Installation of Lowest Achievable Emissions Rate (LAER) control technology;
Offsetting new emissions with creditable emissions reductions;
A certification that all major sources owned and operated in the State by the same owner are in compliance with all applicable requirements under the CAA;
An alternative siting analysis demonstrating that the benefits of a proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
Public comment on the permit.
Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires ``* * * regulation of the modification and construction of any stationary source * * * as necessary to assure that the [NAAQS] are achieved.'' Areas which are newly designated as nonattainment for the NO2 NAAQS as a result of any changes made to the NAAQS will be required to adopt a nonattainment NSR program to address major sources of NO2 where the program does not currently exist for the NO2 NAAQS and may need to amend their minor source program as well. Prior to adoption of the SIP revision addressing major source nonattainment NSR for NO2 nonattainment areas, the requirements of 40 CFR part 51, appendix S may apply.
b. Public Comments
One commenter claimed that EPA's setting of a more stringent standard, i.e., short-term NO2 NAAQS, could have important implications for NSR and PSD and title V permits. Another commenter indicated that the promulgation of a new 1-hr NO2 short-term standard could create the need for a short-term PSD increment. Another commenter stated that a 1-hr NO2 Significant Impact Level (SIL) should be developed.
The EPA acknowledges that a decision to promulgate a new short-term NO2 NAAQS will clearly have implications for the air permitting process. The full extent of how a new short-term NO2 NAAAQS will affect the NSR process will need to be carefully evaluated. First, major new and modified sources applying for NSR/PSD permits will initially be required to demonstrate that their proposed emissions increases of NOX will not cause or contribute to a violation of either the annual or 1-hour NO2 NAAQS and the annual PSD increment. In addition, we believe that section 166 of the CAA authorizes us to consider the need to promulgate a new 1-hour increment. Historically, EPA has developed increments for each applicable averaging period for which a NAAQS has been promulgated. However, increments for a particular pollutant do not necessarily need to match the averaging periods that have been established for NAAQS for the same pollutant. Environmental Defense Fund, Inc. v. EPA, 898 F.2d 183, 189-190 (DC Cir. 1990) (`` * * * the `goals and purposes' of the PSD program, set forth in 160, are not identical to the criteria on which the ambient standards are based.'') Thus, we would need to evaluate the need for a new 1-hour NO2 increment in association with the goals and purposes of the statutory PSD program requirements.
We also believe that there may be a need to revise the screening tools currently used under the NSR/PSD program for completing NO2 analyses. These screening tools include the significant impact levels (SILs), as mentioned by one commenter, but also include the significant emissions rate for emissions of NOX and the significant monitoring concentration (SMC) for NO2. EPA

intends to evaluate the need for possible changes or additions to each of these important screening tools for NOX/NO2 due to the addition of a 1-hour NO2 NAAQS. If changes or additions are deemed necessary, EPA will propose any such changes for public notice and comment in a separate action.

c. Final

The EPA is not making any changes to the discussion concerning the requirements for NSR and PSD as stated in the proposed rule.

3. General Conformity

a. Proposal

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 et seq.), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. The EPA rules, developed under the authority of section 176(c) of the CAA, prescribe the criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. Each Federal agency must determine that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment areas and those areas redesignated attainment since 1990 (``maintenance areas'') with respect to the criteria pollutants under the CAA: \30\ carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO2), ozone (O3), particulate matter (PM2.5 and PM10), and sulfur dioxide (SO2). The general conformity rules apply one year following the effective date of designations for any new or revised NAAQS.

\30\ Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. The general conformity rule also requires that notices of draft and final general conformity determinations be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion concerning general conformity stated in the proposed rule.

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4. Transportation Conformity

a. Proposal

Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that transportation plans, transportation improvement programs (TIPs) and Federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: Carbon monoxide (CO), ozone (O3), nitrogen dioxide (NO2), and particulate matter (PM2.5 and PM10). Transportation conformity for a revised NO2 NAAQS does not apply until one year after the effective date of a nonattainment designation. (See CAA section 176(c)(6) and 40 CFR 93.102(d)).

EPA's Transportation Conformity Rule (40 CFR 51.390, and Part 93, Subpart A establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not making changes to the Transportation Conformity rule in this rulemaking. However, in the future, EPA will review the need to conduct a rulemaking to establish any new or revised transportation conformity tests that would apply under a revision to the NO2 NAAQS for transportation plans, TIPs, and applicable highway and transit projects.

b. Public Comments

Several commenters stated that transportation conformity could stop the funding of highway and transit projects in NO2 nonattainment areas. These commenters stated that if an area fails to demonstrate conformity, it enters a conformity lapse and only certain types of projects can be funded during a lapse. The commenters further stated that the NO2 NAAQS will require more areas to determine conformity for the first time. The commenters also expressed concern that the NO2 NAAQS proposal did not contain sufficient information to understand to what extent revisions to the NAAQS, and the NO2 monitoring requirements, will result in transportation conformity requirements for individual transportation projects such as the need for a hot-spot analysis. The commenters further stated that hot-spot analyses could result in needless delays for transportation improvement projects.

With regard to the comment that more areas will have to demonstrate conformity for the first time due to the revisions to the NO2 NAAQS, given that today's final rule is requiring that near roadway monitoring be carried out in urban areas with populations greater than 350K, EPA believes that most areas with such populations that would be designated nonattainment for NO2 are already designated nonattainment or maintenance for one or more of the other transportation-related criteria pollutants (ozone, PM2.5, PM10 and carbon monoxide). As such, these areas would have experience in making transportation conformity determinations. If areas with no conformity experience are designated nonattainment for the NO2 NAAQS, EPA and U.S. DOT would be available to assist areas in implementing the transportation conformity requirements.

The commenter expressed concern that transportation conformity could stop highway and transit funding because areas could experience a conformity lapse and in such cases only certain types of projects could be funded. A conformity lapse occurs when an area misses a deadline for a required conformity determination. A new nonattainment area must demonstrate conformity within one year after the effective date of its designation. For any areas designated nonattainment for the revised NO2 NAAQS in early-2012, they would have to determine conformity within one year of the effective date of that designation which would be in early-2013. If that date was missed, a lapse would occur and only projects exempt from conformity such as safety projects, transportation control measures in an approved SIP for the area and projects or project phases that were approved by U.S. DOT before the lapse began can proceed during the lapse. EPA's experience in implementing the 1997 ozone and PM2.5 NAAQS shows that nearly all areas make their initial conformity determinations within the one-year grace period. Areas can also lapse if they fail to determine conformity by an applicable deadline such as determining conformity within two years after motor vehicle emissions budgets are found adequate. However, areas that miss one of these conformity deadlines have a one-year grace period before the lapse goes into effect. During the grace period, the area can continue to advance projects from the transportation plan and transportation improvement program. EPA's experience is that areas generally are able to make a conformity determination before the end of the grace period.

The commenter expressed concern that the NO2 NAAQS proposal did not contain sufficient detail concerning possible project-level requirements for transportation projects and that any requirements for hot-spot analyses could needlessly delay transportation projects. As EPA indicated in the NPRM, EPA is considering whether to revise the transportation conformity rule to establish requirements that would apply to transportation plans, transportation improvement programs and/or transportation projects in NO2 nonattainment and maintenance areas. If EPA concludes that the conformity rule must be revised in light of the final NO2 NAAQS, we will conduct notice and comment rulemaking to accomplish the revisions. At that time interested parties will have the opportunity to comment on any transportation conformity NPRM. This is the same course of action that EPA has taken with respect to revising the transportation conformity rule for the ozone and PM2.5 NAAQS.

With regard to the commenter's assertion that a requirement for hot-spot analyses for individual projects would needlessly delay transportation projects, EPA disagrees. First, CAA section 176(c)(1)(B) requires that transportation projects not cause new violations or make existing violations worse, or delay timely attainment or cause an interim milestone to be missed. EPA would only impose a hot-spot requirement for projects in NO2 nonattainment and maintenance areas if they are necessary to comply with CAA conformity requirements and therefore are needed to protect public health by reducing exposures to unhealthy levels of NO2 that could be created by the implementation of a proposed highway or transit project. The public would be exposed to unhealthy levels of NO2 if a highway or transit project caused a new violation of the NO2 NAAQS, made an existing violation worse, or delayed timely attainment or delayed achieving an interim emissions milestone. If any delay in the project did occur, it would not be viewed as needless as it occurred for the important purpose of protecting the exposed public's health. Second, EPA does not agree that requiring a hot-spot analysis would needlessly delay projects in NO2 nonattainment areas. Such hot-spot analyses, if they are eventually required, generally would be done as part of the NEPA process, which these projects are already subject to; therefore, conducting an NO2 hot-spot analysis would not be introducing a new step to a project's approval process, but rather would add one additional analysis which must be completed as part of an existing project approval process.

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c. Final

EPA is not making any changes to the discussion concerning transportation conformity as stated in the proposed rule.

VII. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. This section describes the conforming changes that were proposed, major comments received on these changes, EPA's responses to these comments and final decisions on the AQI breakpoints. Recognizing the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS, EPA proposed conforming changes to the AQI in connection with the final decision on the NO2 NAAQS if revisions to the primary standard were promulgated. Conforming changes would include setting the 100 level of the AQI at the same level as the revised primary NO2 NAAQS and also setting the other AQI breakpoints at the lower end of the AQI scale (i.e., AQI values of 50 and 150). EPA did not propose to change breakpoints at the higher end of the AQI scale (from 200 to 500), which would apply to State contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this review does not inform decisions about breakpoints at those higher levels.

With regard to an AQI value of 50, the breakpoint between the good and moderate categories, EPA proposed to set this value to be between 0.040 and 0.053 ppm NO2, 1-hour average. EPA proposed that the figure towards the lower end of this range would be appropriate if the standard is set towards the lower end of the proposed range for the standard (e.g. 80 ppb), while figures towards the higher end of the range would be more appropriate for standards set at the higher end of the range for the standard (e.g., 100 ppb). EPA noted that historically this value is set at the level of the annual NAAQS, if there is one, or one-half the level of the short-term NAAQS in the absence of an annual NAAQS, and solicited comments on this range for an AQI of 50 and the appropriate basis for selecting an AQI of 50 within this range.

With regard to an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, the range of 0.360 to 0.370 ppm NO2, 1-hour average, represents the midpoint between the proposed range for the short-term standard and the level of an AQI value of 200 (0.64 ppm NO2, 1-hour average). Therefore, EPA proposed to set the AQI value of 150 to be between 0.360 and 0.370 ppm NO2, 1-hour average.

EPA received comments from several State environmental agencies and organizations of State and local agencies that generally expressed the view that the AQI was designed to provide the public with information about regional air quality and therefore it should be based on community-wide monitors. These commenters went on to state that using near-road NO2 monitors for the AQI would present problems because they would not represent regional NO2 concentrations and it would be difficult to communicate this type of information to the public using the AQI. Some expressed concern that NO2 measured at near-roadway monitors could be the critical pollutant and could drive the AQI even though it may not represent air quality across the area. Other agencies expressed concern that there is currently no way to forecast ambient NO2 levels near roadways. One State agency commented that the AQI is intended to represent air quality where people live, work and play.

EPA agrees with commenters that the AQI should represent regional air quality, and that measurements that apply to a limited area should not be used to characterize air quality across the region. Community-wide NO2 monitors should be used to characterize air quality across the region. However, the AQI reporting requirements encourage, but do not require, the reporting of index values of sub-areas of an MSA. We agree with the commenter that stated the view that the AQI is intended to represent air quality where people live, work and play. To the extent that near-roadway monitoring occurs in areas where people live, work or play, EPA encourages reporting of the AQI for that specific sub-area of the MSA (64 FR 42548, August 4, 1999). We also agree that it may be difficult to communicate this type of information and we plan to work with State and local air agencies to figure out the best way to present this information to the public using the AQI. Air quality forecasting is recommended but not required (64 FR 42548, August 4, 1999). EPA will work with State agencies that want to develop a forecasting program.

With regard to the proposed breakpoints, EPA received few comments. The National Association of Clean Air Agencies commented that it would be confusing to the public to have an AQI value of 50 set below the level of the annual NO2 standard. We agree with this comment, and therefore have decided that it is appropriate to set the AQI value of 50, the breakpoint between the good and moderate ranges, set at the numerical level of the annual standard, 53 ppb NO2, 1-hour average. The AQI value of 100, the breakpoint between the moderate and unhealthy for sensitive groups category, is set at 100 ppb, 1-hour average, the level of the primary NO2 NAAQS. EPA is setting an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, at 0.360 ppm NO2, 1-hour average.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ``significant regulatory action'' because it was deemed to ``raise novel legal or policy issues.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in developing this final rule.

B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The information collection requirements are not enforceable until OMB approves them.

The Information Collection Request (ICR) document prepared by EPA for these revisions to part 58 has been assigned EPA ICR number 2358.02.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet

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the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). We do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with NO2 FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 2358.01). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The amendments would revise the technical requirements for NO2 monitoring sites, require the siting and operation of additional NO2 ambient air monitors, and the reporting of the collected ambient NO2 monitoring data to EPA's Air Quality System (AQS). The annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) is $3,261,007. Burden is defined at 5 CFR 1320.3(b). State, local, and Tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdlctions.

For purposes of assesslng the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of NO2 in ambient air as required by section 109 of the CAA. American Trucking Ass'ns v. EPA, 175 F.3d 1027, 1044-45 (DC cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The revisions to the NO2 NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed $100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the NO2 NAAQS. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the NO2 NAAQS. In this final rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Tribes. The rule does not alter the relationship between the

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Federal government and Tribes as established in the CAA and the TAR. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, this rule does not infringe existing Tribal authorities to regulate air quality under their own programs or under programs submitted to EPA for approval. Furthermore, this rule does not affect the flexibility afforded to Tribes in seeking to implement CAA programs consistent with the TAR, nor does it impose any new obligation on Tribes to adopt or implement any NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The final rule will establish uniform national ambient air quality standards for NO2; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. The protection offered by these standards may be especially important for asthmatics, including asthmatic children, because respiratory effects in asthmatics are among the most sensitive health endpoints for NO2 exposure. Because asthmatic children are considered a sensitive population, we have evaluated the potential health effects of exposure to NO2 pollution among asthmatic children. These effects and the size of the population affected are discussed in chapters 3 and 4 of the ISA; chapters 3, 4, and 8 of the REA, and sections II.A through II.E of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ``significant energy action'' as defined in Executive Order 13211, ``Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for NO2. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rulemaking involves technical standards. Therefore the Agency conducted a search to identify potential applicable voluntary consensus standards. However, we identified no such standards, and none were brought to our attention in comments. Therefore, EPA has decided to use the technical standard described in Section III.A of the preamble.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health effects on any population, including any minority or low-income population. The final rule will establish uniform national standards for NO2 in ambient air.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A Major rule cannot take effect until 60 days after it is published in the Federal Register. This action is a ``major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective on April 12, 2010.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 22, 2010.
Lisa P. Jackson,
Administrator.

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For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 50--NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

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1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

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2. Section 50.11 is revised to read as follows:

Sec. 50.11 National primary and secondary ambient air quality standards for oxides of nitrogen (with nitrogen dioxide as the indicator).

(a) The level of the national primary annual ambient air quality standard for oxides of nitrogen is 53 parts per billion (ppb, which is 1 part in 1,000,000,000), annual average concentration, measured in the ambient air as nitrogen dioxide.
(b) The level of the national primary 1-hour ambient air quality standard for oxides of nitrogen is 100 ppb, 1-hour average concentration, measured in the ambient air as nitrogen dioxide.
(c) The level of the national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.
(d) The levels of the standards shall be measured by:
(1) A reference method based on appendix F to this part; or
(2) By a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter.
(e) The annual primary standard is met when the annual average concentration in a calendar year is less than or equal to 53 ppb, as determined in accordance with Appendix S of this part for the annual standard.
(f) The 1-hour primary standard is met when the three-year average of the annual 98th percentile of the daily maximum 1-hour average concentration is less than or equal to 100 ppb, as determined in accordance with Appendix S of this part for the 1-hour standard.
(g) The secondary standard is attained when the annual arithmetic mean concentration in a calendar year is less than or equal to 0.053 ppm, rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm must be rounded up). To demonstrate attainment, an annual mean must be based upon hourly data that are at least 75 percent complete or upon data derived from manual methods that are at least 75 percent complete for the scheduled sampling days in each calendar quarter.

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3. Section 50.14 is amended by adding an entry to the end of table in paragraph (c)(2)(vi) to read as follows:

Sec. 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *
(c) * * *
(2) * * *
(vi) * * *

Table 1--Schedule for Exceptional Event Flagging and Documentation Submission for Data To Be Used in Designations Decisions for New or Revised NAAQS

NAAQS pollutant/ standard/ (level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
	* * * * * * *		
NO2/1-Hour Standard (100 PPB)........	2008	July 1, 2010 \a\........	January 22, 2011.
	2009	July 1, 2010...........	January 22, 2011.
	2010	April 1, 2011 \a\.......	July 1, 2011 \a\.

\a\ Indicates change from general schedule in 40 CFR 50.14.
Note: EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

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4. Appendix S to Part 50 is added to read as follows:

Appendix S to Part 50--Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen (Nitrogen Dioxide)

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for oxides of nitrogen as measured by nitrogen dioxide (``NO2 NAAQS'') specified in 50.11 are met. Nitrogen dioxide (NO2) is measured in the ambient air by a Federal reference method (FRM) based on appendix F to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported NO2 concentrations and the levels of the NO2 NAAQS are specified in the following sections.
(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in 50.1, 50.14 and 51.930 of this chapter.
(c) The terms used in this appendix are defined as follows:
Annual mean refers to the annual average of all of the 1-hour concentration values as defined in section 5.1 of this appendix.
Daily maximum 1-hour values for NO2 refers to the maximum 1-hour NO2 concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.
Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance, calculated as specified in section 5 of this appendix. The design values for the primary NAAQS are:
(1) The annual mean value for a monitoring site for one year (referred to as the ``annual primary standard design value'').
(2) The 3-year average of annual 98th percentile daily maximum 1-hour values for a monitoring site (referred to as the ``1-hour primary standard design value'').
98th percentile daily maximum 1-hour value is the value below which nominally 98 percent of all daily maximum 1-hour concentration values fall, using the ranking and selection method specified in section 5.2 of this appendix.
Quarter refers to a calendar quarter.
Year refers to a calendar year.

2. Requirements for Data Used for Comparisons With the NO2 NAAQS and Data Reporting Considerations

(a) All valid FRM/FEM NO2 hourly data required to be submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.
(b) When two or more NO2 monitors are operated at a site, the State may in advance designate one of them as the primary monitor. If the State has not made this designation, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a

valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the State has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

3. Comparisons With the NO2 NAAQS

3.1 The Annual Primary NO2 NAAQS

(a) The annual primary NO2 NAAQS is met at a site when the valid annual primary standard design value is less than or equal to 53 parts per billion (ppb).

(b) An annual primary standard design value is valid when at least 75 percent of the hours in the year are reported.

(c) An annual primary standard design value based on data that do not meet the completeness criteria stated in section 3.1(b) may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(d) The procedures for calculating the annual primary standard design values are given in section 5.1 of this appendix.

3.2 The 1-hour Primary NO2 NAAQS

(a) The 1-hour primary NO2 NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to 100 parts per billion (ppb).

(b) An NO2 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if one of the following conditions is true.

(i) At least 75 percent of the days in each quarter of each of three consecutive years have at least one reported hourly value, and the design value calculated according to the procedures specified in section 5.2 is above the level of the primary 1-hour standard.

(ii)(A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3.2(c)(ii)(B) results in a ``test design value'' that is below the level of the NAAQS. The test substitutes actual ``high'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same calendar quarter) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the ``test design value'', as defined in section 3.2(c)(ii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator; if any quarter has less than 50 percent data capture then this substitution test cannot be used. Identify for each quarter (e.g., January-March) the highest reported daily maximum 1-hour value for that quarter, excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than

75 percent data capture. If after substituting the highest non-excluded reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ``test design value'' below the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been met in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

(iii)(A) A 1-hour primary standard design value that is above the level of the NAAQS can be validated if the substitution test in section 3.2(c)(iii)(B) results in a ``test design value'' that is above the level of the NAAQS. The test substitutes actual ``low'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same three months of the calendar) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true above-NAAQS-level status for that 3-year period; the result of this data substitution test (the ``test design value'', as defined in section 3.2(c)(iii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are a minimum number of available daily data points from which to identify the low quarter-specific daily maximum 1-hour values, specifically if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. Only days with at least 75 percent of the hours reported shall be considered in identifying the low value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture. Identify for each quarter (e.g., January-March) the lowest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days with at least 75 percent capture in the quarter period shall be considered when identifying this lowest value. If after substituting the lowest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 75 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ``test design value'' above the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been exceeded in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in 3.2(b) and also do not satisfy section 3.2(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5.2 of this appendix.

4. Rounding Conventions

4.1 Rounding Conventions for the Annual Primary NO2 NAAQS

(a) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) The annual primary standard design value is calculated pursuant to section 5.1 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.2 Rounding Conventions for the 1-hour Primary NO2 NAAQS

(a) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5.2 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the Primary NO2 NAAQS

5.1 Procedures for the Annual Primary NO2 NAAQS

(a) When the data for a site and year meet the data completeness requirements in section 3.1(b) of this appendix, or if the Administrator exercises the discretionary authority in section 3.1(c), the annual mean is simply the arithmetic average of all of the reported 1-hour values.

(b) The annual primary standard design value for a site is the valid annual mean rounded according to the conventions in section 4.1.

5.2 Calculation Procedures for the 1-hour Primary NO2 NAAQS

(a) Procedure for identifying annual 98th percentile values. When the data for a particular site and year meet the data completeness requirements in section 3.2(b), or if one of the conditions of section 3.2(c) is met, or if the Administrator exercises the discretionary authority in section 3.2(d), identification of annual 98th percentile value is accomplished as follows.

(i) The annual 98th percentile value for a year is the higher of the two values resulting from the following two procedures.

(1) Procedure 1.

(A) For the year, determine the number of days with at least 75 percent of the hourly values reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum hourly values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cny) as determined from step (A). The corresponding ``n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, P0.98, y = the nth largest value.

(2) Procedure 2.

(A) For the year, determine the number of days with at least one hourly value reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from all the days with at least one hourly value reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cny) as determined from step (A). The corresponding ``n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, P0.98, y = the nth largest value.

(b) The 1-hour primary standard design value for a site is mean of the three annual 98th percentile values, rounded according to the conventions in section 4.

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Table 1

Annual number of days with valid data for year ``y'' (cny)	P0.98, y is the nth maximum value of the year, where n is the listed number
1-50	1
51-100	2
101-150	3
151-200	4
201-250	5
251-300	6
301-350	7
351-366	8

PART 58--AMBIENT AIR QUALITY SURVEILLANCE

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5. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart A--[Amended]

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6. Section 58.1, is amended by adding the definitions for ``AADT'' and ``Near-road NO2 Monitor'' in alphabetical order to read as follows:

Sec. 58.1 Definitions

* * * * *

AADT means the annual average daily traffic.

* * *

Near-road NO2 Monitor means any NO2 monitor meeting the specifications in 4.3.2 of Appendix D and paragraphs 2, 4(d), 6.1, and 6.4 of Appendix E of this part.

* * * * *

Subpart B [Amended]

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7. Section 58.10, is amended by adding paragraphs (a)(5) and (b)(12) to read as follows:

Sec. 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(5) A plan for establishing NO2 monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the Administrator by July 1, 2012. The plan shall provide for all required monitoring stations to be operational by January 1, 2013.

* * * * *

(b) * * *

(12) The identification of required NO2 monitors as either near-road or area-wide sites in accordance with Appendix D, Section 4.3 of this part.

* * * * *

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8. Section 58.13 is amended by adding paragraph (c) to read as follows:

Sec. 58.13 Monitoring network completion.

* * * * *

(c) The network of NO2 monitors must be physically established no later than January 1, 2013, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

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9. Section 58.16 is amended by revising paragraph (a) to read as follows:

Sec. 58.16 Data submittal and archiving requirements.

* * * * *

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO2; CO; O3; NO2; NO; NOY; NOX; Pb-TSP mass concentration; Pb-PM10 mass concentration; PM10 mass concentration; PM2.5mass concentration; for filter-based PM2.5FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated PM2.5 mass concentration data; PM10-2.5 mass concentration; chemically speciated PM10-2.5 mass concentration data; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm). The State, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

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10. Appendix A to Part 58 is amended by adding paragraph 2.3.1.5 to read as follows:

Appendix A to Part 58--Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

2.3.1.5 Measurement Uncertainty for NO2. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

* * * * *

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11. Appendix C to Part 58 is amended by adding paragraph 2.1.1 to read as follows:

Appendix C to Part 58--Ambient Air Quality Monitoring Methodology

* * * * *

2.1.1 Any NO2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data.

* * * * *

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12. Appendix D to Part 58 is amended by revising paragraph 4.3 to read as follows:

Appendix D to Part 58--Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.3 Nitrogen Dioxide (NO2) Design Criteria

4.3.1 General Requirements

(a) State and, where appropriate, local agencies must operate a minimum number of required NO2 monitoring sites as described below.

4.3.2 Requirement for Near-road NO2 Monitors

(a) Within the NO2 network, there must be one microscale near-road NO2 monitoring station in each CBSA with a population of 500,000 or more persons to monitor a location of expected maximum hourly concentrations sited near a major road with high AADT counts as specified in paragraph 4.3.2(a)(1) of this appendix. An additional near-road NO2 monitoring station is required for any CBSA with a population of 2,500,000 persons or more, or in any CBSA with a population of 500,000 or more persons that has one or more roadway segments with 250,000 or greater AADT counts to monitor a second location of expected maximum hourly concentrations. CBSA populations shall be based on the latest available census figures.

(1) The near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO2 concentrations are expected to occur and siting criteria can be met in accordance with appendix E of this part. Where a State or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO2 concentrations are expected to occur, the monitoring agency shall consider the potential for population exposure in the criteria utilized to select the final site location. Where one CBSA is required to have two near-road NO2 monitoring stations, the sites shall be differentiated from each other by one or more of the following factors: fleet mix; congestion patterns; terrain; geographic area within the

[[Page 6535]]

CBSA; or different route, interstate, or freeway designation.

(b) Measurements at required near-road NO2 monitor sites utilizing chemiluminescence FRMs must include at a minimum: NO, NO2, and NOX.

4.3.3 Requirement for Area-wide NO2 Monitoring

(a) Within the NO2 network, there must be one monitoring station in each CBSA with a population of 1,000,000 or more persons to monitor a location of expected highest NO2 concentrations representing the neighborhood or larger spatial scales. PAMS sites collecting NO2 data that are situated in an area of expected high NO2 concentrations at the neighborhood or larger spatial scale may be used to satisfy this minimum monitoring requirement when the NO2 monitor is operated year round. Emission inventories and meteorological analysis should be used to identify the appropriate locations within a CBSA for locating required area-wide NO2 monitoring stations. CBSA populations shall be based on the latest available census figures.

4.3.4 Regional Administrator Required Monitoring

(a) The Regional Administrators, in collaboration with States, must require a minimum of forty additional NO2 monitoring stations nationwide in any area, inside or outside of CBSAs, above the minimum monitoring requirements, with a primary focus on siting these monitors in locations to protect susceptible and vulnerable populations. The Regional Administrators, working with States, may also consider additional factors described in paragraph (b) below to require monitors beyond the minimum network requirement.

(b) The Regional Administrators may require monitors to be sited inside or outside of CBSAs in which:

(i) The required near-road monitors do not represent all locations of expected maximum hourly NO2 concentrations in an area and NO2 concentrations may be approaching or exceeding the NAAQS in that area;

(ii) Areas that are not required to have a monitor in accordance with the monitoring requirements and NO2 concentrations may be approaching or exceeding the NAAQS; or

(iii) The minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives.

(c) The Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO2 network to address the data needs for an area, and include all monitors under this provision in the annual monitoring network plan.

4.3.5 NO2 Monitoring Spatial Scales

(a) The most important spatial scale for near-road NO2 monitoring stations to effectively characterize the maximum expected hourly NO2 concentration due to mobile source emissions on major roadways is the microscale. The most important spatial scales for other monitoring stations characterizing maximum expected hourly NO2 concentrations are the microscale and middle scale. The most important spatial scale for area-wide monitoring of high NO2 concentrations is the neighborhood scale.

(1) Microscale--This scale represents areas in close proximity to major roadways or point and area sources. Emissions from roadways result in high ground level NO2 concentrations at the microscale, where concentration gradients generally exhibit a marked decrease with increasing downwind distance from major roads. As noted in appendix E of this part, near-road NO2 monitoring stations are required to be within 50 meters of target road segments in order to measure expected peak concentrations. Emissions from stationary point and area sources, and non-road sources may, under certain plume conditions, result in high ground level concentrations at the microscale. The microscale typically represents an area impacted by the plume with dimensions extending up to approximately 100 meters.

(2) Middle scale--This scale generally represents air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may include locations of expected maximum hourly concentrations due to proximity to major NO2 point, area, and/or non-road sources.

(3) Neighborhood scale--The neighborhood scale represents air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Emissions from stationary point and area sources may, under certain plume conditions, result in high NO2 concentrations at the neighborhood scale. Where a neighborhood site is located away from immediate NO2 sources, the site may be useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(4) Urban scale--Measurements in this scale would be used to estimate concentrations over large portions of an urban area with dimensions from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Urban scale sites may also support other monitoring objectives of the NO2 monitoring network identified in paragraph 4.3.4 above.

4.3.6 NOy Monitoring

(a) NO/NOy measurements are included within the NCore multi-pollutant site requirements and the PAMS program. These NO/NOy measurements will produce conservative estimates for NO2 that can be used to ensure tracking continued compliance with the NO2 NAAQS. NO/NOy monitors are used at these sites because it is important to collect data on total reactive nitrogen species for understanding O3 photochemistry.

* * * * *

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13. Appendix E to Part 58 is amended as follows:

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a. By revising paragraphs 2, and 6.1.

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b. By adding paragraphs 4(d) and 6.4.

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c. By revising paragraphs 9(c), 11 and Table E-4.

Appendix E to Part 58--Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

2. Horizontal and Vertical Placement

The probe or at least 80 percent of the monitoring path must be located between 2 and 15 meters above ground level for all ozone and sulfur dioxide monitoring sites, and for neighborhood or larger spatial scale Pb, PM10, PM10-2.5, PM2.5, NO2 and carbon monoxide sites. Middle scale PM10-2.5 sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale Pb, PM10, PM10-2.5 and PM2.5 sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale near-road NO2 monitoring sites are required to have sampler inlets between 2 and 7 meters above ground level. The inlet probes for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be 3\1/2\ meters above ground level. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building or wall, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest concentration potential for the pollutant being measured.

* * * * *

4. * * *

(d) For near-road NO2 monitoring stations, the monitor probe shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment.

* * * * *

6. * * *

6.1 Spacing for Ozone Probes and Monitoring Paths

In siting an O3 analyzer, it is important to minimize destructive interferences form sources of NO, since NO readily reacts with O3. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as microscale or middle scale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent the middle scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring

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path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from the Table E-1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

* * * * *

6.4 Spacing for Nitrogen Dioxide (NO2) Probes and Monitoring Paths

(a) In siting near-road NO2 monitors as required in paragraph 4.3.2 of appendix D of this part, the monitor probe shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment.

(b) In siting NO2 monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference form automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined form the Table E-1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

* * * * *

9. * * *

(c) No matter how nonreactive the sampling probe material is initially, after a period of use reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is also critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses even in the most inert probe material when the residence time exceeds 20 seconds.\26\ Other studies \27-28\ indicate that a 10 second or less residence time is easily achievable. Therefore, sampling probes for reactive gas monitors at NCore and at NO2 sites must have a sample residence time less than 20 seconds.

* * * * *

11. Summary

Table E-4 of this appendix presents a summary of the general requirements for probe and monitoring path siting criteria with respect to distances and heights. It is apparent from Table E-4 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor, probe, or monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For CO and near-road NO2 monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a single manifold or monitoring path for monitoring more than one pollutant.

Table E-4 of Appendix E to Part 58. Summary of Probe and Monitoring Path Siting Criteria

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path \1\	Horizontal and vertical distance from supporting structures\2\ to probe, inlet or 90% of monitoring path\1\ (meters)	Distance from trees to probe, inlet or 90% of monitoring path\1\ (meters)	Dista roadway inlet or path\1
SO2 3,4,5,6	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2-15	>1	>10	N/A
CO 4,5,7	Micro, middle (300 m), Neighborhood (1 km).	3\1/2\: 2-15	>1	>10	2-10; see of this middle a neighbor
O3 3,4,5	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2-15	>1	>10	See Table appendix scales.
NO2 3,4,5	Micro (Near-road [50-300]).	2-7 (micro);	>1	>10	<=50 mete road mic
	Middle (300m)	2-15 (all other scales).			
	Neighborhood, Urban, and Regional (1 km).				See Table appendix other sc
Ozone precursors (for PAMS) 3 4 5	Neighborhood and Urban (1 km).	2-15	>1	>10	See Table appendix scales.
PM, Pb 3,4,5,6,8	Micro: Middle, Neighborhood, Urban and Regional.	2-7 (micro); 2-7 (middle PM10 2.5); 15 (all other scales).	>2 (all scales, horizontal distance only).	>10 (all scales)	2-10 (mic Fig appendix other sc

N/A--Not applicable.
\1\ Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, a scale NO2 monitoring, and all applicable scales for monitoring SO2,O3, and O3 precursors.
\2\ When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.
\3\ Should be >20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.
\4\ Distance from sampler, probe, or 90% of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (see text).
\5\ Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.

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\6\ The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fu ash, or lead content). This criterion is designed to avoid undue influences from minor sources.
\7\ For microscale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.
\8\ Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at 1 apart for samplers having flow rates less than 200 liters/min to preclude airflow interference.

* * * * *

14. Appendix G to Part 58 is amended as by revising paragraph 9 and Table 2 to read as follows:

Appendix G to Part 58--Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How Does the AQI Relate to Air Pollution Levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term (i.e., averaging time of 24-hours or less) standard for each pollutant. The index value of 50 is associated with one of the following: the numerical level of the annual standard for a pollutant, if there is one; one-half the level of the short-term standard for the pollutant; or the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects that affect increasing proportions of the population. An index value is calculated each day for each pollutant (as described in section 12 of this appendix), unless that pollutant is specifically excluded (see section 8 of this appendix). The pollutant with the highest index value for the day is the ``critical'' pollutant, and must be included in the daily AQI report. As a result, the AQI for any given day is equal to the index value of the critical pollutant for that day. For the purposes of reporting the AQI, the indexes for PM10 and PM2.5 are to be considered separately.

* * * * *

Table 2--Breakpoints for the AQI

These breakpoints	Equal these AQIs

O3 (ppm) 8-hour	O3 (ppm) 1-hour\1\	PM2.5 ([micro]g/m\3\)	PM10 ([micro]g/m\3\)	CO (ppm)	SO2 (ppm)	NO2 (ppm) 1-hour	AQI	Category
0.000-0.059	....	0.0-15.4	0-54	0.0-4.4	0.000-0.034	0-0.053	0-50	Good.
0.060-0.075	....	15.5-40.4	55-154	4.5-9.4	0.035-0.144	0.054-0.100	51-100	Moderate.
0.076-0.095	0.125-0.164	40.5-65.4	155-254	9.5-12.4	0.145-0.224	0.101-0.360	101-150	Unhealthy for Sensitive Groups.
0.096-0.115	0.165-0.204	\3\ 65.5-150.4	255-354	12.5-15.4	0.225-0.304	0.361-0.64	151-200	Unhealthy.
0.116-0.374	0.205-0.404	\3\ 150.5-250.4	355-424	15.5-30.4	0.305-0.604	0.65-1.24	201-300	Very Unhealthy.
(\2\)	0.405-0.504	\3\ 250.5-350.4	425-504	30.5-40.4	0.605-0.804	1.25-1.64	301-400	Hazardous.
(\2\)	0.505-0.604	\3\ 350.5-500.4	505-604	40.5-50.4	0.805-1.004	1.65-2.04	401-500	Hazardous.

\1\ Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI bas ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index calculated, and the maximum of the two values reported.

\2\ 8-hours O3 values do not define higher AQI values (>=301). AQI values of 301 or greater are calculated with 1-hour O3 concentrations.

\3\ If a different SHL for PM2.5 is promulgated, these numbers will change accordingly.

[FR Doc. 2010-1990 Filed 2-8-10; 8:45 am]
BILLING CODE 6560-50-P

[Federal Register Volume 75, Number 26 (Tuesday, February 9, 2010)]
[Rules and Regulations]
[Pages 6473-6537]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2010-1990]

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Part III

Environmental Protection Agency

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40 CFR Parts 50 and 58

Primary National Ambient Air Quality Standards for Nitrogen Dioxide; Final Rule

Federal Register / Vol. 75, No. 26 / Tuesday, February 9, 2010 / Rules and Regulations

[[Page 6474]]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 58

[EPA-HQ-OAR-2006-0922; FRL 9107-9]
RIN 2060-AO19

Primary National Ambient Air Quality Standards for Nitrogen Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Based on its review of the air quality criteria for oxides of nitrogen and the primary national ambient air quality standard (NAAQS) for oxides of nitrogen as measured by nitrogen dioxide (NO_2), EPA is making revisions to the primary NO_2 NAAQS in order to provide requisite protection of public health. Specifically, EPA is establishing a new 1-hour standard at a level of 100 ppb, based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations, to supplement the existing annual standard. EPA is also establishing requirements for an NO_2 monitoring network that will include monitors at locations where maximum NO_2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO_2 concentrations that occur more broadly across communities.

DATES: This final rule is effective on April 12, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2006-0922. All documents in the docket are listed on the http://www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through http://www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Dr. Scott Jenkins, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-1167; fax: 919-541-0237; e-mail: jenkins.scott@epa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

The following topics are discussed in this preamble:

I. Background

A. Summary of Revisions to the NO2 Primary NAAQS

Based on its review of the air quality criteria for oxides of nitrogen and the primary national ambient air quality standard (NAAQS) for oxides of nitrogen as measured by nitrogen dioxide (NO2), EPA is making revisions to the primary NO2 NAAQS in order to provide requisite protection of public health as appropriate under section 109 of the Clean Air Act (Act or CAA). Specifically, EPA is supplementing the existing annual standard for NO2 of 53 parts per billion (ppb) by establishing a new short-term standard based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. EPA is setting the level of this new standard at 100 ppb. EPA is making changes in data handling conventions for NO2 by adding provisions for this new 1-hour primary standard. EPA is also establishing requirements for an NO2 monitoring network. These new provisions require monitors at locations where maximum NO2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO2 concentrations that occur more broadly across communities. EPA is making conforming changes to the air quality index (AQI).

B. Legislative Requirements

Two sections of the CAA govern the establishment and revision of the NAAQS. Section 108 of the Act directs the Administrator to identify and list air pollutants that meet certain criteria, including that the air pollutant ``in [her] judgment, cause[s] or contribute[s] to air pollution which may reasonably be anticipated to endanger public health and welfare'' and ``the presence of which in the ambient air results from numerous or diverse mobile or stationary sources.'' 42 U.S.C. 21 7408(a)(1)(A) & (B). For those air pollutants listed, section 108 requires the Administrator to issue air quality criteria that ``accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *'' 42 U.S.C. 7408(2).

Section 109(a) of the Act directs the Administrator to promulgate ``primary'' and ``secondary'' NAAQS for pollutants for which air quality criteria have been issued. 42 U.S.C. 7409(1).\1\ Section 109(b)(1) defines a primary standard as one ``the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' \2\ 42 U.S.C. 7409(b)(1). A secondary standard, in turn, must ``specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such pollutant in the ambient air.'' \3\ 42 U.S.C. 7409(b)(2).

\1\ EPA notes that as the promulgation of a NAAQS is identified in section 307(d)(1) of the Clean Air Act, all of the provisions of this rulemaking are subject to the requirements of section 307(d) of the Clean Air Act.

\2\ The legislative history of section 109 indicates that a primary standard is to be set at ``the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ``reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10(1970).

\3\ EPA is currently conducting a separate review of the secondary NO2 NAAQS jointly with a review of the secondary SO2 NAAQS.

The requirement that primary standards include an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified. Lead Industries Association v. EPA, 647 F.2d 1130, 1154 (DC Cir 1980), cert. denied, 449 U.S.

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1042 (1980); American Petroleum Institute v. Costle, 665 F.2d 1176, 1186 (DC Cir. 1981), cert. denied, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In addressing the requirement for a margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. Lead Industries Association v. EPA, supra, 647 F.2d at 1161-62.

In setting standards that are ``requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. Whitman v. American Trucking Associations, 531 U.S. 457, 471, 475-76 (2001).

Section 109(d)(1) of the Act requires the Administrator to periodically undertake a thorough review of the air quality criteria published under section 108 and the NAAQS and to revise the criteria and standards as may be appropriate. 42 U.S.C. 7409(d)(1). The Act also requires the Administrator to appoint an independent scientific review committee composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies, to review the air quality criteria and NAAQS and to ``recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.'' 42 U.S.C. 7409(d)(2). This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

C. Related NO2 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program that covers these pollutants. See 42 U.S.C. 7470-7479. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521-7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

Currently there are no areas in the United States that are designated as nonattainment of the NO2 NAAQS. With the revisions to the NO2 NAAQS that result from this review, however, some areas could be classified as non-attainment. Certain States will be required to develop SIPs that identify and implement specific air pollution control measures to reduce ambient NO2 concentrations to attain and maintain the revised NO2 NAAQS, most likely by requiring air pollution controls on sources that emit oxides of nitrogen (NOX).\4\

\4\ In this document, the terms ``oxides of nitrogen'' and ``nitrogen oxides'' (NOX) refer to all forms of oxidized nitrogen (N) compounds, including NO, NO2, and all other oxidized N-containing compounds formed from NO and NO2. This follows usage in the Clean Air Act Section 108(c): ``Such criteria [for oxides of nitrogen] shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.'' By contrast, within the air pollution research and control communities, the terms ``oxides of nitrogen'' and ``nitrogen oxides'' are restricted to refer only to the sum of NO and NO2, and this sum is commonly abbreviated as NOX. The category label used by this community for the sum of all forms of oxidized nitrogen compounds including those listed in Section 108(c) is NOY.

While NOX is emitted from a wide variety of source types, the top three categories of sources of NOX emissions are on-road mobile sources, electricity generating units, and non-road mobile sources. EPA anticipates that NOX emissions will decrease substantially over the next 20 years as a result of the ongoing implementation of mobile source emissions standards. In particular, Tier 2 NOX emission standards for light-duty vehicle emissions began phasing into the fleet beginning with model year 2004, in combination with low-sulfur gasoline fuel standards. For heavy-duty engines, new NOX standards are phasing in between the 2007 and 2010 model years, following the introduction of ultra-low sulfur diesel fuel. Lower NOX standards for nonroad diesel engines, locomotives, and certain marine engines are becoming effective throughout the next decade. In future decades, these lower-NOX vehicles and engines will become an increasingly large fraction of in-use mobile sources, effecting large NOX emission reductions.

D. Review of the Air Quality Criteria and Standards for Oxides of Nitrogen

On April 30, 1971, EPA promulgated identical primary and secondary NAAQS for NO2 under section 109 of the Act. The standards were set at 0.053 parts per million (ppm) (53 ppb), annual average (36 FR 8186). EPA completed reviews of the air quality criteria and NO2 standards in 1985 and 1996 with decisions to retain the standard (50 FR 25532, June 19, 1985; 61 FR 52852, October 8, 1996).

EPA initiated the current review of the air quality criteria for oxides of nitrogen and the NO2 primary NAAQS on December 9, 2005 (70 FR 73236) with a general call for information. EPA's draft Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide (EPA, 2007a) was made available in February, 2007 for public comment and was discussed by the CASAC via a publicly accessible teleconference on May 11, 2007. As noted in that plan, NOX includes multiple gaseous (e.g., NO2, NO) and particulate (e.g., nitrate) species. Because the health effects associated with particulate species of NOX have been considered within the context of the health effects of ambient particles in the Agency's review of the NAAQS for particulate matter (PM), the current review of the primary NO2 NAAQS is focused on the gaseous species of NOX and is not intended to address health effects directly associated with particulate species.

The first draft of the Integrated Science Assessment for Oxides of Nitrogen-Health Criteria (ISA) and the Nitrogen Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment (EPA, 2007b) were reviewed by CASAC at a public meeting held on October 24-25, 2007. Based on comments received from CASAC and the public, EPA developed the second

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draft of the ISA and the first draft of the Risk and Exposure Assessment to Support the Review of the NO2 Primary National Ambient Air Quality Standard (Risk and Exposure Assessment (REA)). These documents were reviewed by CASAC at a public meeting held on May 1-2, 2008. Based on comments received from CASAC and the public at this meeting, EPA released the final ISA in July of 2008 (EPA, 2008a). In addition, comments received were considered in developing the second draft of the REA, which was released for public review and comment in two parts. The first part of this document, containing chapters 1-7, 9 and appendices A and C as well as part of appendix B, was released in August 2008. The second part of this document, containing chapter 8 (describing the Atlanta exposure assessment) and a completed appendix B, was released in October of 2008. This document was the subject of CASAC reviews at public meetings on September 9 and 10, 2008 (for the first part) and on October 22, 2008 (for the second part). In preparing the final REA (EPA, 2008b), EPA considered comments received from the CASAC and the public at those meetings.

In the course of reviewing the second draft REA, CASAC expressed the view that the document would be incomplete without the addition of a policy assessment chapter presenting an integration of evidence-based considerations and risk and exposure assessment results. CASAC stated that such a chapter would be ``critical for considering options for the NAAQS for NO2'' (Samet, 2008a). In addition, within the period of CASAC's review of the second draft REA, EPA's Deputy Administrator indicated in a letter to the chair of CASAC, addressing earlier CASAC comments on the NAAQS review process, that the risk and exposure assessment will include ``a broader discussion of the science and how uncertainties may effect decisions on the standard'' and ``all analyses and approaches for considering the level of the standard under review, including risk assessment and weight of evidence methodologies'' (Peacock, 2008, p. 3; September 8, 2008).

Accordingly, the final REA included a new policy assessment chapter. This policy assessment chapter considered the scientific evidence in the ISA and the exposure and risk characterization results presented in other chapters of the REA as they relate to the adequacy of the current NO2 primary NAAQS and potential alternative primary NO2 standards. In considering the current and potential alternative standards, the policy assessment chapter of the final REA focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: Indicator, averaging time, form,\5\ and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the health protection afforded. CASAC discussed the final version of the REA, with an emphasis on the policy assessment chapter, during a public teleconference held on December 5, 2008. Following that teleconference, CASAC offered comments and advice on the NO2 primary NAAQS in a letter to the Administrator (Samet, 2008b).

\5\ The ``form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

The schedule for completion of this review is governed by a judicial order resolving a lawsuit filed in September 2005, concerning the timing of the current review. The order that now governs this review, entered by the court in August 2007 and amended in December 2008, provides that the Administrator will sign, for publication, notices of proposed and final rulemaking concerning the review of the primary NO2 NAAQS no later than June 26, 2009 and January 22, 2010, respectively. In accordance with this schedule, the Administrator signed a notice of proposed rulemaking on June 26, 2009 (FR 74 34404). This action presents the Administrator's final decisions on the primary NO2 standard.

E. Summary of Proposed Revisions to the NO2 Primary NAAQS

For the reasons discussed in the preamble of the proposal for the NO2 primary NAAQS (74 FR 34404), EPA proposed to make revisions to the primary NO2 NAAQS and to make related revisions for NO2 data handling conventions in order to provide requisite protection of public health. EPA also proposed to make corresponding changes to the AQI for NO2. Specifically, EPA proposed to supplement the current annual standard by establishing a new short-term NO2 standard that would reflect the maximum allowable NO2 concentration anywhere in an area. EPA proposed that this new short-term standard would be based on the 3-year average of the 99th percentile (or 4th highest) of the yearly distribution of 1[dash]hour daily maximum NO2 concentrations and solicited comment on using the 3-year average of the 98th percentile (or 7th or 8th highest) of the yearly distribution of 1-hour daily maximum NO2 concentrations. EPA proposed to set the level of this new 1-hour standard within the range of 80 to 100 ppb and solicited comment on standard levels as low as 65 ppb and as high as 150 ppb. EPA proposed to specify the level of the standard to the nearest ppb. EPA also proposed to establish requirements for an NO2 monitoring network at locations where maximum NO2 concentrations are expected to occur, including monitors within 50 meters of major roadways, as well as area-wide monitors sited to measure the NO2 concentrations that can occur more broadly across communities. EPA also solicited comment on the alternative approach of setting a 1-hour standard that would reflect the allowable area-wide NO2 concentration.

F. Organization and Approach to Final NO2 Primary NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current NO2 primary NAAQS. Revisions to the primary NAAQS for NO2, and the rationale supporting those revisions, are described below in section II. Requirements for the NO2 ambient monitoring network are described in section III. Related requirements for data completeness, data handling, data reporting, rounding conventions, and exceptional events are described in section IV. Implementation of the revised NO2 primary NAAQS is discussed in sections V and VI. Communication of public health information through the AQI is discussed in section VII and a discussion of statutory and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the ISA of scientific information on known and potential human health effects associated with exposure to NO2 in the air. These final decisions also take into account: (1) Assessments in the REA of the most policy-relevant information in the ISA as well as quantitative exposure and risk analyses based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator and its public discussions of the ISA, the REA, and the notice of proposed rulemaking; (3) public comments received during the development of ISA and REA; and (4) public comments received on the proposed rulemaking.

Some commenters have referred to and discussed individual scientific analyses on the health effects of NO2 that were not included in the ISA (EPA, 2008a) (``new studies''). In considering

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and responding to comments for which such ``new studies'' were cited in support, EPA has provisionally considered the cited studies in the context of the findings of the ISA.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the ISA and staff's policy assessment, which have undergone CASAC and public review. In this NO2 NAAQS review, staff's policy assessment was presented in the form of a policy assessment chapter of the REA (EPA, 2008b). The studies assessed in the ISA and REA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. EPA's provisional consideration of ``new studies'' did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. See 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone (O3), ``new studies'' may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013-13014, March 9, 1993). In the present case, EPA's provisional consideration of ``new studies'' concludes that, taken in context, the ``new'' information and findings do not materially change any of the broad scientific conclusions regarding the health effects of NO2 made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the NO2 air quality criteria that have undergone CASAC and public review. EPA will consider the ``new studies'' for purposes of decision-making in the next periodic review of the NO2 NAAQS, which will provide the opportunity to fully assess these studies through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these ``new studies'' can be found below, in section II.E, and in the Response to Comments document.

II. Rationale for Final Decisions on the NO2 Primary Standard

This section presents the rationale for the Administrator's decision to revise the existing NO2 primary standard by supplementing the current annual standard with a new 1-hour standard. In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence on human health effects associated with the presence of NO2 in the air. As summarized below in section II.B, this body of evidence addresses a broad range of health endpoints associated with exposure to NO2. In considering this entire body of evidence, EPA focuses in particular on those health endpoints for which the ISA finds associations with NO2 to be causal or likely causal. This rationale also draws upon the results of quantitative exposure and risk assessments, summarized below in section II.C.

As discussed below, a substantial amount of new research has been conducted since the last review of the NO2 NAAQS, with important new information coming from epidemiologic studies in particular. The newly available research studies evaluated in the ISA have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. While important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to exposure to ambient NO2, the review of this information has been extensive and deliberate.

The remainder of this section provides background information that informed the Administrator's decisions on the primary standard and discusses the rationale for those decisions. Section II.A presents a discussion of NO2 air quality. Section II.B includes an overview of the scientific evidence related to health effects associated with NO2 exposure. This overview includes discussion of the health endpoints and at-risk populations considered in the ISA. Section II.C discusses the approaches taken by EPA to assess exposures and health risks associated with NO2, including a discussion of key results. Section II.D summarizes the approach that was used in the current review of the NO2 NAAQS with regard to consideration of the scientific evidence and exposure-/risk-based results related to the adequacy of the current standard and potential alternative standards. Sections II.E-II.G discuss the Administrator's decisions regarding the adequacy of the current standard, elements of a new 1-hour standard, and retention of the current annual standard, respectively, taking into consideration public comments on the proposed decisions. Section II.H summarizes the Administrator's decisions with regard to the NO2 primary NAAQS.

A. Characterization of NO2 Air Quality

1. Current Patterns of NO2 Air Quality

The size of the State and local NO2 monitoring network has remained relatively stable since the early 1980s, and currently has approximately 400 monitors reporting data to EPA's Air Quality System (AQS) database.\6\ At present, there are no minimum monitoring requirements for NO2 in 40 CFR part 58 Appendix D, other than a requirement for EPA Regional Administrator approval before removing any existing monitors, and that any ongoing NO2 monitoring must have at least one monitor sited to measure the maximum concentration of NO2 in that area (though, as discussed below monitors in the current network do not measure peak concentrations associated with on-road mobile sources that can occur near major roadways because the network was not designed for this purpose). EPA removed the specific

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minimum monitoring requirements for NO2 of two monitoring sites per area with a population of 1,000,000 or more in the 2006 monitoring rule revisions (71 FR 61236), based on the fact that there were no NO2 nonattainment areas at that time, coupled with trends evidence showing an increasing gap between national average NO2 concentrations and the current annual standard. Additionally, the minimum requirements were removed to provide State, local, and Tribal air monitoring agencies flexibility in meeting higher priority monitoring needs for pollutants such as O3 and PM2.5, or implementing the new multi-pollutant sites (NCore network) required by the 2006 rule revisions, by allowing them to discontinue lower priority monitoring. There are requirements in 40 CFR part 58 Appendix D for NO2 monitoring as part of the Photochemical Assessment Monitoring Stations (PAMS) network. However, of the approximately 400 NO2 monitors currently in operation, only about 10 percent may be due to the PAMS requirements.

\6\ It should be noted that the ISA (section 2.4.1) references a different number of active monitors in the NO2 network. The discrepancy between the ISA numbers and the number presented here is due to differing metrics used in pulling data from AQS. The ISA only references SLAMS, NAMS, and PAMS sites with defined monitoring objectives, while Watkins and Thompson (2008) considered all NO2 sites reporting data at any point during the year. Based on this approach, Watkins and Thompson (2008) also noted that the size of the NO2 monitoring network has remained relatively stable since the early 1980s.

An analysis of the approximately 400 monitors comprising the current NO2 monitoring network (Watkins and Thompson, 2008) indicates that the current NO2 network has largely remained unchanged in terms of size and target monitor objective categories since it was introduced in the May 10, 1979 monitoring rule (44 FR 27571). The review of the current network found that the assessment of concentrations for general population exposure and maximum concentrations at neighborhood and larger scales were the top objectives. A review of the distribution of listed spatial scales of representation shows that only approximately 3 monitors are described as microscale, representing an area on the order of several meters to 100 meters, and approximately 23 monitors are described as middle scale, which represents an area on the order of 100 to 500 meters. This low percentage of smaller spatially representative scale sites within the network of approximately 400 monitoring sites indicates that the majority of monitors have, in fact, been sited to assess area-wide exposures on the neighborhood, urban, and regional scales, as would be expected for a network sited to support the current annual NO2 standard and PAMS objectives. The current network does not include monitors placed near major roadways and, therefore, monitors in the current network do not necessarily measure the maximum concentrations that can occur on a localized scale near these roadways (as discussed in the next section). It should be noted that the network not only accommodates NAAQS related monitoring but also serves other monitoring objectives, such as support for photochemistry analysis, O3 modeling and forecasting, and particulate matter precursor tracking.

2. NO2 Air Quality and Gradients Around Roadways

On-road and non-road mobile sources account for approximately 60% of NOX emissions (ISA, table 2.2-1) and traffic-related exposures can dominate personal exposures to NO2 (ISA section 2.5.4). While driving, personal exposure concentrations in the cabin of a vehicle could be substantially higher than ambient concentrations measured nearby (ISA, section 2.5.4). For example, estimates presented in the REA suggest that on/near roadway NO2 concentrations could be approximately 80% (REA, section 7.3.2) higher on average across locations than concentrations away from roadways and that roadway-associated environments could be responsible for the majority of 1-hour peak NO2 exposures (REA, Figures 8-17 and 8-18). Because monitors in the current network are not sited to measure peak roadway-associated NO2 concentrations, individuals who spend time on and/or near major roadways could experience NO2 concentrations that are considerably higher than indicated by monitors in the current area-wide NO2 monitoring network.

Research suggests that the concentrations of on-road mobile source pollutants such as NOX, carbon monoxide (CO), directly emitted air toxics, and certain size distributions of particulate matter (PM), such as ultrafine PM, typically display peak concentrations on or immediately adjacent to roads (ISA, section 2.5). This situation typically produces a gradient in pollutant concentrations, with concentrations decreasing with increasing distance from the road, and concentrations generally decreasing to near area-wide ambient levels, or typical upwind urban background levels, within a few hundred meters downwind. While such a concentration gradient is present on almost all roads, the characteristics of the gradient, including the distance from the road that a mobile source pollutant signature can be differentiated from background concentrations, are heavily dependent on factors such as traffic volumes, local topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf, et al., 2009; Beckerman et al., 2008; Clements et al., 2008; Hagler et al., 2009; Janssen et al., 2001; Rodes and Holland, 1981; Roorda-Knape et al., 1998; Singer et al., 2004; Zhou and Levy, 2007).

Because NO2 in the ambient air is due largely to the atmospheric oxidation of NO emitted from combustion sources (ISA, section 2.2.1), elevated NO2 concentrations can extend farther away from roadways than the primary pollutants also emitted by on-road mobile sources. More specifically, review of the technical literature suggests that NO2 concentrations may return to area-wide or typical urban background concentrations within distances up to 500 meters of roads, though the actual distance will vary with topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf et al., 2009; Beckerman et al., 2008; Clements et al., 2008; Gilbert et al. 2003; Rodes and Holland, 1981; Singer et al., 2004; Zhou and Levy, 2007). Efforts to quantify the extent and slope of the concentration gradient that may exist from peak near-road concentrations to the typical urban background concentrations must consider the variability that exists across locations and for a given location over time. As a result, we have identified a range of concentration gradients in the technical literature which indicate that, on average, peak NO2 concentrations on or immediately adjacent to roads may typically be between 30 and 100 percent greater than concentrations monitored in the same area but farther away from the road (ISA, Section 2.5.4; Beckerman et al., 2008; Gilbert et al., 2003; Rodes and Holland, 1981; Roorda-Knape et al., 1998; Singer et al., 2004). This range of concentration gradients has implications for revising the NO2 primary standard and for the NO2 monitoring network (discussed in sections II.F.4 and III).

B. Health Effects Information

In the last review of the NO2 NAAQS, the 1993 NOX Air Quality Criteria Document (1993 AQCD) (EPA, 1993) concluded that there were two key health effects of greatest concern at ambient or near-ambient concentrations of NO2 (ISA, section 5.3.1). The first was increased airway responsiveness in asthmatic individuals after short-term exposures. The second was increased respiratory illness among children associated with longer-term exposures to NO2. Evidence also was found for increased risk of emphysema, but this appeared to be of major concern only with exposures to NO2 at levels much higher than then current ambient levels (ISA, section 5.3.1). Controlled human

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exposure and animal toxicological studies provided qualitative evidence for airway hyperresponsiveness and lung function changes while epidemiologic studies provided evidence for increased respiratory symptoms with increased indoor NO_2 exposures. Animal toxicological findings of lung host defense system changes with NO_2 exposure provided a biologically-plausible basis for the epidemiologic results. Subpopulations considered potentially more susceptible to the effects of NO_2 exposure included persons with preexisting respiratory disease, children, and the elderly. The epidemiologic evidence for respiratory health effects was limited, and no studies had considered endpoints such as hospital admissions, emergency department visits, or mortality (ISA, section 5.3.1).

As summarized below and discussed more fully in section II.B of the proposal notice, evidence published since the last review generally has confirmed and extended the conclusions articulated in the 1993 AQCD (ISA, section 5.3.2). The epidemiologic evidence has grown substantially with the addition of field and panel studies, intervention studies, time-series studies of endpoints such as hospital admissions, and a substantial number of studies evaluating mortality risk associated with short-term NO_2 exposures. While not as marked as the growth in the epidemiologic literature, a number of recent toxicological and controlled human exposure studies also provide insights into relationships between NO_2 exposure and health effects. This body of evidence focuses the current review on NO_2-related respiratory effects at lower ambient and exposure concentrations than considered in the previous review.

1. Adverse Respiratory Effects and Short-Term Exposure to NO_2

The ISA concluded that the findings of epidemiologic, controlled human exposure, and animal toxicological studies provide evidence that is sufficient to infer a likely causal relationship for respiratory effects following short-term NO_2 exposure (ISA, sections 3.1.7 and 5.3.2.1). The ISA (section 5.4) concluded that the strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms, emergency department visits, and hospital admissions. These studies include panel and field studies, studies that control for the effects of co-occurring pollutants, and studies conducted in areas where the whole distribution of ambient 24-hour average NO_2 concentrations was below the current NAAQS level of 53 ppb (annual average). With regard to this evidence, the ISA concluded that NO_2 epidemiologic studies provide ``little evidence of any effect threshold'' (ISA, section 5.3.2.9, p. 5-15). In studies that have evaluated concentration-response relationships, they appear linear within the observed range of data (ISA, section 5.3.2.9).

Overall, the epidemiologic evidence for respiratory effects has been characterized in the ISA as consistent, in that associations are reported in studies conducted in numerous locations with a variety of methodological approaches, and coherent, in that the studies report associations with respiratory health outcomes that are logically linked together. In addition, a number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1). These epidemiologic studies are supported by evidence from toxicological and controlled human exposure studies, particularly those that evaluated airway hyperresponsiveness in asthmatic individuals (ISA, section 5.4). The ISA concluded that together, the epidemiologic and experimental data sets form a plausible, consistent, and coherent description of a relationship between NO_2 exposures and an array of adverse respiratory health effects that range from the onset of respiratory symptoms to hospital admissions.

In considering the uncertainties associated with the epidemiologic evidence, the ISA (section 5.4) noted that it is difficult to determine ``the extent to which NO_2 is independently associated with respiratory effects or if NO_2 is a marker for the effects of another traffic-related pollutant or mix of pollutants.'' On-road vehicle exhaust emissions are a widespread source of combustion pollutant mixtures that include NO_X and are an important contributor to NO_2 levels in near-road locations. Although the presence of other pollutants from vehicle exhaust emissions complicates efforts to quantify specific NO_2-related health effects, a number of epidemiologic studies have evaluated associations with NO_2 in models that also include co-occurring pollutants such as PM, O_3, CO, and/or SO_2. The evidence summarized in the ISA indicates that NO_2 associations generally remain robust in these multi-pollutant models and supports a direct effect of short-term NO_2 exposure on respiratory morbidity (see ISA Figures 3.1-7, 3.1-10, 3.1-11). The plausibility and coherence of these effects are also supported by epidemiologic studies of indoor NO_2 as well as experimental (i.e., toxicological and controlled human exposure) studies that have evaluated host defense and immune system changes, airway inflammation, and airway responsiveness (see subsequent sections of this proposal and the ISA, section 5.3.2.1). The ISA (section 5.4) concluded that the robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO_2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO_2 and other traffic related pollutants.

The epidemiologic and experimental studies encompass a number of respiratory-related health endpoints, including emergency department visits and hospitalizations, respiratory symptoms, airway hyperresponsiveness, airway inflammation, and lung function. The findings relevant to these endpoints, which provide the rationale to support the judgment of a likely causal relationship, are described in more detail in section II.B.1 of the proposal.

2. Other Effects With Short-Term Exposure to NO_2

a. Mortality

The ISA concluded that the epidemiologic evidence is suggestive, but not sufficient, to infer a causal relationship between short-term exposure to NO_2 and all-cause and cardiopulmonary-related mortality (ISA, section 5.3.2.3). Results from several large United States and European multicity studies and a meta-analysis study indicate positive associations between ambient NO2 concentrations and the risk of all-cause (nonaccidental) mortality, with effect estimates ranging from 0.5 to 3.6% excess risk in mortality per standardized increment (20 ppb for 24-hour averaging time, 30 ppb for 1-hour averaging time) (ISA, section 3.3.1, Figure 3.3-2, section 5.3.2.3). In general, the ISA concluded that NO2 effect estimates were robust to adjustment for co-pollutants. Both cardiovascular and respiratory mortality have been associated with increased NO2 concentrations in epidemiologic studies (ISA, Figure 3.3-3); however, similar associations were observed for other pollutants, including PM and SO2. The range of risk estimates for excess mortality is generally smaller than that for other pollutants such as PM. In addition, while NO2 exposure, alone or in conjunction with other pollutants,

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may contribute to increased mortality, evaluation of the specificity of this effect is difficult. Clinical studies showing hematologic effects and animal toxicological studies showing biochemical, lung host defense, permeability, and inflammation changes with short-term exposures to NO2 provide limited evidence of plausible pathways by which risks of mortality may be increased, but no coherent picture is evident at this time (ISA, section 5.3.2.3).

b. Cardiovascular Effects

The ISA concluded that the available evidence on cardiovascular health effects following short-term exposure to NO2 is inadequate to infer the presence or absence of a causal relationship at this time (ISA, section 5.3.2.2). Evidence from epidemiologic studies of heart rate variability, repolarization changes, and cardiac rhythm disorders among heart patients with ischemic cardiac disease are inconsistent (ISA, section 5.3.2.2). In most studies, associations with PM were found to be similar or stronger than associations with NO2. Generally positive associations between ambient NO2 concentrations and hospital admissions or emergency department visits for cardiovascular disease have been reported in single-pollutant models (ISA, section 5.3.2.2); however, most of these effect estimate values were diminished in multi-pollutant models that also contained CO and PM indices (ISA, section 5.3.2.2). Mechanistic evidence of a role for NO2 in the development of cardiovascular diseases from studies of biomarkers of inflammation, cell adhesion, coagulation, and thrombosis is lacking (ISA, section 5.3.2.2). Furthermore, the effects of NO2 on various hematological parameters in animals are inconsistent and, thus, provide little biological plausibility for effects of NO2 on the cardiovascular system (ISA, section 5.3.2.2).

3. Health Effects With Long-Term Exposure to NO2

a. Respiratory Morbidity

The ISA concluded that overall, the epidemiologic and experimental evidence is suggestive, but not sufficient, to infer a causal relationship between long-term NO2 exposure and respiratory morbidity (ISA, section 5.3.2.4). The available database evaluating the relationship between respiratory illness in children and long-term exposures to NO2 has increased since the 1996 review of the NO2 NAAQS (see section II.B.3 of the proposal for a more detailed discussion). A number of epidemiologic studies have examined the effects of long-term exposure to NO2 and reported positive associations with decrements in lung function and partially irreversible decrements in lung function growth (ISA, section 3.4.1, Figures 3.4-1 and 3.4-2). While animal toxicological studies may provide biological plausibility for the chronic effects of NO2 that have been observed in epidemiologic studies (ISA, sections 3.4.5 and 5.3.2.4), the high correlation among traffic-related pollutants in epidemiologic studies makes it difficult to accurately estimate independent effects (ISA, section 5.3.2.4).

b. Mortality

The ISA concluded that the epidemiologic evidence is inadequate to infer the presence or absence of a causal relationship between long-term exposure to NO2 and mortality (ISA, section 5.3.2.6). In the United States and European cohort studies examining the relationship between long-term exposure to NO2 and mortality, results have been inconsistent (ISA, section 5.3.2.6). Further, when associations were suggested, they were not specific to NO2 but also implicated PM and other traffic indicators. The relatively high correlations reported between NO2 and PM indices make it difficult to interpret these observed associations at this time (ISA, section 5.3.2.6).

c. Carcinogenic, cardiovascular, and reproductive/developmental effects

The ISA concluded that the available epidemiologic and toxicological evidence is inadequate to infer the presence or absence of a causal relationship for carcinogenic, cardiovascular, and reproductive and developmental effects related to long-term NO2 exposure (ISA, section 5.3.2.5). Epidemiologic studies conducted in Europe have shown an association between long-term NO2 exposure and increased incidence of cancer (ISA, section 5.3.2.5). However, the animal toxicological studies have provided no clear evidence that NO2 acts as a carcinogen (ISA, section 5.3.2.5). The very limited epidemiologic and toxicological evidence do not suggest that long-term exposure to NO2 has cardiovascular effects (ISA, section 5.3.2.5). The epidemiologic evidence is not consistent for associations between NO2 exposure and fetal growth retardation; however, some evidence is accumulating for effects on preterm delivery (ISA, section 5.3.2.5). Scant animal evidence supports a weak association between NO2 exposure and adverse birth outcomes and provides little mechanistic information or biological plausibility for the epidemiologic findings.

4. NO2-related Impacts on Public Health

Specific groups within the general population are likely at increased risk for suffering adverse effects from NO2

exposure. This could occur because they are affected by lower levels of NO2 than the general population or because they experience a larger health impact than the general population to a given level of exposure (susceptibility) and/or because they are exposed to higher levels of NO2 than the general population (vulnerability).
The term susceptibility generally encompasses innate (e.g., genetic or developmental) and/or acquired (e.g., age or disease) factors that make individuals more likely to experience effects with exposure to pollutants. The severity of health effects experienced by a susceptible subgroup may be much greater than that experienced by the population at large. Factors that may influence susceptibility to the effects of air pollution include age (e.g., infants, children, elderly); gender; race/ ethnicity; genetic factors; and pre-existing disease/condition (e.g., obesity, diabetes, respiratory disease, asthma, chronic obstructive pulmonary disease (COPD), cardiovascular disease, airway hyperresponsiveness, respiratory infection, adverse birth outcome) (ISA, sections 4.3.1, 4.3.5, and 5.3.2.8). In addition, certain groups may experience relatively high exposure to NO2, thus forming a potentially vulnerable population (ISA, section 4.3.6). Factors that may influence susceptibility and vulnerability to air pollution include socioeconomic status (SES), education level, air conditioning use, proximity to roadways, geographic location, level of physical activity, and work environment (e.g., indoor versus outdoor) (ISA, section 4.3.5). The ISA discussed factors that can confer susceptibility and/or vulnerability to air pollution with most of the discussion devoted to factors for which NO2-specific evidence exists (ISA, section 4.3). These factors include pre-existing disease (e.g., asthma), age (i.e., infants, children, older adults), genetic factors, gender, socioeconomic status, and proximity to roadways (see section II.B.4 in proposal for more detailed discussion of these factors).

As discussed in more detail in the proposal (section II.B.4), the population potentially affected by NO2 is large. A considerable fraction of the population resides, works, or attends school near major roadways, and these individuals are likely to have increased exposure to NO2 (ISA, section 4.4). Based on data

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from the 2003 American Housing Survey, approximately 36 million individuals live within 300 feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).\7\ Furthermore, in California, 2.3% of schools, with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads, with a higher proportion of non-white and economically disadvantaged students attending those schools (ISA, section 4.4). Of this population, asthmatics and members of other susceptible groups discussed above will have even greater risks of experiencing health effects related to NO2 exposure. In the United States, approximately 10% of adults and 13% of children (approximately 22.2 million people in 2005) have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4). The prevalence and severity of asthma is higher among certain ethnic or racial groups such as Puerto Ricans, American Indians, Alaskan Natives, and African Americans (ISA, section 4.4). A higher prevalence of asthma among persons of lower SES and an excess burden of asthma hospitalizations and mortality in minority and inner-city communities have been observed (ISA, section 4.4). In addition, based on United States census data from 2000, about 72.3 million (26%) of the United States population are under 18 years of age, 18.3 million (7.4%) are under 5 years of age, and 35 million (12%) are 65 years of age or older. Therefore, large portions of the United States population are in age groups that are likely at-risk for health effects associated with exposure to ambient NO2. The size of the potentially at-risk population suggests that exposure to ambient NO2 could have a significant impact on public health in the United States.

\7\ The most current American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs.html) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary than do prior surveys. According to Table 1A-6 from that report (http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf), out of 128,203,000 total housing units in the United States, 20,016,000 were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.613% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306,330,199, that means that there would be 47.8 million people meeting the 300 foot criteria.

C. Human Exposure and Health Risk Characterization

To put judgments about NO2-associated health effects into a broader public health context, EPA has drawn upon the results of the quantitative exposure and risk assessments. Judgments reflecting the nature of the evidence and the overall weight of the evidence are taken into consideration in these quantitative exposure and risk assessments, discussed below. These assessments provide estimates of the likelihood that asthmatic individuals would experience exposures of potential concern and estimates of the incidence of NO2-associated respiratory emergency department visits under varying air quality scenarios (e.g., just meeting the current or alternative standards), as well as characterizations of the kind and degree of uncertainties inherent in such estimates. As discussed more fully in section II.C of the proposal, this section summarizes the approach taken in the REA to characterize NO2-related exposures and health risks. Goals of the REA included estimating short-term exposures and potential human health risks associated with (1) recent levels of ambient NO2; (2) NO2 levels adjusted to simulate just meeting the current standard; and (3) NO2 levels adjusted to simulate just meeting potential alternative standards.

For purposes of the quantitative characterization of NO2 health risks, the REA determined that it was appropriate to focus on endpoints for which the ISA concluded that the available evidence is sufficient to infer either a causal or a likely causal relationship. This was generally consistent with judgments made in other recent NAAQS reviews (e.g., see EPA, 2005). As noted above in section II.A, the only health effect category for which the evidence was judged in the ISA to be sufficient to infer either a causal or a likely causal relationship is respiratory morbidity following short-term NO2 exposure. Therefore, for purposes of characterizing health risks associated with NO2, the REA focused on respiratory morbidity endpoints that have been associated with short-term NO2 exposures.

In evaluating the appropriateness of specific endpoints for use in the NO2 risk characterization, the REA considered both epidemiologic and controlled human exposure studies. As described in more detail in the proposal (section II.C.1), the characterization of NO2-associated health risks was based on an epidemiology study conducted in Atlanta, Georgia by Tolbert et al. (2007) and a meta-analysis of controlled human exposure studies of NO2 and airway responsiveness in asthmatics (ISA, Table 3.1-3).\8\

\8\ The study by Tolbert et al. (2007) reported positive associations between 1-hour ambient NO2 concentrations and respiratory-related emergency department visits. The meta-analysis was included in the ISA and reported that short-term exposures to NO2 concentrations at or above 100 ppb increased airway responsiveness in most asthmatics.

As noted above, the purpose of the assessments described in the REA was to characterize air quality, exposures, and health risks associated with recent ambient levels of NO2, with NO2 levels that could be associated with just meeting the current NO2 NAAQS, and with NO2 levels that could be associated with just meeting potential alternative standards. To characterize health risks, the REA employed three approaches. In the first approach, for each air quality scenario, NO2 concentrations at fixed-site monitors and simulated concentrations on/near roadways were compared to potential health effect benchmark values derived from the controlled human exposure literature. In the second approach, modeled estimates of exposures in asthmatics were compared to potential health effect benchmarks. In the third approach, concentration-response relationships from an epidemiologic study were used in conjunction with baseline incidence data and recent or simulated ambient concentrations to estimate health impacts. An overview of the approaches to characterizing health risks is provided in the proposal (section II.C.2) and each approach, along with its limitations and uncertainties (see proposal, section II.C.3) has been described in more detail in the REA (chapters 6 through 9).

Chapters 7-9 of the REA estimated exposures and health risks associated with recent air quality and with air quality, as measured at monitors in the current area-wide network, which had been adjusted to simulate just meeting the current and potential alternative standards. The specific standard levels evaluated, for an area-wide standard based on the 3-year average of the 98th and 99th percentile 1-hour daily maximum NO2 concentrations, were 50, 100, 150, and 200 ppb. In interpreting these results within the context of the current revisions to the NO2 primary NAAQS (see below), we note that simulation of different standard levels was based on adjusting NO2 concentrations at available area-wide monitors. Therefore, the standard levels referred to above reflect the allowable area-wide NO2 concentrations, not the maximum allowable concentrations. As a consequence, the maximum concentrations in an area that just meets one of these standard levels would be expected to be higher than the standard level. For example, given that near-road

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NO2 concentrations can be 30% to 100% higher than area-wide concentrations (see section II.E.2), an area-wide concentration of 50 ppb could correspond to near-road concentrations from 65 to 100 ppb.

Key results of the air quality, exposure, and risk analyses were presented in the policy assessment chapter of the REA and summarized in the proposal (Table 1 in proposal). In considering these results, the policy assessment chapter of the REA concluded that the risks estimated to be associated with just meeting the current annual standard can be judged important from a public health perspective. The results for specific 1-hour standard levels estimate that limiting the 98th/99th percentile of the distribution of 1-hour daily maximum NO2 concentrations measured at area-wide monitors to 50 or 100 ppb could substantially reduce exposures to ambient NO2 and associated health risks (compared to just meeting the current standard). In contrast, limiting these area-wide NO2 concentrations to 150 or 200 ppb is estimated to result in similar, or in some cases higher, NO2-associated exposures and health risks than just meeting the current standard. The pattern of results was similar for standards just meeting either the 98th or the 99th percentile 1-hour daily maximum area-wide standards (REA, Chapters 7, 8, and 9).

D. Approach for Reviewing the Need To Retain or Revise the Current Standard

EPA notes that the final decision on retaining or revising the current primary NO2 standard is a public health policy judgment to be made by the Administrator. This judgment has been informed by a recognition that the available health effects evidence reflects a continuum consisting of ambient levels of NO2 at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. The Administrator's final decisions draw upon scientific information and analyses related to health effects, population exposures, and risks; judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses; and comments received from CASAC and the public.

To evaluate whether the current primary NO2 standard is requisite or whether consideration of revisions is appropriate, EPA has used an approach in this review that was described in the policy assessment chapter of the REA. This approach builds upon those used in reviews of other criteria pollutants, including the most recent reviews of the Pb, O3, and PM NAAQS (EPA, 2007c; EPA, 2007d; EPA, 2005), and reflects the body of evidence and information that is currently available. As in other recent reviews, EPA's considerations included the implications of placing more or less weight or emphasis on different aspects of the scientific evidence and the exposure/risk-based information, recognizing that the weight to be given to various elements of the evidence and exposure/risk information is part of the public health policy judgments that the Administrator will make in reaching decisions on the standard.

A series of general questions framed this approach to considering the scientific evidence and exposure-/risk-based information. First, EPA's consideration of the scientific evidence and exposure/risk information with regard to the adequacy of the current standard has been framed by the following questions:

To what extent does evidence that has become available since the last review reinforce or call into question evidence for NO2-associated effects that were identified in the last review?

To what extent has evidence for different health effects and/or sensitive populations become available since the last review?

To what extent have uncertainties identified in the last review been reduced and/or have new uncertainties emerged?

To what extent does evidence and exposure-/risk-based information that has become available since the last review reinforce or call into question any of the basic elements of the current standard?

To the extent that the available evidence and exposure-/risk-based information suggests it may be appropriate to consider revision of the current standard, EPA considers that evidence and information with regard to its support for consideration of a standard that is either more or less protective than the current standard. This evaluation has been framed by the following questions:

Is there evidence that associations, especially causal or likely causal associations, extend to ambient NO2 concentrations as low as, or lower than, the concentrations that have previously been associated with health effects? If so, what are the important uncertainties associated with that evidence?

Are exposures above benchmark levels and/or health risks estimated to occur in areas that meet the current standard? If so, are the estimated exposures and health risks important from a public health perspective? What are the important uncertainties associated with the estimated risks?

To the extent that there is support for consideration of a revised standard, EPA then considers the specific elements of the standard (indicator, averaging time, form, and level) within the context of the currently available information. In so doing, the Agency has addressed the following questions:

Does the evidence provide support for considering a different indicator for gaseous NOX?

Does the evidence provide support for considering different averaging times?

What ranges of levels and forms of alternative standards are supported by the evidence, and what are the associated uncertainties and limitations?

To what extent do specific averaging times, levels, and forms of alternative standards reduce the estimated exposures above benchmark levels and risks attributable to NO2, and what are the uncertainties associated with the estimated exposure and risk reductions?

The questions outlined above have been addressed in the REA, the proposal, and in this final rulemaking. The following sections present the rationale for proposed decisions, discussion of public comments, and the Administrator's conclusions on the adequacy of the current standard and potential alternative standards in terms of indicator, averaging time, form, and level.

E. Adequacy of the Current Standard

This section discusses considerations related to the decision as to whether the current NO2 primary NAAQS is requisite to protect public health with an adequate margin of safety. Specifically, section II.E.1 provides an overview of the rationale supporting the Administrator's conclusion in the proposal that the current standard alone does not provide adequate public health protection; section II.E.2 discusses comments received on the adequacy of the current standard; and section II.E.3 discusses the Administrator's final decision on whether the current NO2 primary NAAQS is requisite to protect public health with an adequate margin of safety.

1. Rationale for Proposed Decision

In reaching a conclusion regarding the adequacy of the current NO2 NAAQS in the proposal (section II.E.5), the Administrator considered the scientific evidence assessed in the ISA and the conclusions of the ISA, the exposure and risk information presented in the REA and the conclusions of the policy assessment chapter of the REA, and the views expressed by CASAC. These considerations are discussed in detail in the proposal (II.E.) and are summarized in this section. In the proposal, the

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Administrator noted the following in considering the adequacy of the current standard:

The ISA concluded that the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a relationship between NO2 exposures and respiratory endpoints, including respiratory symptoms and respiratory-related hospital admissions and emergency department visits, at ambient concentrations that are present in areas that meet the current NO2 NAAQS (ISA, section 5.4).

The policy assessment chapter of the REA concluded that risks estimated to be associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be judged important from a public health perspective (REA, section 10.3.3).

The policy assessment chapter of the REA concluded that exposure- and risk-based results reinforce the scientific evidence in supporting the conclusion that consideration should be given to revising the current NO2 NAAQS so as to provide increased public health protection, especially for at-risk groups, from NO2-related adverse health effects associated with short-term, and potential long-term, exposures (REA, section 10.3.3).

CASAC agreed that the current annual standard alone is not sufficient to protect public health against the types of exposures that could lead to these health effects. Specifically, in their letter to the Administrator on the final REA, they stated that ``CASAC concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised'' (Samet, 2008b).

Based on these considerations (discussed in more detail in the proposal, section II.E), the Administrator concluded in the proposal that the current NO2 primary NAAQS is not requisite to protect public health with an adequate margin of safety against adverse respiratory effects associated with short-term exposures. In considering approaches to revising the current standard, the Administrator concluded that it is appropriate to consider setting a new short-term standard in addition to retaining the current annual standard. The Administrator noted that such a short-term standard could provide increased public health protection, especially for members of at-risk groups, from effects described in both epidemiologic and controlled human exposure studies to be associated with short-term exposures to NO2.

2. Comments on the Adequacy of the Current Standard

This section discusses comments received from CASAC and public commenters on the proposal that either supported or opposed the Administrator's proposed decision to revise the current NO2 primary NAAQS. Comments on the adequacy of the current standard that focused on the scientific and/or the exposure/risk basis for the Administrator's proposed conclusions are discussed in sections II.E.2.a-II.E.2.c. Comments on the epidemiologic evidence are considered in section II.E.2.a. Comments on the controlled human exposure evidence are considered in section II.E.2.b. Comments on human exposure and health risk assessments are considered in section II.E.2.c. To the extent these comments on the evidence and information are also used to justify commenters' conclusions on decisions related to indicator, averaging time, level, or form, they are noted in the appropriate sections below (II.F.1-II.F.4).

In their comments on the proposal (Samet, 2009), CASAC reiterated their support for the need to revise the current annual NO2 NAAQS in order to increase public health protection. As noted above, in its letter to the Administrator on the final REA (Samet, 2008b) CASAC stated that it ``concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised.'' In supporting adoption of a more stringent NAAQS for NO2, CASAC considered the assessment of the scientific evidence presented in the ISA, the results of assessments presented in the REA, and the conclusions of the policy assessment chapter of the REA. As such, CASAC's rationale for revising the current standard was consistent with the Administrator's rationale as discussed in the proposal.

Many public commenters agreed with CASAC that, based on the available information, the current NO2 standard is not requisite to protect public health with an adequate margin of safety and that revisions to the standard are appropriate. Among those calling for revisions to the standard were environmental groups (e.g., Clean Air Council (CAC), Earth Justice (EJ), Environmental Defense Fund (EDF), Natural Resources Defense Council (NRDC), Group Against Smog and Pollution (GASP)); medical/public health organizations (e.g., American Lung Association (ALA), American Medical Association (AMA), American Thoracic Society (ATS), National Association for the Medical Direction of Respiratory Care (NAMDRC), National Association of Cardiovascular and Pulmonary Rehabilitation (NACPR), American College of Chest Physicians (ACCP)); a large number of State agencies and organizations (e.g., National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management (NESCAUM), and State or local agencies in CA, IA, IL, MI, MO, NC, NM, NY, TX, VA, WI); Tribes (e.g., National Tribal Air Association (NTAA), Fond du Lac Band of Lake Superior Chippewa (Fond du Lac)), and a number of individual commenters. These commenters concluded that the current NO2 standard needs to be revised and that a more stringent standard is needed to protect the health of sensitive population groups. In supporting the need to adopt a more stringent NAAQS for NO2, these commenters often referenced the conclusions of CASAC and relied on the evidence and information presented in the proposal. As such, similar to CASAC, the rationale offered by these commenters was consistent with that presented in the proposal to support the

Administrator's proposed decision to revise the current NO2 NAAQS.

Some industry commenters (e.g., Alliance of Automobile Manufacturers (AAM), American Petroleum Institute (API), Interstate Natural Gas Association of America (INGAA), Utility Air Regulatory Group (UARG)) and one State commenter (IN Department of Environmental Management) expressed support for retaining the current annual standard alone. In supporting this view, these commenters generally concluded that the current standard is requisite to protect public health with an adequate margin of safety and that the available evidence is not sufficient to support revision of the standard. For example, UARG stated that ``EPA has failed to demonstrate that the present NO2 NAAQS is no longer at the level requisite to protect public health with an adequate margin of safety.'' In addition, INGAA stated that

``* * * EPA should be compelled to retain the current standard and defer a decision on a new short-term standard until the science is more clearly defined.''

In support of their views, these commenters provided specific comments on the epidemiologic and controlled human exposure evidence as discussed below. In responding to these specific comments, we note that the Administrator relied in the proposal on the evidence, information and judgments contained in the ISA and the

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REA (including the policy assessment chapter) as well as on the advice of CASAC. In considering the evidence, information, and judgments of the ISA and the REA, the Agency notes that these documents have been reviewed extensively by CASAC and have been discussed by CASAC at multiple public meetings (see section I.D). In their letter to the Administrator regarding the second draft ISA (Henderson, 2008), CASAC noted the following:

Panel members concur with the primary conclusions reached in the ISA with regard to health risks that are associated with NO2 exposure. In particular, the Panel agrees with the conclusion that the current scientific evidence is ``sufficient to infer a likely causal relationship between short-term NO2 exposure and adverse effects on the respiratory system.'' The strongest evidence in support of this conclusion comes from epidemiology studies that show generally positive associations between NO2 and respiratory symptoms, hospitalizations or emergency department visits, as summarized in Figure 5.3.1.''

Similarly, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC noted the following:

Overall, CASAC found this version of the REA satisfactory in its approach to moving from the scientific foundation developed in the Integrated Science Assessment (ISA) to setting out evidence-based options for the NAAQS. The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure. It draws on toxicological and epidemiological evidence and addresses risk to an identified susceptible population, people with asthmatic conditions. EPA has also systematically described uncertainties associated with the risk assessments. We commend EPA for developing a succinct and thoughtfully developed synthesis in chapter 10. This summary chapter represents a long-needed and transparent model for linking a substantial body of scientific evidence to the four elements of the NAAQS.

Therefore, in discussing comments on the interpretation of the scientific evidence and exposure/risk information, we note that CASAC has endorsed the approaches and conclusions of the ISA and the REA. These approaches and conclusions are discussed below in more detail, within the context of specific public comments.

a. Comments on EPA's Interpretation of the Epidemiologic Evidence

Several industry groups (e.g., API, National Mining Association (NMA), American Chemistry Council (ACC), AAM, Annapolis Center for Science-Based Public Policy (ACSBPP), Engine Manufacturers Association (EMA), ExxonMobil (Exxon), National Association of Manufacturers (NAM)) commented that, given the presence of numerous co-pollutants in the air, epidemiologic studies do not support the contention that NO2 itself is causing health effects.

While EPA has recognized that multiple factors can contribute to the etiology of respiratory disease and that more than one air pollutant could independently impact respiratory health, we continue to judge, as discussed in the ISA, that the available evidence supports the conclusion that there is an independent effect of NO2 on respiratory morbidity. In reaching this judgment, we recognize that a major methodological issue affecting NO2 epidemiologic studies concerns the evaluation of the extent to which other air pollutants may confound or modify NO2-related effect estimates. The use of multipollutant regression models is the most common approach for controlling potential confounding by co-pollutants in epidemiologic studies. The issues related to confounding and the evidence of potential confounding by co-pollutants has been thoroughly reviewed in the ISA (see Figures 3.1-10 and 3.1-11) and in previous assessments (e.g., the criteria document for PM) (EPA, 2004). NO2 risk estimates for respiratory morbidity endpoints, in general, were not sensitive to the inclusion of co-pollutants, including particulate and gaseous pollutants. As observed in Figures 3.1-10 and 3.1-11 in the ISA, relative risks for hospital admissions or emergency department visits are generally unchanged, nor is their interpretation modified, upon inclusion of PM or gaseous co-pollutants in the models. Similarly, associations between short-term NO2 exposure and asthma symptoms are generally robust to adjustment for co-pollutants in multipollutant models, as shown in

Figures 3.1-5 and 3.1-7 of the ISA. These results, in conjunction with the results of a randomized intervention study evaluating respiratory effects of indoor exposure to NO2 (ISA, section 3.1.4.1), led to the conclusion that the effect of NO2 on respiratory health outcomes is robust and independent of the effects of other ambient co-pollutants.

In addition, experimental studies conducted in animals and humans provide support for the plausibility of the associations reported in epidemiologic studies. These controlled human exposure and animal toxicological studies have reported effects of NO2 on immune system function, lung host defense, airway inflammation, and airway responsiveness (ISA, section 5.4). These experimental study results support an independent contribution of NO2 to the respiratory health effects reported in epidemiologic studies (ISA Section 5.4).

In considering the entire body of evidence, including epidemiologic and experimental studies, the ISA (section 5.4, p. 5-16) concluded the following:

Although this [presence of co-pollutants] complicates the efforts to disentangle specific NO2-related health effects, the evidence summarized in this assessment indicates that NO2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS. The robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO2 and other traffic-related pollutants.

Comments on specific epidemiologic studies are discussed below.

The National Association of Manufacturers (NAM) commented that the final REA relied on an epidemiologic study (Delfino et al. 2002) not critically reviewed in the final ISA. Contrary to NAM's contention, the study by Delfino et al. (2002) was critically reviewed by EPA staff and pertinent information was extracted from the study. The respiratory health effects of NO2 on asthma reported in this study are included in Figure 5.3-1, Table 5.4-1, and Annex Table AX6.3-2 of the ISA. While NAM comments on the narrative discussion of this study in the final ISA, their contention that EPA scientists did not critically analyze the study while preparing the final ISA is incorrect. The inclusion of the study in the figures and tables in this ISA, as well as inclusion in the 2004 PM AQCD, indicate critical analysis of the study that was implemented throughout the review process. The narrative discussion in the ISA focused on multicity studies (specifically those by Schwartz et al. 1994, Mortimer et al. 2002 and Schildcrout et al. 2006), which provide substantial epidemiologic evidence for the respiratory health effects of NO2 on asthma among children.

Additional comments from NAM contend that EPA's interpretation of three individual epidemiologic studies (e.g. Krewski et al. 2000; Schildcrout et al. 2006; Mortimer et al. 2002) is inconsistent across different NAAQS reviews. The NAM comments on all three studies are discussed below.

NAM stated the following regarding the study by Krewski et al:

In the Final ISA, EPA cites the Krewski, et al. (2000) study as evidence of a significant

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association between NO2 exposure and mortality. Although EPA acknowledges that exposure to NO2 was ``highly correlated'' with other pollutants, including PM2.5 and SO2, EPA does not consider the analysis of the respective contributions of single pollutants in the same study that EPA included in its prior Staff Paper for Particulate Matter. In that document, EPA stated: ``In single-pollutant models, none of the gaseous co-pollutants was significantly associated with mortality except SO2.'' If EPA has not altered its scientific views concerning this study as expressed in the PM Staff Paper, it is entirely inappropriate for EPA to suggest that the Krewski, et al. (2000) study provides any evidence of an association between NO2 exposure and mortality.

In these comments, NAM fails to recognize that the report from Krewski et al. (2000) contains a reanalysis of two cohort studies, the Harvard Six Cities and the American Cancer Society (ACS) studies. The characterization in the NOX ISA of the study by Krewski et al. (2000), referenced by NAM in their comments, refers to the reanalysis of the Harvard Six Cities Study. As stated in the NOX ISA (p. 3-74):

Krewski et al. (2000) conducted a sensitivity analysis of the Harvard Six Cities study and examined associations between gaseous pollutants (i.e., O3, NO2, SO2, CO) and mortality. NO2 showed risk estimates similar to those for PM2.5 per ``low to high'' range increment with total (1.15 [95% CI: 1.04, 1.27] per 10-ppb increase), cardiopulmonary (1.17 [95% CI: 1.02, 1.34]), and lung cancer (1.09 [95% CI: 0.76, 1.57]) deaths; however, in this dataset NO2 was highly correlated with PM2.5 (r = 0.78), SO4 2- (r = 0.78), and SO2 (r = 0.84).

In contrast, the characterization in the PM Staff Paper (EPA, 2005) of the study by Krewski et al. (2000), referenced by NAM in their comments, refers to the results of the ACS study. Therefore, NAM appears to have confused the conclusions on the results of the reanalysis of the Harvard Six Cities Study in the NOX ISA with the conclusions on the results of the reanalysis of the ACS study in the PM Staff Paper.

Further, in considering the reanalysis of the ACS study by Krewski et al. (2000), the NOX ISA observed that ``NO2 showed no associations with mortality outcomes'' (ISA, p. 3-74). This statement is consistent with the interpretation of that reanalysis as discussed in the PM Staff Paper. Thus, there is no inconsistency in the interpretation of the results of the study by Krewski et al. (2000) in the PM Staff Paper (EPA, 2005) and the NOX ISA (EPA, 2008a).

NAM also commented that EPA has relied on a study by Schildcrout et al. (2006) in the NOX ISA but declined to rely on the same study for the previous review of the O3 NAAQS. NAM made the following comment regarding the study by Schildcrout et al:

> Another example of how EPA has reached different scientific conclusions in the Final ISA than in prior NAAQS documents is provided by the Schildcrout, et al. (2006) study. In the Final ISA, EPA includes an extensive discussion of this study of asthmatic children and the relationship purportedly found in this study between NO2 and various respiratory symptoms. In contrast, as part of the NAAQS review for ozone, EPA expressly declined to rely on this same study because of specific limitations in the study design. Among the limitations EPA cites were the fact that the Schildcrout, et al. (2006) study included ``children in which the severity of their asthma was not clearly identified,'' and the use of a study population that was ``not comparable to other large multi-city studies.'' EPA must explain why it chose to discount the value of the Schildcrout, et al. (2006) study when evaluating the effects of ozone, but has relied on it extensively in the Final ISA for NO2.

The study by Schildcrout et al. (2006) appeared in the peer-review literature too late to be considered in the 2006 O3 AQCD; however, this study was included in the O3 Provisional Assessment. The purpose of the Provisional Assessment was to determine if new literature materially changed any of the broad scientific conclusions regarding the health effects of O3 exposure as stated in the 2006 O3 AQCD. EPA concluded that, taken in context, the ``new'' information and findings did not materially change any of the broad scientific conclusions regarding the health effects of O3 exposure made in the O3 AQCD. Therefore, NAM's contention that EPA ``declined'' to rely on the Schildcrout study for the O3 review because of limitations in study design is not correct.

The observations NAM draws from the O3 Provisional Assessment regarding severity of asthma and the study population do not indicate limitations that resulted in EPA ``discounting'' the study results. Rather, these observations were intended to put the study in perspective for purposes of interpreting the results within the context of the larger body of O3 health effects evidence. These observations were drawn from comments submitted by Dr. Schildcrout regarding the interpretation of the results of his study in the decision to revise the ozone standards (see docket ID EPA-HQ-OAR-2005-0172-6991). The results of this study are being fully considered in the ongoing review of the ozone NAAQS.

Finally, NAM contends that EPA reached differing scientific conclusions on the use of self-reported peak expiratory flow (PEF) depending on regulatory context, particularly in the large multi-city trial by Mortimer et al. (2002). We disagree with this contention. EPA consistently examines clinical measurements of lung function, which include PEF, forced expiratory flow in 1 second (FEV1), forced vital capacity (FVC), maximal midexpiratory flow (MMEF), maximal expiratory flow at 50% (MEF50), maximal expiratory flow at 25% (MEF25), and forced expiratory flow at 25 to 75% of FVC (FEF25-75). Evidence for all of these clinical measurements is considered before drawing a conclusion related to the association of lung function with a criteria pollutant. In different reviews, there may be more evidence from one of these clinical measurements than another. In the previous review of the O3 NAAQS, EPA identified statistically significant associations between increased ozone levels and morning PEF, which remained significant even when concentrations exceeding 0.08 ppm were excluded from the analysis (Mortimer et al. 2002). EPA considered this evidence, along with evidence of other clinical measurements of changes in lung function, in drawing conclusions on the relationship between ozone and lung function. Using a similar approach to weigh the evidence pertinent to lung function, including studies that produced no statistically significant results for PEF, the NOX ISA (section 3.1.5.3) states:

> In summary, epidemiologic studies using data from supervised lung function measurements (spirometry or peak flow meters) report small decrements in lung function (Hoek and Brunekreef, 1994; Linn et al., 1996; Moshammer et al., 2006; Peacock et al., 2003; Schindler et al., 2001). No significant associations were reported in any studies using unsupervised, self-administered peak flow (PEF) measurements with portable devices.

The evaluation of the evidence in the NOX ISA is consistent with the way the evidence from multiple clinical measures of lung function was used in the review of the O3 NAAQS.

b. Comments on EPA's Interpretation of the Controlled Human Exposure Evidence

A number of industry groups (e.g., AAM, ACC, API, Dow Chemical Company (Dow), EMA, NAM, UARG) disagreed with EPA's reliance on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics. Based on this meta-analysis (ISA, Table 3.1-3 for results), the ISA concluded that ``small but significant increases in nonspecific airway hyperresponsiveness were

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observed * * * at 0.1 ppm NO2 for 60-min exposures in asthmatics'' (ISA, p. 5-11). Industry groups raised a number of objections to this analysis and the way in which it has been used in the current review.

Several of these industry groups concluded that, in relying on this analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. For example, as part of a Request for Correction submitted under EPA's Information Quality Guidelines, NAM stated that ``EPA's substantial reliance on an unpublished assessment described as a ``meta-analysis'' of the relation between NO2 exposure and changes in airway responsiveness violates EPA Guidelines requiring ``transparency about data and methods.''

EPA disagrees with this characterization of the updated meta-analysis included in the final ISA. As described in the ISA (p. 3-16), this meta-analysis is based on an earlier analysis by Folinsbee (1992) that has been subject to peer-review, that was published in a scientific journal (Toxicol Ind Health. 8:1-11, 1992), and that was reviewed by CASAC as part of the previous review of the NO2 NAAQS (EPA, 1993, Table 15-10). The updates to this earlier analysis did not include substantive changes to the approach. As discussed in the final ISA (p. 3-16), the changes made to the analysis were to remove the results of one allergen study and add results from a non-specific responsiveness study, which focused the meta-analysis on non-specific airway responsiveness, and to discuss results for an additional exposure concentration (i.e., 100 ppb). The information needed to reproduce this meta-analysis is provided in the ISA (Tables 3.1-2 and 3.1-3, including footnotes).

While the ISA meta-analysis reports findings on airway responsiveness in asthmatics following exposure to 100 ppb NO2, a concentration not specifically discussed in the findings of the original report by Folinsbee (1992), this does not constitute a substantive change to that original analysis. For exposures at rest, four of the studies included in the analysis by Folinsbee evaluated the effects of exposure to 100 ppb NO2. In that original meta-analysis, these studies were grouped with another study that evaluated exposures to 140 ppb NO2. When analyzed together, exposures to NO2 concentrations of 100 ppb and 140 ppb (grouped together in the manuscript and described as less than 0.2 ppm) increased airway responsiveness in 65% of resting asthmatics (p < 0.01). Therefore, reporting results at 100 ppb NO2 in the ISA meta-analysis reflects a change in the way the data are presented and does not reflect a substantive change to the study. This change in presentation allows specific consideration of the potential for exposures to 100 ppb NO2 to increase airway responsiveness, rather than grouping results at 100 ppb with results at other exposure concentrations.

In addition, the updated meta-analysis was considered by CASAC during their review of the REA (REA, Table 4-5 reports the results of the updated meta-analysis), which based part of the assessment of NO2-associated health risks on the results of the meta-analysis. In their letter to the Administrator on the final REA (Samet, 2008b), CASAC stated that ``[t]he evidence reviewed in the REA indicates that adverse health effects have been documented in clinical studies of persons with asthma at 100 ppb'' and that ``CASAC firmly recommends that the upper end of the range [of standard levels] not exceed 100 ppb, given the findings of the REA.'' In addition, in their comments on the proposal, CASAC reiterated this advice in their statement that ``the level of the one-hour NO2 standard should be within the range of 80-100 ppb and not above 100 ppb.'' These statements indicate that CASAC did specifically consider the results of the updated meta-analysis and that they used those results to inform their recommendations on the range of standard levels supported by the scientific evidence.

In summary, we note the following:

The original meta-analysis was published in a peer-reviewed journal and was reviewed by CASAC in the previous review of the NO2 NAAQS.

The updated meta-analysis does not include substantive changes to the methodology of this original analysis.

The changes that were made are clearly described in the ISA.

CASAC specifically reviewed and considered the ISA meta-analysis in making recommendations regarding the range of standard levels supported by the science.

Many of these same industry groups also referred in their comments to a recent meta-analysis of controlled human exposure studies evaluating the airway response in asthmatics following NO2 exposure (Goodman et al., 2009). These groups generally recommended that EPA rely on this meta-analysis and on the authors' conclusions with regard to NO2 and airway responsiveness. Specific comments based on the manuscript by Goodman et al., as well as EPA's responses, are discussed below in more detail.\9\

\9\ EPA considers the Goodman study to be a ``new study'' on which, as discussed above in section 1.B, it would not be appropriate to base a standard in the absence of thorough CASAC and public review of the study and its methodology. However, as discussed below, EPA has considered the study in the context of responding to public comments on the proposal and has concluded it does not provide a basis to materially change any of the broad scientific conclusions regarding the health effects of NO2 made in the air quality criteria.

Industry commenters generally claimed that the meta-analysis by Goodman et al. supports the conclusion that no adverse effects occur following exposures up to 600 ppb NO2. However, Table 4 of the Goodman study reports that 64% (95% Confidence Interval: 58%, 71%) of resting asthmatics exposed to NO2 experienced an increase in airway responsiveness. Furthermore, Figure 2a of this manuscript reports that for exposures < 0.2 ppm, the fraction affected is 0.61 (95% CI: 0.52, 0.70) while for exposures of 0.2 ppm to < 0.3 ppm, the fraction affected is 0.66 (95% CI: 0.59, 0.74). These findings are consistent with those reported in the meta-analysis by Folinsbee and in the updated meta-analysis that was included in the final ISA.

Also based on the meta-analysis by Goodman et al. (2009), several industry commenters concluded that NO2-induced airway hyperresponsiveness is not adverse and, therefore, should not be considered in setting standards. The basis for this comment appears to be the conclusions reached by Goodman et al. that there is no dose-response relationship for NO2 and that the magnitude of any NO2 effect on airway responsiveness is too small to be considered adverse.

Due to differences in study protocols in the NO2-airway response literature (ISA, section 3.1.3), EPA disagrees with the approach taken in the Goodman study to use existing data to attempt to evaluate the presence of a dose-response relationship and to determine the magnitude of the NO2 response. Examples of differences in the study protocols include the NO2 exposure method (i.e., mouthpiece versus chamber), subject activity level (i.e., rest versus exercise) during NO2 exposure, choice of airway challenge agent, and physiological endpoint used to quantify airway responses. Goodman et al. (2009) also recognized heterogeneity among studies as a limitation in their analyses.

As a result of these differences, EPA judged it appropriate in the ISA meta-analysis to assess only the fraction of asthmatics experiencing increased or decreased airway responsiveness

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following NO2 exposure. We have acknowledged in the REA, the proposal, and in this final rulemaking that there is uncertainty with regard to the magnitude and the clinical-significance of NO2-induced increases in airway responsiveness (see sections II.C.3 and II.F.4.a in the proposed rulemaking as well as II.F.3 in this final rulemaking). The REA stated the following (p. 302):

[O]ne of the important uncertainties associated with these [NO2-induced airway hyperresponsiveness] results is that, because the meta-analysis evaluated only the direction of the change in airway responsiveness, it is not possible to discern the magnitude of the change from these data. This limitation makes it particularly difficult to quantify the public health implications of these results.

While we acknowledge this uncertainty, EPA disagrees with the conclusion that the NO2-induced increase in airway responsiveness in asthmatics exposed to NO2 concentrations up to 600 ppb is not adverse and should not be considered in setting standards. Specifically, we note that the ISA concluded that ``[t]ransient increases in airway responsiveness following NO2 exposure have the potential to increase symptoms and worsen asthma control'' (ISA, section 5.4). The uncertainty over the adversity of the response reported in controlled human exposure studies does not mean that the NO2-induced increase in airway responsiveness is not adverse. Rather, it means that there is a risk of adversity, especially for asthmatics with more than mild asthma, but that this risk cannot be fully characterized based on existing studies. The studies of NO2 and airway responsiveness included in the meta-analysis have generally evaluated mild asthmatics, rather than more severely affected asthmatics who could be more susceptible to the NO2-induced increase in airway responsiveness (ISA, section 3.1.3.2). Given that this is the case, and given the large percentage of asthmatics that experienced an NO2-induced increase in airway responsiveness in the studies and the large size of the asthmatic population in the United States, the REA concluded that it is appropriate to consider NO2-induced airway hyperresponsiveness in characterizing NO2-associated health risks (REA, section 10.3.2). As noted above, CASAC endorsed this conclusion in their letters to the Administrator on the final REA and on the proposal (Samet, 2008b; Samet, 2009).

c. Comments on EPA's Characterization of NO2-Associated Exposures and Health Risks

Several commenters discussed the analyses of NO2-associated exposures and health risks presented in the REA. As in past reviews (EPA 2005, 2007c, 2007d), EPA has estimated allowable risks associated with the current standard and potential alternative standards to inform judgments on the public health risks that could exist under different standard options. Some industry commenters (e.g., API, NMA) concluded that the Administrator should consider modeled exposures and risks associated with actual NO2 air quality rather than with NO2 concentrations adjusted to simulate just meeting the current annual standard or potential alternative 1-hour standards. These commenters pointed out that such simulations require large adjustments to air quality and are highly uncertain and that NAAQS are intended to address actual, rather than highly improbable, risks to health.

We disagree with these commenters that exposure- and risk-related considerations in the NAAQS review should rely only on unadjusted air quality. In considering whether the current standard is requisite to protect public health with an adequate margin of safety, air quality adjustments allow estimates of NO2-related exposures and health risks that could exist in areas that just meet that standard. That is, these adjustments allow consideration of exposures and risks that would be permissible under the current standard. Therefore, such adjustments are clearly useful to inform a decision on the issue before EPA (i.e., the adequacy of the level of public health protection associated with allowable NO2 air quality under the standard). Similarly, air quality adjustments to simulate different potential alternative standards provide information on exposures and risks that would be permissible under these alternatives.\10\ As noted above, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC concluded that ``The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure.''

\10\ Once EPA determines whether to retain or revise the current standard, the actual air quality levels in various areas of the country are clearly relevant under the NAAQS implementation provisions for the Act, such as the provision for designation of areas based on whether or not they attain the required NAAQS.

We agree that there are uncertainties inherent in air quality adjustments. These uncertainties are discussed thoroughly in the REA (sections 7.4, 8.12, 9.6, and 10.3.2.1) and in the proposed rule (section II.C.3). For example, the policy assessment chapter of the REA (section 10.3.2.1) noted the following regarding adjustment of NO2 concentrations:

In order to simulate just meeting the current annual standard and many of the alternative 1-h standards analyzed, an upward adjustment of recent ambient NO2 concentrations was required. We note that this adjustment does not reflect a judgment that levels of NO2 are likely to increase under the current standard or any of the potential alternative standards under consideration. Rather, these adjustments reflect the fact that the current standard, as well as some of the alternatives under consideration, could allow for such increases in ambient NO2 concentrations. In adjusting air quality to simulate just meeting these standards, we have assumed that the overall shape of the distribution of NO2 concentrations would not change. While we believe this is a reasonable assumption in the absence of evidence supporting a different distribution and we note that available analyses support this approach (Rizzo, 2008), we recognize this as an important uncertainty. It may be an especially important uncertainty for those scenarios where considerable upward adjustment is required to simulate just meeting one or more of the standards.

These air quality adjustments are not meant to imply an expectation that NO2 concentrations will increase broadly across the United States or in any given area (REA, section 10.3.2.1). Rather, as noted above, they are meant to estimate NO2-related exposures and health risks that would be permitted under the current and potential alternative standards. Such estimates can inform decisions on whether the current standard, or particular potential alternative standards, provide the requisite protection of public health.

3. Conclusions Regarding the Adequacy of the Current Standard

In considering the adequacy of the current standard, the Administrator has considered the scientific evidence assessed in the ISA, the exposure and risk results presented in the REA, the conclusions of the policy assessment chapter of the REA, and comments from CASAC and the public. These considerations are described below.

In considering the scientific evidence as it relates to the adequacy of the current standard, the Administrator notes that the epidemiologic evidence has grown substantially since the last review with the addition of field and panel studies, intervention studies, and time-series studies of effects such as emergency department visits and hospital admissions associated with

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short-term NO2 exposures. No epidemiologic studies were available in 1993 assessing relationships between NO2 and outcomes such as hospital admissions or emergency department visits. In contrast, dozens of epidemiologic studies on such outcomes, conducted at recent and current ambient NO2 concentrations, are now included in this evaluation (ISA, chapter 3).

As an initial consideration with regard to the adequacy of the current standard, the Administrator notes that the evidence relating long-term (weeks to years) NO2 exposures at current ambient concentrations to adverse health effects was judged in the ISA to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). In contrast, the evidence relating short-term (minutes to hours) NO2 exposures to respiratory morbidity was judged to be ``sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1). This conclusion was supported primarily by a large body of recent epidemiologic studies that evaluated associations of short-term NO2 concentrations with respiratory symptoms, emergency department visits, and hospital admissions. Given these conclusions from the ISA, the Administrator judges that, at a minimum, consideration of the adequacy of the current annual standard should take into account the extent to which that standard provides protection against respiratory effects associated with short-term NO2 exposures.

In considering the NO2 epidemiologic studies as they relate to the adequacy of the current standard, the Administrator notes that annual average NO2 concentrations were below the level of the current annual NO2 NAAQS in many of the locations where positive, and often statistically significant, associations with respiratory morbidity endpoints have been reported (ISA, section 5.4). As discussed previously, the ISA characterized that evidence for respiratory effects as consistent and coherent. The evidence is consistent in that associations are reported in studies conducted in numerous locations and with a variety of methodological approaches (ISA, section 5.3.2.1). It is coherent in the sense that the studies report associations with respiratory health outcomes that are logically linked together (ISA, section 5.3.2.1). The ISA noted that when the epidemiologic literature is considered as a whole, there are generally positive associations between NO2 and respiratory symptoms, hospital admissions, and emergency department visits. A number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1).

As discussed in the proposal (II.E.1) and above, the Administrator acknowledges that the interpretation of these NO2 epidemiologic studies is complicated by the fact that on-road vehicle exhaust emissions are a nearly ubiquitous source of combustion pollutant mixtures that include NO2. She notes that, in order to provide some perspective on the uncertainty related to the presence of co-pollutants the ISA evaluated epidemiologic studies that employed multi-pollutant models, epidemiologic studies of indoor NO2 exposure, and experimental studies. Specifically, the ISA noted that a number of NO2 epidemiologic studies have attempted to disentangle the effects of NO2 from those of co-occurring pollutants by employing multi-pollutant models. When evaluated as a whole, NO2 effect estimates in these models generally remained robust when co-pollutants were included. Therefore, despite uncertainties associated with separating the effects of NO2 from those of co-occurring pollutants, the ISA (section 5.4, p. 5-16) concluded that ``the evidence summarized in this assessment indicates that NO2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS.'' With regard to indoor studies, the ISA noted that these studies can test hypotheses related to NO2 specifically (ISA, section 3.1.4.1). Although confounding by indoor combustion sources is a concern, indoor studies are not confounded by the same mix of co-pollutants present in the ambient air or by the contribution of NO2 to the formation of secondary particles or O3 (ISA, section 3.1.4.1). The ISA noted that the findings of indoor NO2 studies are consistent with those of studies using ambient concentrations from central site monitors and concluded that indoor studies provide evidence of coherence for respiratory effects (ISA, section 3.1.4.1). With regard to experimental studies, the REA noted that they have the advantage of providing information on health effects that are specifically associated with exposure to NO2 in the absence of co-pollutants. The ISA concluded that the NO2 epidemiologic literature is supported by (1) evidence from controlled human exposure studies of airway hyperresponsiveness in asthmatics, (2) controlled human exposure and animal toxicological studies of impaired host-defense systems and increased risk of susceptibility to viral and bacterial infection, and (3) controlled human exposure and animal toxicological studies of airway inflammation (ISA, section 5.3.2.1 and 5.4). Given the above consideration of the evidence, particularly the epidemiologic studies reporting NO2-associated health effects in locations that meet the current standard, the Administrator agrees with the conclusion in the policy assessment chapter of the REA that the scientific evidence calls into question the adequacy of the current standard to protect public health.

In addition to the evidence-based considerations described above, the Administrator has considered the extent to which exposure- and risk-based information can inform decisions regarding the adequacy of the current annual NO2 standard. While she acknowledges the uncertainties associated with adjusting air quality in these analyses, she judges that such analyses are appropriate for consideration in this review of the NO2 primary NAAQS. In reaching this conclusion she notes the considerations discussed above, particularly the endorsement by CASAC of the REA and its characterization of NO2-associated exposures and health risks.

In considering the exposure- and risk-based information with regard to the adequacy of the current annual NO2 standard to protect the public health, the Administrator notes the conclusion in the policy assessment chapter of the REA that risks estimated to be associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be concluded to be important from a public health perspective. In particular, a large percentage (8-9%) of respiratory-related ED visits in Atlanta could be associated with short-term NO2 exposures, most asthmatics in Atlanta could be exposed on multiple days per year to NO2 concentrations at or above 300 ppb, and most locations evaluated could experience on-/near-road NO2 concentrations above 100 ppb on more than half of the days in a given year. Therefore, after considering the results of the exposure and risk analyses presented in the REA the Administrator agrees with the conclusion of the policy assessment chapter of the REA that exposure- and risk-based results reinforce the scientific evidence in

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supporting the conclusion that consideration should be given to revising the current standard so as to provide increased public health protection, especially for at-risk groups, from NO2-related adverse health effects associated with short-term, and potential long-term, exposures.

In reaching a conclusion on the adequacy of the current standard, the Administrator has also considered advice received from CASAC. In their comments on the final REA, CASAC agreed that the primary concern in this review is to protect against health effects that have been associated with short-term NO2 exposures. CASAC also agreed that the current annual standard is not sufficient to protect public health against the types of exposures that could lead to these health effects. As noted in their letter to the EPA Administrator, ``CASAC concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised'' (Samet, 2008b).

Based on the considerations discussed above, the Administrator concludes that the current NO2 primary NAAQS alone is not requisite to protect public health with an adequate margin of safety. Accordingly, she concludes that the NO2 primary standard should be revised in order to provide increased public health protection against respiratory effects associated with short-term exposures, particularly for susceptible populations such as asthmatics, children, and older adults. In considering approaches to revising the current standard, the Administrator concludes that it is appropriate to consider setting a new short-term standard (see below). The Administrator notes that such a short-term standard could provide increased public health protection, especially for members of at-risk groups, from effects described in both epidemiologic and controlled human exposure studies to be associated with short-term exposures to NO2.

F. Elements of a New Short-Term Standard

In considering a revised NO2 primary NAAQS, the Administrator notes the need to protect at-risk individuals from short-term exposures to NO2 air quality that could cause the types of respiratory morbidity effects reported in epidemiologic studies and the need to protect at-risk individuals from short-term exposure to NO2 concentrations reported in controlled human exposure studies to increase airway responsiveness in asthmatics. The Administrator's considerations with regard to her decisions are discussed in the following sections in terms of indicator (II.F.1), averaging time (II.F.2), level (II.F.3), and form (II.F.4).

1. Indicator

a. Rationale for Proposed Decision

In past reviews, EPA has focused on NO2 as the most appropriate indicator for ambient NOX. In making a decision in the current review on the most appropriate indicator, the Administrator considered the conclusions of the ISA and the policy assessment chapter of the REA as well as the view expressed by CASAC. The policy assessment chapter of the REA noted that, while the presence of NOX species other than NO2 has been recognized, no alternative to NO2 has been advanced as being a more appropriate surrogate. Controlled human exposure studies and animal toxicology studies assessed in the ISA provide specific evidence for health effects following exposure to NO2. Epidemiologic studies also typically report levels of NO2 though the degree to which monitored NO2 reflects actual NO2 levels, as opposed to NO2 plus other gaseous NOX, can vary (REA, section 2.2.3). In addition, because emissions that lead to the formation of NO2 generally also lead to the formation of other NOX oxidation products, measures leading to reductions in population exposures to NO2 can generally be expected to lead to reductions in population exposures to other gaseous NOX. Therefore, an NO2 standard can also be expected to provide some degree of protection against potential health effects that may be independently associated with other gaseous NOX even though such effects are not discernable from currently available studies indexed by NO2 alone. Given these key points, the policy assessment chapter of the REA concluded that the evidence supports retaining NO2 as the indicator. Consistent with this conclusion, the CASAC Panel stated in its letter to the EPA Administrator that it ``concurs with retention of NO2 as the indicator'' (Samet, 2008b). In light of the above considerations, the Administrator proposed to retain NO2 as the indicator in the current review.

b. Comments on Indicator

A relatively small number of comments directly addressed the issue of the indicator for the standard (CASAC, Dow, API, AAM, and the Missouri Department of Natural Resources Air Pollution Control Program (MODNR)). All of these commenters endorsed the proposal to continue to use NO2 as the indicator for ambient NOX.

c. Conclusions on Indicator

Based on the available information discussed above, and consistent with the views of CASAC and other commenters, the Administrator concludes that it is appropriate to continue to use NO2 as the indicator for a standard that is intended to address effects associated with exposure to NO2, alone or in combination with other gaseous NOX. In so doing, the Administrator recognizes that measures leading to reductions in population exposures to NO2 will also reduce exposures to other nitrogen oxides.

2. Averaging Time

This section discusses considerations related to the averaging time of the NO2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding averaging time (II.F.2.a; see section II.F.2 of the proposal for more detail), discusses comments related to averaging time (II.F.2.b), and presents the Administrator's final conclusions regarding averaging time (II.F.2.c).

a. Rationale for Proposed Decision

In considering the most appropriate averaging time for the NO2 primary NAAQS, the Administrator noted in the proposal the conclusions and judgments made in the ISA about available scientific evidence, air quality correlations discussed in the REA, conclusions of the policy assessment chapter of the REA, and CASAC recommendations (section II.F.2 in the proposal). Specifically, she noted the following:

Experimental studies in humans and animals have reported respiratory effects following NO2 exposures lasting from less than 1-hour up to several hours. Epidemiologic studies have reported associations between respiratory effects and both 1 hour and 24-hour NO2 concentrations. Therefore, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (e.g., 1 hour) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. At a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO2 concentrations.

Air quality correlations presented in the policy assessment chapter of the REA illustrated the relatively high degree of variability in the ratios of annual average to short-term NO2 concentrations (REA, Table 10-2). This

variability suggests that a standard based on annual average NO2 concentrations would not likely be an effective or efficient approach to focus protection on short-term exposures.

These air quality correlations (REA, Table 10-1) suggested that a standard based on 1-hour daily maximum NO2 concentrations could also be effective at protecting against 24-hour NO2 concentrations.

The policy assessment chapter of the REA concluded that the scientific evidence, combined with the air quality correlations, support the appropriateness of a standard based on 1-hour daily maximum NO2 concentrations to protect against health effects associated with short-term exposures.

CASAC concurred ``with having a short-term NAAQS primary standard for oxides of nitrogen and using the one-hour maximum NO2 value'' (Samet, 2008b).

Based on these considerations, the Administrator proposed to set a new standard based on 1-hour daily maximum NO2 concentrations.

b. Comments on averaging time

As discussed above, CASAC endorsed the establishment of a new standard with a 1-hour averaging time. CASAC stated the following in their comments on the proposal (Samet, 2009):

In reviewing the REA, CASAC supported a short-term standard for NO2 and in reviewing the proposal, CASAC supports the proposed one-hour averaging time in EPA's proposed rule.

The supporting rationale offered by CASAC in support of a new 1-hour standard was generally the same as that put forward in the final REA and the proposal. Specifically, that rationale considered the available scientific evidence, which supports a link between 1-hour NO2 concentrations and adverse respiratory effects, and air quality information presented in the REA, which suggests that a 1-hour standard can protect against effects linked to short-term NO2 exposures while an annual standard would not be an effective or efficient approach to protecting against these effects.

A large number of public commenters also endorsed the establishment of a new standard with a 1-hour averaging time. These included a number of State agencies and organizations (e.g., NACAA, NESCAUM and agencies in CA, IL, NM, TX, VA); environmental, medical, and public health organizations (e.g., ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC); and most individual commenters. The supporting rationales offered by these commenters often acknowledged the recommendations of CASAC and the Administrator's rationale as discussed in the proposal.

Though many industry commenters recommended not revising the current annual standard (as discussed above in section II.E.2), several of these groups did conclude that if a short-term standard were to be set, a 1-hour averaging time would be appropriate (e.g., Colorado Petroleum Association (CPA), Dow, NAM, Petroleum Association of Wyoming (PAW), Utah Petroleum Association (UPA)). As discussed above, industry commenters who disagreed with setting a new 1-hour standard generally based this conclusion on their interpretation of the scientific evidence and their conclusion that this evidence does not support the need to revise the current annual standard. These comments, and EPA's responses, are discussed in more detail above (section II.E) and in the Response to Comments document.

c. Conclusions on Averaging Time

In considering the most appropriate averaging time for the NO2 primary NAAQS, the Administrator notes the available scientific evidence as assessed in the ISA, the air quality analyses presented in the REA, the conclusions of the policy assessment chapter of the REA, CASAC recommendations, and public comments received. These considerations are described below.

When considering averaging time, the Administrator notes that the evidence relating short-term (minutes to hours) NO2 exposures to respiratory morbidity was judged in the ISA to be ``sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1) while the evidence relating long-term (weeks to years) NO2 exposures to adverse health effects was judged to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). Thus, the Administrator concludes that these judgments most directly support an averaging time that focuses protection on short-term exposures to NO2.

As in past reviews of the NO2 NAAQS, the Administrator notes that it is instructive to evaluate the potential for a standard based on annual average NO2 concentrations, as is the current standard, to provide protection against short-term NO2 exposures. To this end, the Administrator notes that

Table 10-1 in the REA reported the ratios of short-term to annual average NO2 concentrations. Ratios of 1-hour daily maximum concentrations (98th and 99th percentile \11\) to annual average concentrations across 14 locations ranged from 2.5 to 8.7 while ratios of 24-hour average concentrations to annual average concentrations ranged from 1.6 to 3.8 (see Thompson, 2008 for more details). The policy assessment chapter of the REA concluded that the variability in these ratios across locations, particularly those for 1-hour concentrations, suggested that a standard based on annual average NO2 concentrations would not likely be an effective or efficient approach to focus protection on short-term NO2 exposures. For example, in an area with a relatively high ratio (e.g., 8), the current annual standard (53 ppb) would be expected to allow 1-hour daily maximum NO2 concentrations of about 400 ppb. In contrast, in an area with a relatively low ratio (e.g., 3), the current standard would be expected to allow 1-hour daily maximum NO2 concentrations of about 150 ppb. Thus, for purposes of protecting against the range of 1-hour NO2 exposures, the REA noted that a standard based on annual average concentrations would likely require more control than necessary in some areas and less control than necessary in others, depending on the standard level selected.

\11\ As discussed below, 98th and 99th percentile forms were evaluated in the REA. A 99th percentile form corresponds approximately to the 4th highest 1-hour concentration in a year while a 98th percentile form corresponds approximately to the 7th or 8th highest 1-hour concentration in a year. A 4th highest concentration form has been used previously in the O3 NAAQS while a 98th percentile form has been used previously in the PM2.5 NAAQS.

In considering the level of support available for specific short-term averaging times, the Administrator notes that the policy assessment chapter of the REA considered evidence from both experimental and epidemiologic studies. Controlled human exposure studies and animal toxicological studies provide evidence that NO2 exposures from less than 1-hour up to 3-hours can result in respiratory effects such as increased airway responsiveness and inflammation (ISA, section 5.3.2.7). Specifically, the ISA concluded that NO2 exposures of 100 ppb for 1-hour (or 200 ppb to 300 ppb for 30-min) can result in small but significant increases in nonspecific airway responsiveness (ISA, section 5.3.2.1). In contrast, the epidemiologic literature provides support for short-term averaging times ranging from approximately 1-hour up to 24-hours (ISA, section 5.3.2.7). A

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number of epidemiologic studies have detected positive associations between respiratory morbidity and 1-hour (daily maximum) and/or 24-hour NO2 concentrations. A few epidemiologic studies have considered both 1-hour and 24-hour averaging times, allowing comparisons to be made. The ISA reported that such comparisons in studies that evaluate asthma emergency department visits failed to reveal differences between effect estimates based on a 1-hour averaging time and those based on a 24-hour averaging time (ISA, section 5.3.2.7). Therefore, the ISA concluded that it is not possible, from the available epidemiologic evidence, to discern whether effects observed are attributable to average daily (or multi-day) concentrations (24-hour average) or high, peak exposures (1-hour maximum) (ISA, section 5.3.2.7).

As noted in the policy assessment chapter of the REA, given the above conclusions, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (e.g., 1-h) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. The Administrator concludes that, at a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO2 concentrations. However, she also notes that it is important to consider the ability of a 1-hour averaging time to protect against 24-hour average NO2 concentrations. To this end, the Administrator notes that Table 10-2 in the REA presented correlations between 1-hour daily maximum NO2 concentrations and 24-hour average NO2 concentrations (98th and 99th percentile) across 14 locations (see Thompson, 2008 for more detail). Typical ratios ranged from 1.5 to 2.0, though one ratio (Las Vegas) was 3.1. These ratios were far less variable than those discussed above for annual average concentrations, suggesting that a standard based on 1-hour daily maximum NO2 concentrations could also be effective at protecting against 24-hour NO2 concentrations. The REA concluded that the scientific evidence, combined with the air quality correlations described above, support the appropriateness of a standard based on 1-hour daily maximum NO2 concentrations to protect against health effects associated with short-term exposures.

Based on these considerations, the Administrator concludes that a standard with a 1-hour averaging time can effectively limit short-term (i.e., 1- to 24-hours) exposures that have been linked to adverse respiratory effects. This conclusion is based on the observations summarized above and in more detail in the proposal, particularly that: (1) The 1-hour averaging time has been directly associated with respiratory effects in both epidemiologic and experimental studies and that (2) results from air quality analyses suggest that a 1-hour standard could also effectively control 24-hour NO2 concentrations. In addition, the Administrator notes the support provided for a 1-hour averaging time in comments from CASAC, States, environmental groups, and medical/public health groups. The Administrator notes that arguments offered by some industry groups against setting a 1-hour NO2 standard generally focus on commenters' conclusions regarding uncertainties in the scientific evidence. As discussed in more detail above (section II.E.2), the Administrator disagrees with the conclusions of these commenters regarding the appropriate interpretation of the scientific evidence and associated uncertainties. Given these considerations, the Administrator judges that it is appropriate to set a new NO2 standard with a 1-hour averaging time.

3. Form

This section discusses considerations related to the form of the 1-hour NO2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding form (II.F.4.a; see section II.F.3 of the proposal for more detail), discusses comments related to form (II.F.4.b), and presents the Administrator's final conclusions regarding form (II.F.4.c).

a. Rationale For Proposed Decision

When considering alternative forms in the proposal, the Administrator noted the conclusions in the policy assessment chapter of the REA. Specifically, she noted the conclusion that the adequacy of the public health protection provided by the combination of standard level and form should be the foremost consideration. With regard to this, she noted that concentration-based forms can better reflect pollutant-associated health risks than forms based on expected exceedances. This is the case because concentration-based forms give proportionally greater weight to years when pollutant concentrations are well above the level of the standard than to years when the concentrations are just above the standard, while an expected exceedance form would give the same weight to years with concentrations that just exceed the standard as to years when concentrations greatly exceed the standard. The Administrator also recognized the conclusion in the policy assessment chapter of the REA that it is desirable from a public health perspective to have a form that is reasonably stable and insulated from the impacts of extreme meteorological events. With regard to this, she noted that a form that calls for averaging concentrations over three years would provide greater regulatory stability than a form based on a single year of concentrations. Therefore, consistent with recent reviews of the O3 and PM NAAQS, the proposal focused on concentration-based forms averaged over 3 years, as evaluated in the REA.

In considering specific concentration-based forms, the REA focused on 98th and 99th percentile concentrations averaged over 3 years. This focus on the upper percentiles of the distribution is appropriate given the reliance, in part, on NO2 health evidence from experimental studies, which provide information on specific exposure concentrations that are linked to specific health effects. The REA noted that a 99th percentile form for a 1-hour daily maximum standard would correspond approximately to the 4th highest daily maximum concentration in a year (which is the form of the current O3 NAAQS) while a 98th percentile form (which is the form of the current short-term PM2.5 NAAQS) would correspond approximately to the 7th or 8th highest daily maximum concentration in a year (REA, Table 10-4; see Thompson, 2008 for methods).

Consideration in the REA of an appropriate form for a 1-hour standard was based on analyses of standard levels that reflected the allowable area-wide NO2 concentration, not the maximum allowable concentration. Therefore, in their review of the final REA, CASAC did not have the opportunity to comment on the appropriateness of specific forms in conjunction with a standard level that reflects the maximum allowable NO2 concentration anywhere in an area. Given this, when considering alternative forms for the 1-hour standard in the proposal, the Administrator judged that it was appropriate to consider both forms evaluated in the REA (i.e., 98th and 99th percentiles). Therefore, she proposed to adopt either a 99th percentile or a 4th highest form, averaged over 3 years, and she solicited comment on both 98th percentile and 7th or 8th highest forms.

b. CASAC and Public Comments on Form

In their letter to the Administrator, CASAC discussed the issue of form within the context of the proposed

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approach of setting a 1-hour standard level that reflects the maximum allowable NO2 concentration anywhere in an area. CASAC recommended that, for such a standard, EPA adopt a form based on the 3-year average of the 98th percentile of the distribution of 1-hour daily maximum NO2 concentrations. Specifically, they stated the following in their comments on the proposal (Samet, 2009):

> The 98th percentile is preferred by CASAC for the form, given the likely instability of measurements at the upper range and the absence of data from the proposed two-tier approach.

As indicated in their letter, CASAC concluded that the potential instability in higher percentile NO2 concentrations near major roads argues for a 98th, rather than a 99th, percentile form. Several State organizations and agencies (e.g., NESCAUM and agencies in IN, NC, SD, VA) and industry groups (e.g., AAM, ACC, API, AirQuality Research and Logistics (AQRL), CPA, Dow, ExxonMobil, IPAMS, PAW, UPA) also recommended a 98th percentile form in order to provide regulatory stability. In contrast, a small number of State and local agencies (e.g., in MO and TX), several environmental organizations (e.g., EDF, EJ, GASP, NRDC), and medical/public health organizations (e.g., ALA, ATS) recommended either a 99th percentile form or a more stringent form (e.g., no exceedance) to further limit the occurrence of NO2 concentrations that exceed the standard level in locations that attain the standard.

c. Conclusions On Form

The Administrator recognizes that there is not a clear health basis for selecting one specific form over another. She also recognizes that the analyses of different forms in the REA are most directly relevant to a standard that reflects NO2 concentrations permitted to occur broadly across a community, rather than the maximum concentration that can occur anywhere in the area. In contrast, as discussed below (section II.F.4.c), the Administrator has judged it appropriate to set a new 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area. In light of this, the Administrator places particular emphasis on the comments received on form from CASAC relating to a 1-hour standard level that reflects the maximum allowable NO2 concentration anywhere in an area. In particular, the Administrator notes that CASAC recommended a 98th percentile form averaged over 3 years for such a standard, given the potential for instability in the higher percentile concentrations around major roadways.

In considering this recommendation, the Administrator recognizes that the public health protection provided by the 1-hour NO2 standard is based on the approach used to set the standard and the level of the standard (see below), in conjunction with the form of the standard. Given that the Administrator is setting a standard that reflects the maximum allowable NO2 concentration anywhere in an area, rather than a standard that reflects the allowable area-wide NO2 concentration, she agrees with CASAC that an appropriate consideration with regard to form is the extent to which specific statistics could be unstable at locations where maximum NO2 concentrations are expected, such as near major roads. When considering alternative forms for the standard, the Administrator notes that an unstable form could result in areas shifting in and out of attainment, potentially disrupting ongoing air quality planning without achieving public health goals. Given the limited available information on the variability in peak NO2 concentrations near important sources of NO2 such as major roadways, and given the recommendation from CASAC that the potential for instability in the 99th percentile concentration is cause for supporting a 98th percentile form, the Administrator judges it appropriate to set the form based on the 3-year average of the 98th percentile of the annual distribution of 1-hour daily maximum NO2 concentrations.

4. Level

As discussed below and in more detail in the proposal (section II.F.4), the Administrator has considered two different approaches to setting the 1-hour NO2 primary NAAQS. In the proposal, each of these approaches was linked with a different range of standard levels. Specifically, the Administrator proposed to set a 1-hour standard reflecting the maximum allowable NO2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. The Administrator also solicited comment on the alternative approach of setting a standard that reflects the allowable area-wide NO2 concentration and setting the standard level from 50 to 75 ppb. This section summarizes the rationale for the Administrator's proposed approach and range of standard levels (II.F.3.a), describes the alternative approach and range of standard levels (II.F.3.b), discusses comments related to each approach and range of standard levels (II.F.3.c), and presents the Administrator's final conclusions regarding the approach and level (II.F.3.d).

a. Rationale For Proposed Decisions on Approach and Level

In assessing the most appropriate approach to setting the 1-hour standard and the most appropriate range of standard levels to propose, the Administrator considered the broad body of scientific evidence assessed in the ISA, including epidemiologic and controlled human exposure studies, as well as the results of exposure/risk analyses presented in the REA. In light of the body of available evidence and analyses, as described above, the Administrator concluded in the proposal that it is necessary to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term (i.e., 30 minutes to 24 hours) exposures to NO2. Such health effects have been associated with exposure to the distribution of short-term ambient NO2 concentrations across an area, including higher short-term (i.e., peak) exposure concentrations, such as those that can occur on or near major roadways and near other sources of NO2, as well as the lower short-term exposure concentrations that can occur in areas not near major roadways or other sources of NO2. The Administrator's proposed decisions on approach and level, as discussed in detail in the proposal (section II.F.4), are outlined below.

In considering a standard-setting approach, the Administrator was mindful in the proposal that the available evidence and analyses from the ISA and REA support the public health importance of roadway-associated NO2 exposures. The exposure assessment described in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). The ISA concluded (section 4.3.6) that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level.'' In considering the potential variability in the NO2 concentration gradient, the proposal noted that available monitoring studies suggest that NO2 concentrations could be 30 to 100% higher than those in the same area but away from the road.\12\

\12\ In addition, the air quality analyses presented in the REA estimated that on-road NO2 concentrations are about 80% higher on average than concentrations away from the road (REA, section 7.3.2) and that NO2 monitors within 20 m of roads measure NO2 concentrations that are, on average across locations, 40% higher than concentrations measured by monitors at least 100 m from the road (REA, compare Tables 7-11 and 7-13).

The Administrator also considered that millions of people in the United States live, work, and/or attend school near important sources of NO2 such as major roadways (ISA, section 4.4), and that ambient NO2 concentrations in these locations vary depending on the distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration) (ISA, section 2.5.4). Therefore, these populations, which likely include a disproportionate number of individuals in groups with higher prevalence of asthma and higher hospitalization rates for asthma (e.g. ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), are likely exposed to NO2 concentrations that are higher than those occurring away from major roadways.

Given the above considerations, the Administrator proposed an approach to setting the 1-hour NO2 primary NAAQS whereby the standard would reflect the maximum allowable NO2 concentration anywhere in an area. In many locations, this concentration is likely to occur on or near a major roadway. EPA proposed to set the level of the standard such that, when available information regarding the concentration gradient around roads is considered, appropriate public health protection would be provided by limiting the higher short-term peak exposure concentrations expected to occur on and near major roadways, as well as the lower short-term exposure concentrations expected to occur away from those roadways. The Administrator concluded that this approach to setting the 1-hour NO2 NAAQS would be expected to protect public health against exposure to the distribution of short-term NO2 concentrations across an area and would provide a relatively high degree of confidence regarding the protection provided against peak exposures to higher NO2 concentrations, such as those that can occur around major roadways. The remainder of this section discusses the proposed range of standard levels.

In considering the appropriate range of levels to propose for a standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator considered the broad body of scientific evidence and exposure/risk information as well as available information on the relationship between NO2 concentrations near roads and those away from roads. Specifically, she considered the extent to which a variety of levels would be expected to protect at-risk individuals against increased airway responsiveness, respiratory symptoms, and respiratory-related emergency department visits and hospital admissions.

After considering the scientific evidence and the exposure/risk information (see sections II.B, II.C, and II.F.4.a.1 through II.F.4.a.3 in the proposal), as well as the available information on the NO2 concentration gradient around roadways (section II.A.2 above and in the proposal), the Administrator concluded that the strongest support is for a standard level at or somewhat below 100 ppb. The Administrator's rationale in reaching this proposed conclusion is provided below.

The Administrator noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to limit short-term NO2 exposures to concentrations that have been reported to increase airway responsiveness in asthmatics (i.e., at or above 100 ppb). While she acknowledged that exposure to NO2 concentrations below 100 ppb could potentially increase airway responsiveness in some asthmatics, the Administrator also noted uncertainties regarding the magnitude and the clinical significance of the NO2-induced increase in airway responsiveness, as discussed in the policy assessment chapter of the REA (section 10.3.2.1, discussed in section II.F.4.e in the proposal). Given these uncertainties, the Administrator concluded in the proposal that controlled human exposure studies provide support for limiting exposures at or somewhat below 100 ppb NO2.

The Administrator also noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to maintain peak area-wide NO2 concentrations considerably below those measured in locations where key U.S. epidemiologic studies have reported associations with more serious respiratory effects, as indicated by increased emergency department visits and hospital admissions. Specifically, the Administrator noted that 5 key U.S. studies provide evidence for such associations in locations where the 99th percentile of the distribution of 1-hour daily maximum NO2 concentrations measured at area-wide monitors ranged from 93 to 112 ppb (Ito et al., 2007; Jaffe et al., 2003; Peel et al., 2005; Tolbert et al., 2007; and a study by the New York State Department of Health, 2006).\13\ The Administrator concluded that these studies provide support for a 1-hour standard that limits the 99th percentile of the distribution of 1-hour daily maximum area-wide NO2 concentrations to below 90 ppb (corresponds to a 98th percentile concentration of 85 ppb), and that limiting area-wide concentrations to considerably below 90 ppb would be appropriate in order to provide an adequate margin of safety. The Administrator noted that, based on available information about the NO2 concentration gradient around roads, a standard level at or somewhat below 100 ppb set in conjunction with the proposed approach would be expected to accomplish this. Specifically, she noted that given available information regarding NO2 concentration gradients around roads (see section II.A.2), a standard level at or below 100 ppb (with either a 99th or 98th percentile form) would be expected to limit peak area-wide NO2 concentrations to approximately 75 ppb or below.\14\ Therefore, the Administrator concluded that a standard level at or somewhat below 100 ppb under the proposed approach would be expected to maintain peak area-wide NO2 concentrations well below 90 ppb across locations despite the expected variation in the NO2 concentration gradient that can exist around roadways in different locations and over time.

\13\ The 98th percentile concentrations in these study locations ranged from 85 to 94 ppb.

\14\ For a standard of 100 ppb, area-wide concentrations would be expected to range from approximately 50 ppb (assuming near-road concentrations are 100% higher than area-wide concentrations) to 75 ppb (assuming near-road concentrations are 30% higher than area-wide concentrations).

The Administrator also noted that a study by Delfino provides mixed evidence for effects in a location with area-wide 98th and 99th percentile 1-hour daily maximum NO2 concentrations of 50 and 53 ppb, respectively. In that study, NO2 effect estimates were positive, but some reported 95% confidence limits for the odds ratio (OR) that included values less than 1.00. Given the mixed results of the Delfino study, the Administrator concluded that it may not be necessary to maintain area-wide NO2 concentrations at or below 50 ppb to provide protection against the effects reported in epidemiologic studies.

In addition to these evidence-based considerations, the Administrator noted that a standard level at or somewhat below 100 ppb under the proposed approach would be consistent with the

results of the exposure and risk analyses presented in the REA. As discussed in section II.C of the proposal, the results of these analyses provide support for setting a standard that limits 1-hour area-wide NO2 concentrations to between 50 and 100 ppb. As described above, a standard level of 100 ppb that reflects the maximum allowable NO2 concentration would be expected to maintain area-wide NO2 concentrations at or below approximately 75 ppb. Given all of these considerations, the Administrator concluded in the proposal that a standard level at or somewhat below 100 ppb (with a 99th percentile form), in conjunction with the proposed approach, would be requisite to protect public health with an adequate margin of safety against the array of NO2-associated health effects.

In addition to the considerations discussed above, which support setting a standard level at or somewhat below 100 ppb, the Administrator also considered the extent to which available evidence could support standard levels below 100 ppb. The Administrator concluded that the evidence could support setting the standard level below 100 ppb to the extent the following were emphasized:

The possibility that an NO2-induced increase in airway responsiveness could occur in asthmatics following exposures to concentrations below 100 ppb and/or the possibility that such an increase could be clinically significant.

The mixed results reported in the study by Delfino et al. (2002) of an association between respiratory symptoms and the relatively low ambient NO2 concentrations measured in the study area.

Specifically, she noted that a standard level of 80 ppb (99th percentile form), in conjunction with the proposed approach, could limit area-wide NO2 concentrations to 50 ppb \15\ and would be expected to limit exposure concentrations to below those that have been reported to increase airway responsiveness in asthmatics. For the reasons stated above, the Administrator proposed to set the level of a new 1-hour standard between 80 ppb and 100 ppb.

\15\ This conclusion assumes that near-road NO2 concentrations are 65% higher than area-wide concentrations, reflecting the mid-point in the range of 30 to 100%. Based on available information suggesting that near-road concentrations can be 30 to 100% higher than area-wide concentrations, a standard level of 80 ppb could limit area-wide concentrations to between 40 and 60 ppb.

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b. Rationale for the Alternative Approach and Range of Levels

As described above, the Administrator proposed to set a 1-hour NO2 NAAQS reflecting the maximum allowable NO2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. However, prior to the proposal, the approach of setting a 1-hour NO2 NAAQS that reflects the maximum allowable NO2 concentration anywhere in an area had not been discussed by EPA in the REA or considered by CASAC. Rather, the potential alternative standards discussed in the REA, and reviewed by CASAC, reflected allowable area-wide NO2 concentrations (i.e., concentrations that occur broadly across communities).

Given this, the Administrator noted in the proposal that comments received on the approach to setting the 1-hour standard (i.e., from CASAC and from members of the public) could provide important new information for consideration. Therefore, the Administrator also solicited comment on the alternative approach of setting a 1-hour NO2 primary NAAQS that would reflect the allowable area-wide NO2 concentration, analogous to the standards evaluated in the REA, and with a level set within the range of 50 to 75 ppb. In discussing this alternative approach with a standard level from 50 to 75 ppb, the Administrator noted the following in the proposal:

Such a standard would be expected to maintain area-wide NO2 concentrations below peak 1-hour area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions.

Standard levels from the lower end of the range would be expected to limit roadway-associated exposures to NO2 concentrations that have been reported in controlled human exposure studies to increase airway responsiveness in asthmatics. Specifically, a standard level of 50 ppb under this approach could limit near-road concentrations to between approximately 65 and 100 ppb, depending on the relationship between near-road NO2 concentrations and area-wide concentrations.

This alternative approach would provide relatively more confidence regarding the degree to which a specific standard level would limit area-wide NO2 concentrations and less confidence regarding the degree to which a specific standard level would limit the peak NO2 concentrations likely to occur near major roadways.

c. Comments on Approach and Level

In the proposal, each approach to setting the 1-hour standard, and each range of standard levels, was linked to different requirements for the design of the NO2 monitoring network. Specifically, in conjunction with the proposed approach (i.e., standard reflects the maximum allowable NO2 concentration anywhere in an area and the level is set within the range of 80 to 100 ppb), the Administrator proposed to establish a 2-tiered monitoring network that would include monitors sited to measure the maximum NO2 concentrations anywhere in an area, including near major roadways, and monitors sited to measure maximum area-wide NO2 concentrations. In conjunction with the alternative approach (i.e., standard reflects the allowable area-wide NO2 concentration and the level is set within the range of 50 to 75 ppb), the Administrator solicited comment on a monitoring network that would only include area-wide NO2 monitors. Because of these linkages in the proposal, most commenters combined their comments on the approach to setting a 1-hour standard and on the standard level with their comments on the monitoring requirements. In this section, we discuss comments from CASAC and public commenters on the approach to setting a 1-hour standard and on the standard level. Comments on the monitoring network are also discussed in this section to the extent they indicate a preference for either the proposed or alternative approach to setting the 1-hour standard. More specific comments on monitor placement and network design are discussed below in section III.B.2 and in the Response to Comments document. EPA responses to technical comments on the scientific evidence and the exposure/response information are discussed above in section II.E.2 and in the Response to Comments document. The Administrator's response to commenters' views on the approach to setting the 1-hour standard and on the standard level is embodied in the discussed in section II.F.4.d.

i. CASAC Comments on the Approach to Setting the Standard

A majority of CASAC and CASAC Panel members \16\ favored the proposed approach of setting a 1-hour standard that reflects the maximum allowable

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NO2 concentration anywhere in an area and linking such a standard with a 2-tiered monitoring network that would include both near-road and area-wide monitors, though CASAC did not reach consensus on this approach. Specifically, in their letter to the Administrator (Samet, 2009), CASAC stated the following:

\16\ CASAC members were also part of the CASAC Panel for the NO2 NAAQS review (i.e., the Oxides of Nitrogen Primary National Ambient Air Quality Standards Panel). Therefore, references to the CASAC Panel include both CASAC members and Panel members.

There was a split view on the two approaches among both CASAC and CASAC panel members with a majority of each favoring the Agency's proposed two-tiered monitoring network because they thought this approach would be more effective in limiting near-roadway exposures that may reach levels in the range at which some individuals with asthma may be adversely affected. Other members acknowledged the need for research and development of near-road monitoring data for criteria pollutants in general but favored retention of EPA's current area-wide monitoring for NO2 regulatory purposes, due to the lack of epidemiological data based on near-roadway exposure measurements and issues related to

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implementing a near-road monitoring system for NO2.

Thus, the recommendation of the majority of CASAC Panel members was based on their conclusion that the proposed approach would be more effective than the alternative at limiting near-roadway exposures to NO2 concentrations that could adversely affect asthmatics. In addition, these CASAC Panel members noted important uncertainties with the alternative approach. Specifically, they stated the following (Samet, 2009):

Panel members also supported the proposed two-tiered approach because basing regulations on area-wide monitoring alone was problematic. Such an approach would require EPA to embed uncertainties and assumptions about the relationship between area-wide and road-side monitoring into the area-wide standard.

A minority of CASAC Panel members expressed support for the alternative approach of setting a 1-hour standard that reflects the allowable area-wide NO2 concentration. These CASAC Panel members concluded that there would be important uncertainties associated with the proposed approach. Specifically, they noted that the key U.S. NO2 epidemiologic studies relied upon area-wide NO2 concentrations. In their view, the use of area-wide concentrations in these studies introduces uncertainty into the selection of a standard level for a standard that reflects the maximum allowable NO2 concentration anywhere in an area and that is linked with a requirement to place monitors near major roads. As a result of this uncertainty, CASAC Panel members who favored the alternative approach noted that ``it would be better to set the standard on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it [the standard] now relies'' (Samet, 2009). These CASAC Panel members also strongly supported obtaining monitoring data near major roads, while recognizing uncertainties associated with identifying appropriate monitoring sites near roads (see section III.B.2 and the Response to Comments document for more discussion of CASAC's monitoring comments).

ii. Public Comments on the Approach to Setting the Standard

Consistent with the views expressed by the majority of CASAC members, a number of commenters concluded that the most appropriate approach would be to set a 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area and to couple that standard with a requirement that monitors be placed in locations where maximum concentrations are expected, including near major roads. This view was expressed by some State and local agencies (e.g., in CA, IA, NY, TX, WA, WI), by a number of environmental organizations (e.g., CAC, EDF, EJ, GASP, NRDC), by the ALA, and individual commenters. Several additional medical and public health organizations (ACCP, AMA, ATS, NADRC, NACPR) did not explicitly express a recommendation regarding the approach though these organizations did recommend that, in setting a 1-hour standard, particular attention should be paid to NOX concentrations around major roadways.

In support of their recommendation to adopt the proposed approach and to focus monitoring around major roads, these commenters generally concluded that a primary consideration should be the extent to which the NO2 NAAQS protects at-risk populations that live and/or attend school near important sources of NO2 such as major roads. As such, these comments supported the rationale in the proposal for setting a 1-hour standard that reflects the maximum allowable NO2 concentration anywhere in an area.

A number of State commenters expressed the view that area-wide monitors should be used for attainment/non-attainment determinations (e.g., NACAA, NESCAUM and agencies in IL, IN, MI, MS, NC, NM, SC). One State commenter (NESCAUM) agreed with EPA concerns about near-road exposures but concluded that it is premature to establish a large near-road monitoring network at this time due to uncertainty regarding the relationship between near-road and area-wide NO2 concentrations and the variability in that relationship. NESCAUM recommended that EPA work with States to establish a targeted monitoring program in select urban areas to gather data that would inform future modifications to the monitoring network, but that ``[t]he existing area-wide monitoring network should be used to identify initial nonattainment areas.'' Other State commenters also concluded that the most appropriate approach would be to base non-attainment determinations only on area-wide monitors. Based on their monitoring comments, many of these commenters appeared to support setting a 1-hour standard that reflects the allowable area-wide NO2 concentration. State concerns with the proposed approach often included uncertainties associated with identifying and accessing appropriate monitor sites near major roads, as well as concerns related to implementation and cost to States (as discussed further in the Response to Comments document, the Administrator may not consider cost of implementation in decisions on a NAAQS).

One commenter (AAM) concluded that the focus of the proposed approach on NO2 concentrations around major roadways is not justified because the REA and the proposal overstate the extent to which NO2 concentrations near roads are higher than NO2 concentrations farther away from the road. This conclusion is based on an analysis of 42 existing NO2 monitors in 6 locations. Comparing NO2 concentrations measured by these monitors, some of which are closer to roads and others of which are farther from roads, AAM concluded that ``roadside monitors are not measuring high NO2 concentrations.''

We agree that there is uncertainty associated with estimates of roadway-associated NO2 concentrations (see REA, sections 7.4.6 and 8.4.8.3 for detailed discussion of these uncertainties) and in identifying locations where maximum concentrations are expected to occur. However, we note that the Administrator's conclusions regarding the relationship between NO2 concentrations near roads and those away from roads rely on multiple lines of scientific evidence and information. Specifically, the Administrator relied in the proposal on the following in drawing conclusions regarding the distribution of NO2 concentrations across areas:

Monitoring studies discussed in the ISA and REA that were designed to characterize the NO2 concentration gradient around roads, which indicated that NO2 concentrations near roads can

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be approximately 30 to 100% higher than concentrations away from the road in the same area.

Air quality and exposure analyses presented in the REA which estimate that, on average across locations, NO2 concentrations on roads could be 80% higher than those away from roads and that roadway-associated exposures account for the majority of exposures to NO2 concentrations at or above 100 ppb.

In contrast, the existing NO2 monitoring network, which was the basis for the analysis submitted by AAM, was not designed to characterize the spatial gradients in NO2 concentrations surrounding roadways. Rather, concentrations of NO2 measured by existing monitors are likely to reflect contributions from a combination of mobile and stationary sources, with one or the other dominating depending on the proximity of these sources to the monitors. Therefore, we conclude that the analysis submitted by AAM, which does not consider other relevant lines of evidence and information, does not appropriately characterize the relationship between NO2 concentrations near roads and those away from roads. (See the Response to Comments document for a more detailed discussion of AAM comments.)

In addition, we note that, although the Administrator concluded in the proposal that maximum NO2 concentrations in many areas are likely to occur around major roads, she also recognized that maximum concentrations can occur elsewhere in an area. For this reason, she proposed to set a 1-hour NO2 standard that reflects the maximum allowable NO2 concentration anywhere in an area, regardless of where that maximum concentration occurs.\17\ Therefore, the proposed approach to setting the standard would be expected to limit the maximum NO2 concentrations anywhere in an area even if in some areas, as is contended by AAM, those maximum NO2 concentrations do not occur near roads.

\17\ To measure maximum concentrations, the Administrator proposed monitoring provisions that would require monitors within 50 meters of major roads and to allow the Regional Administrator to require additional monitors in situations where maximum concentrations would be expected to occur in locations other than near major roads (e.g., due to the influence of multiple smaller roads and/or stationary sources).

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iii. CASAC Comments on Standard Level

In commenting on the proposal, CASAC discussed both the proposed range of standard levels (i.e., 80-100 ppb) and the alternative range of standard levels (i.e., 50-75 ppb). CASAC did express the consensus conclusion that if the Agency finalizes a 1-hour standard in accordance with the proposed approach (i.e., standard level reflects the maximum allowable NO2 concentration anywhere in an area), then it is appropriate to consider the proposed range of standard levels from 80 to 100 ppb. Specifically, the CASAC letter to the Administrator on the proposal (Samet, 2009) stated the following with regard to the proposed approach:

[T]he level of the one-hour NO2 standard should be within the range of 80-100 ppb and not above 100 ppb. In its letter of December 2, 2008, CASAC strongly voiced a consensus view that the upper end of the range should not exceed 100 ppb, based on evidence of risk at that concentration. The lower limit of 80 ppb was viewed as reasonable by CASAC; selection of a value lower than 80 ppb would represent a policy judgment based on uncertainty and the degree of public health protection sought, given the limited health-based evidence at concentrations below 100 ppb.

CASAC also recommended that this level be employed with a 98th percentile form, in order to promote the stability of the standard (see above for discussion of form).

iv. Public Comments on Standard Level

A number of State and local agencies and organizations expressed support for setting the level of the 1-hour NO2 standard within the proposed range of 80 to 100 ppb. While some State and local agencies (e.g., in CA, IA, MI, NY, TX) made this recommendation in conjunction with a recommendation to focus monitoring near major roads and other important sources of NO2, a number of State commenters (e.g., NACAA, NESCAUM and agencies in IL, NC, NM, TX, VA) recommended a standard level from 80 to 100 ppb in conjunction with a recommendation that only area-wide monitors be deployed for purposes of determining attainment with the standard. Based on these monitoring comments, these State commenters appear to favor an approach where a standard level from 80 to 100 ppb would reflect the allowable area-wide NO2 concentration. As discussed above (and in more detail in section III.B.2 and the Response to Comments document), State commenters often based these recommendations on uncertainties associated with designing an appropriate national near-road monitoring network.

A number of environmental organizations (e.g., CAC, EDF, EJ, GASP, NRDC) and medical/public health organizations (e.g., ACCP, ALA, AMA, ATS, NACPR, NAMDRC) supported setting a standard level below 80 ppb for a standard that reflects the maximum allowable NO2 concentration anywhere in an area. Several of these groups recommended a standard level of 50 ppb. This recommendation was typically based on the commenters' interpretation of the epidemiologic and controlled human exposure evidence, as described below.

Some of these commenters noted that the 98th percentile area-wide NO2 concentration was below 80 ppb in the location of a single key U.S. epidemiologic study (i.e., 50 ppb in study by Delfino). Given this, commenters concluded that the standard level should be set at 50 ppb. Their comments on the monitoring network generally favored a requirement to place monitors near major roads and, therefore, these commenters appeared to favor a standard level as low as 50 ppb and to recommend that such a standard level reflect the maximum allowable NO2 concentration anywhere in an area. In their comments, the ALA, EDF, EJ, and NRDC stated the following:

Considering the Delfino study alone on EPA's terms, that is, focusing on the 98th percentile of the 1-hour daily maximum concentrations, EPA reports a concentration of 50 ppb where asthma symptoms were observed. Based primarily on this study, EPA concluded in the REA that it was appropriate to set the lower end of the range at 50 ppb, which corresponded to the lowest-observed effects level of airway hyperresponsiveness in asthmatics. To provide the strongest public health protection, we therefore urge the level of the standard be set at 50 ppb.

In some cases, the same commenters also appeared to recommend setting a standard level below 50 ppb because mean area-wide NO2 concentrations reported in locations of key U.S. epidemiologic studies are below this concentration. Specifically, with regard to the key U.S. epidemiologic studies, these commenters (e.g., ALA, EDF, EJ, NRDC) stated the following:

These studies clearly identify adverse health effects such as emergency room visits and hospital admissions for respiratory causes at concentrations currently occurring in the United States. Mean concentrations for all but two of these studies are about or below 50 ppb, suggesting that the standard must be set below this level to allow for a margin of safety.

The Administrator's consideration of the Delfino study as it relates to a decision on standard level is discussed below (section II.F.4.d). Regarding the recommendation to set the level below 50 ppb based on mean area-wide NO2 concentrations in epidemiologic study

locations, we note that the Administrator proposed to set a standard that reflects the maximum allowable NO2 concentration anywhere in an area and to set the form of that standard at the upper end of the distribution of 1-hour daily maximum NO2 concentrations.\18\ As described in the proposal, such a standard, with a level from the proposed range of 80 to 100 ppb, would be expected to maintain peak area-wide NO2 concentrations below the peak area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Because reducing NOX emissions to meet a 98th percentile NO2 standard should lower the distribution of NO2 concentrations, including the mean, a standard that limits the 98th percentile of the distribution of 1-hour daily maximum concentrations would also be expected to limit mean concentrations. Therefore, although we acknowledge that the relationship between peak and mean NO2 concentrations will likely vary across locations and over time, if peak area-wide NO2 concentrations are maintained below those in key epidemiologic study locations, mean area-wide NO2 concentrations would also be expected to be maintained below the mean area-wide concentrations in those locations (see ISA, figure 2.4-13 for information on the relationship between peak and mean NO2 concentrations).

\18\ As discussed above, the Administrator has selected the 98th percentile as the form for the new 1-hour NO2 standard.

As discussed above (section, II.E.2), a number of industry groups did not support setting a new 1-hour NO2 standard. However, several of these groups (e.g., AAM, Dow, NAM, NPRA) also concluded that, if EPA does choose to set a new 1-hour standard, the level of that standard should be above 100 ppb. As a basis for this recommendation, these groups emphasized uncertainties in the scientific evidence. Specifically, as discussed in more detail above (section II.E.2), these commenters typically concluded that available epidemiologic studies do not support the conclusion that NO2 causes reported health effects. This was based on their assertion that the presence of co-pollutants in the ambient air precludes the identification of a specific NO2 contribution to reported effects. As a result, these commenters recommended that a 1-hour standard should be based on the controlled human exposure evidence and that, in considering that evidence, EPA should rely on the meta-analysis of NO2 airway responsiveness studies conducted by Goodman et al., (2009) rather than the meta-analysis included in the final ISA. As described above, they concluded that in relying on the ISA meta-analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. EPA recognizes the uncertainties in the scientific evidence that are discussed by these industry commenters; however, we strongly disagree with their conclusions regarding the implications of these uncertainties for decisions on the NO2 NAAQS. These comments, and EPA's responses, are discussed in detail above (section II.E.2) and in the Response to Comments document and are summarized briefly below.

As noted in section II.E.2, we agree that the presence of co-pollutants in the ambient air complicates the interpretation of epidemiologic studies; however, our conclusions regarding causality are based on consideration of the broad body of epidemiologic studies (including those employing multi-pollutant models) as well as animal toxicological and controlled human exposure studies. The ISA concluded that this body of evidence ``supports a direct effect of short-term NO2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS level'' (ISA, p. 5-16). In addition, the ISA (p. 5-15) concluded the following:

[T]he strongest evidence for an association between NO2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED visits and hospital admissions. These new findings were based on numerous studies, including panel and field studies, multipollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-h avg NO2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average).

Given that epidemiologic studies provide the strongest support for an association between NO2 and respiratory morbidity, and that a number of these studies controlled for the presence of other pollutants with multi-pollutant models (in which NO2 effect estimates remained robust), we disagree that NO2 epidemiologic studies should not be used to inform a decision on the level of the 1-hour NO2 standard.

In addition, we agree that uncertainty exists regarding the extent to which the NO2-induced increase in airway responsiveness is adverse (REA, section 10.3.2.1); however, as discussed in detail above (section II.E.2), we disagree with the conclusion by many industry commenters that this effect is not adverse in asthmatics following exposures from 100 to 600 ppb NO2. Specifically, we do not agree that the approach taken in the study by Goodman et al.

(2009), which was used by many industry commenters to support their conclusions, was appropriate. The authors of the Goodman study used data from existing NO2 studies to characterize the dose-response relationship of NO2 and airway responsiveness and to calculate the magnitude of the NO2 effect. Given the protocol differences in existing studies of NO2 and airway responsiveness, we do not agree that it is appropriate to base such an analysis on these studies.

The Administrator's consideration of these uncertainties, within the context of setting a standard level, is discussed in the next section.

d. Conclusions on Approach and Standard Level

Having carefully considered the public comments on the appropriate approach and level for a 1-hour NO2 standard, as discussed above, the Administrator believes the fundamental conclusions reached in the ISA and REA remain valid. In considering the approach, the Administrator continues to place primary emphasis on the conclusions of the ISA and the analyses of the REA, both of which focus attention on the importance of roadways in contributing to peak NO2 exposures, given that roadway-associated exposures can dominate personal exposures to NO2. In considering the level at which the 1-hour primary NO2 standard should be set, the Administrator continues to place primary emphasis on the body of scientific evidence assessed in the ISA, as summarized above in section II.B, while viewing the results of exposure and risk analyses, discussed above in section II.C, as providing information in support of her decision.

With regard to her decision on the approach to setting the 1-hour standard, the Administrator continues to judge it appropriate to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term exposures to NO2, where such health effects have been associated with exposure to the distribution of short-term ambient NO2 concentrations across

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an area. In protecting public health against exposure to the distribution of short-term NO2 concentrations across an area, the Administrator is placing emphasis on providing a relatively high degree of confidence regarding the protection provided against exposures to peak concentrations of NO2, such as those that can occur around major roadways. Available evidence and information suggest that roadways account for the majority of exposures to peak NO2 concentrations and, therefore, are important contributors to NO2-associated public health risks. In reaching this conclusion, the Administrator notes the following:

Mobile sources account for the majority of NOX emissions (ISA, Table 2.2-1).

The ISA stated that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level,'' that ``exposure in traffic can dominate personal exposure to NO2,'' and that ``NO2 levels are strongly associated with distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration)'' (ISA, sections 2.5.4, 4.3.6).

The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18).

Monitoring studies suggest that NO2 concentrations near roads can be considerably higher than those in the same area but away from roads (e.g., by 30-100%, see section II.A.2).

In their comments on the approach to setting the 1-hour NO2 standard, the majority of CASAC Panel members emphasized the importance of setting a standard that limits roadway-associated exposures to NO2 concentrations that could adversely affect asthmatics. These CASAC Panel members favored the proposed approach, including its focus on roads.

In addition, the Administrator notes that a considerable fraction of the population resides, works, or attends school near major roadways or other sources of NO2 and that these populations are likely to have increased exposure to NO2 (ISA, section 4.4). Based on data from the 2003 American Housing Survey, approximately 36 million individuals live within 300 feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).\19\ Furthermore, in California, 2.3% of schools with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads (ISA, section 4.4). Of this population, which likely includes a disproportionate number of individuals in groups with a higher prevalence of asthma and higher hospitalization rates for asthma (e.g., ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), asthmatics and members of other susceptible groups (e.g., children, elderly) will have the greatest risks of experiencing health effects related to NO2 exposure. In the United States, approximately 10% of adults and 13% of children have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4).

\19\ The most current American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs.html) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary. According to Table 1A-6 from that report (http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf), out of 128.2 million total housing units in the United States, about 20 million were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.6% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306.3 million, that means that there would be 47.8 million people meeting the 300 foot criteria.

In considering the approach to setting the 1-hour standard, the Administrator also notes that concerns with the proposed approach expressed by the minority of CASAC Panel members included concern with the uncertainty in the relationship between near-road and area-wide NO2 concentrations, given that U.S. epidemiologic studies have been based on concentrations measured at area-wide monitors. However, as discussed by the majority of CASAC Panel members, a similar uncertainty would be involved in setting a standard with the alternative approach (Samet, 2009). The Administrator agrees with the majority of CASAC Panel members and concludes that uncertainty in the relationship between near-road and area-wide NO2 concentrations should be considered regardless of the approach selected to set the standard. She recognizes that this uncertainty can and should be taken into consideration when considering the level of the standard.

In drawing conclusions on the approach, the Administrator has considered the extent to which each approach, in conjunction with the ranges of standard levels discussed in the proposal, would be expected to limit the distribution of NO2 concentrations across an area and, therefore, would be expected to protect against risks associated with NO2 exposures. Specifically, she has considered the extent to which a standard set with each approach would be expected to limit maximum NO2 concentrations and area-wide NO2 concentrations.

With regard to expected maximum concentrations, the Administrator notes the following:

A standard reflecting the maximum allowable NO2 concentration anywhere in an area would provide a relatively high degree of confidence regarding the level of protection provided against peak exposures, such as those that can occur on or near major roadways. A standard level from anywhere within the proposed range (i.e., 80 to 100 ppb) would be expected to limit exposures to NO2 concentrations reported to increase airway responsiveness in asthmatics.

A standard reflecting the allowable area-wide NO2 concentration would not provide a high degree of confidence regarding the extent to which maximum NO2 concentrations would be limited. Maximum NO2 concentrations would be expected to be controlled to varying degrees across locations and over time depending on the NO2 concentration gradient around roads. Given the expected variability in gradients across locations and over time, most standard levels within the range considered in the proposal with this option (i.e., 50 to 75 ppb) would not be expected to consistently limit the occurrence of NO2 concentrations that have been reported to increase airway responsiveness in asthmatics.

With regard to expected area-wide concentrations, the Administrator notes the following:

The extent to which a standard reflecting the maximum allowable NO2 concentration anywhere in an area would be expected to limit area-wide NO2 concentrations would vary across locations, e.g., depending on the NO2 concentration gradient around roads. However, in conjunction with a standard level from anywhere within the proposed range (i.e., 80-100 ppb), such an approach would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits (based on available information regarding the NO2 concentration gradient around roads as discussed below).

A standard reflecting the maximum allowable area-wide NO2 concentration would provide a relatively high degree of certainty regarding the extent to which area-wide NO2 concentrations are limited. In conjunction with a standard level from anywhere within the range of

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levels discussed in the proposal (i.e., 50-75 ppb) with this alternative approach, such a standard would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits.

Given the above considerations, the Administrator concludes that both approaches, in conjunction with appropriate standard levels, would be expected to maintain area-wide NO2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO2 and respiratory-related hospital admissions and emergency department visits. In contrast, the Administrator concludes that only a standard reflecting the maximum allowable NO2 concentration anywhere in an area, in conjunction with an appropriate standard level, would be expected to consistently limit exposures, across locations and over time, to NO2 concentrations reported to increase airway responsiveness in asthmatics. After considering the evidence and uncertainties, and the advice of the CASAC Panel, the Administrator judges that the most appropriate approach to setting a 1-hour standard to protect against the distribution of short-term NO2 concentrations across an area, including the higher concentrations that can occur around roads and result in elevated exposure concentrations, is to set a standard that reflects the maximum allowable NO2 concentration anywhere in an area.

In considering the level of a 1-hour NO2 standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator notes that there is no bright line clearly directing the choice of level. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. Specifically, the Administrator notes the following:

Controlled human exposure studies have reported that various NO2 exposure concentrations increased airway responsiveness in mostly mild asthmatics (section II above and II.B.1.d in proposal). These studies can inform an evaluation of the risks associated with exposure to specific NO2 concentrations, regardless of where those exposures occur in an area. Because concentrations evaluated in controlled human exposure studies are at the high end of the distribution of ambient NO2 concentrations (ISA, section 5.3.2.1), these studies most directly inform consideration of the risks associated with exposure to peak short-term NO2 concentrations.

Epidemiologic studies (section II.B.1.a and b) conducted in the United States have reported associations between ambient NO2 concentrations measured at area-wide monitors in the current network and increased respiratory symptoms, emergency department visits, and hospital admissions. Area-wide monitors in the urban areas in which these epidemiologic studies were conducted are not sited in locations where localized peak concentrations are likely to occur. Thus, they do not measure the full range of ambient NO2 concentrations across the area. Rather, the area-wide NO2 concentrations measured by these monitors are used as surrogates for the distribution of ambient NO2 concentrations across the area, a distribution that includes NO2 concentrations both higher than (e.g., around major roadways) and lower than the area-wide concentrations measured in study locations. Epidemiologic studies evaluate whether area-wide NO2 concentrations are associated with the risk of respiratory morbidity. Available information on NO2 concentration gradients around roadways can inform estimates of the relationship between the area-wide NO2 concentrations measured in epidemiologic study locations and the higher NO2 concentrations likely to have occurred around roads in those locations, which can then inform the decision on the level of a standard reflecting the maximum allowable NO2 concentration anywhere in an area.

The risk and exposure analyses presented in the REA provide information on the potential public health implications of setting standards that limit area-wide NO2 concentrations to specific levels. While the Administrator acknowledges the uncertainties associated with these analyses which, as discussed in the REA, could result in either over- or underestimates of NO2-associated health risks, she judges that these analyses are informative for considering the relative levels of public health protection that could be provided by different standards.

The Administrator's consideration of the controlled human exposure evidence, epidemiologic evidence, and exposure/risk information are discussed below specifically with regard to a decision on the level of a standard that reflects the maximum allowable NO2 concentration anywhere in an area.

In considering the potential for controlled human exposure studies of NO2 and airway responsiveness to inform a decision on standard level, the Administrator notes the following:

NO2-induced increases in airway responsiveness, as reported in controlled human exposure studies, are logically linked to the adverse respiratory effects that have been reported in NO2 epidemiologic studies.

The meta-analysis of controlled human exposure data in the ISA reported increased airway responsiveness in a large percentage of asthmatics at rest following exposures at and above 100 ppb NO2, the lowest NO2 concentration for which airway responsiveness data are available in humans.

This meta-analysis does not provide any evidence of a threshold below which effects do not occur. The studies included in the meta-analysis evaluated primarily mild asthmatics while more severely affected individuals conld respond to lower concentrations. Therefore, it is possible that exposure to NO2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics.

In considering the evidence, the Administrator recognizes that the NO2-induced increases in airway responsiveness reported for exposures to NO2 concentrations at or above 100 ppb could be adverse for some asthmatics. However, she also notes that important uncertainties exist with regard to the extent to which NO2-induced increases in airway responsiveness are adverse. Specifically, she notes the following with regard to these uncertainties:

The magnitude of the NO2-induced increase in airway responsiveness, and the extent to which it is adverse, cannot be quantified from the ISA meta-analysis (REA, section 10.3.2.1).

The NO2-induced increase in airway responsiveness in resting asthmatics was typically not accompanied by increased respiratory symptoms, even following exposures to NO2 concentrations well above 100 ppb (ISA, section 3.1.3.3).

The increase in airway responsiveness that was reported for resting asthmatics was not present in exercising asthmatics (ISA, Table 3.1-3).

Taking into consideration all of the above, the Administrator concludes that existing evidence supports the conclusion that the NO2-induced increase in airway responsiveness at or above 100 ppb presents a risk of adverse

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effects for some asthmatics, especially those with more serious (i.e., more than mild) asthma. The Administrator notes that the risks associated with increased airway responsiveness cannot be fully characterized by these studies, and thus she is not able to determine whether the increased airway responsiveness experienced by asthmatics in these studies is an adverse health effect. However, based on these studies the Administrator concludes that asthmatics, particularly those suffering from more severe asthma, warrant protection from the risk of adverse effects associated with the NO2-induced increase in airway responsiveness. Therefore, the Administrator concludes that the controlled human exposure evidence supports setting a standard level no higher than 100 ppb to reflect a cautious approach to the uncertainty regarding the adversity of the effect. However, those uncertainties lead her to also conclude that this evidence does not support setting a standard level lower than 100 ppb.

In considering the more serious health effects reported in NO2 epidemiologic studies, as they relate to the level of a standard that reflects the maximum allowable NO2 concentration anywhere in an area, the Administrator notes the following:

A cluster of 5 key U.S. epidemiologic studies (Ito et al., 2007; Jaffe et al., 2003; Peel et al., 2005; Tolbert et al., 2007; and a study by the New York State Department of Health, 2006) provide evidence for associations between NO2 and respiratory-related emergency department visits and hospital admissions in locations where 98th percentile 1-hour daily maximum NO2 concentrations measured at area-wide monitors ranged from 85 to 94 ppb. The Administrator judges it appropriate to place substantial weight on this cluster of key U.S. epidemiologic studies in selecting a standard level, as they are a group of studies that reported positive, and often statistically significant, associations between NO2 and respiratory morbidity in multiple cities across the United States.\20\

\20\ Some of these studies also included susceptible and vulnerable populations (e.g., children in Peel et al. (2005); poor and minority populations in Ito et al., 2007).

A single study (Delfino et al., 2002) provides mixed evidence for NO2 effects (i.e., respiratory symptoms) in a location with a 98th percentile 1-hour daily maximum NO2 concentration, as measured by an area-wide monitor, of 50 ppb. In that study, most of the reported NO2 effect estimates were positive, but not statistically significant. Given the variability in the NO2 effect estimates in this study, as well as the lack of studies in other locations with similarly low NO2 concentrations, the Administrator judges it appropriate to place limited weight on this study, compared to the cluster of 5 studies as noted above.

Given these considerations, the Administrator concludes that the epidemiologic evidence provides strong support for setting a standard that limits the 98th percentile of the distribution of 1-hour daily maximum area-wide NO2 concentrations to below 85 ppb. This judgment takes into account the determinations in the ISA, based on a much broader body of evidence, that there is a likely causal association between exposure to NO2 and the types of respiratory morbidity effects reported in these studies. Given the considerations discussed above, the Administrator judges that it is not necessary, based on existing evidence, to set a standard that maintains peak area-wide NO2 concentrations to below 50 ppb.

In considering specific standard levels supported by the epidemiologic evidence, the Administrator notes that a level of 100 ppb, for a standard reflecting the maximum allowable NO2 concentration anywhere in the area, would be expected to maintain area-wide NO2 concentrations well below 85 ppb, which is the lowest 98th percentile concentration in the cluster of 5 studies. With regard to this, she specifically notes the following:

If NO2 concentrations near roads are 100% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 50 ppb.

If NO2 concentrations near roads are 30% higher than concentrations away from roads, a standard level of 100 ppb would limit area-wide concentrations to approximately 75 ppb.

The Administrator has also considered the NO2 exposure and risk information within the context of the above conclusions on standard level. Specifically, she notes that the results of exposure and risk analyses were interpreted as providing support for limiting area-wide NO2 concentrations to no higher than 100 ppb. Specifically, these analyses estimated that a standard that limits area-wide NO2 concentrations to approximately 100 ppb or below would be expected to result in important reductions in respiratory risks, relative to the level of risk permitted by the current annual standard alone. As discussed above, a standard reflecting the maximum allowable NO2 concentration with a level of 100 ppb would be expected to maintain area-wide NO2 concentrations to within a range of approximately 50 to 75 ppb. Given this, the Administrator concludes that a standard level of 100 ppb is consistent with conclusions based on the NO2 exposure and risk information.

Finally, the Administrator notes that a standard level of 100 ppb is consistent with the consensus recommendation of CASAC.

Given the above considerations and the comments received on the proposal, the Administrator determines that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties, is a standard level of 100 ppb (for a standard that reflects the maximum allowable NO2 concentration anywhere in an area). She concludes that such a standard, with the averaging time and form discussed above, will provide a significant increase in public health protection compared to that provided by the current annual standard alone and would be expected to protect against the respiratory effects that have been linked with NO2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concludes that such a standard will limit exposures at and above 100 ppb for the vast majority of people, including those in at-risk groups, and will maintain maximum area-wide NO2 concentrations well below those in locations where key U.S. epidemiologic studies have reported that ambient NO2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits.

In setting the standard level at 100 ppb rather than a lower level, the Administrator notes that a 1-hour standard with a level lower than 100 ppb would only result in significant further public health protection if, in fact, there is a continuum of serious, adverse health risks caused by exposure to NO2 concentrations below 100 ppb and/or associated with area-wide NO2 concentrations well-below those in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Based on the available evidence, the Administrator does not believe that such assumptions are warranted. Taking into account the uncertainties that remain in interpreting the evidence from available controlled human exposure and epidemiologic studies, the Administrator notes that the likelihood of obtaining benefits to public health with a standard set below

100 ppb decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases.

Therefore, the Administrator judges that a standard reflecting the maximum allowable NO2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO2 and for which the evidence supports a likely causal relationship with NO2 exposures. The Administrator does not believe that a lower standard level is needed to provide this degree of protection. These conclusions by the Administrator appropriately consider the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that reduces risk sufficiently so as to protect the public health with an adequate margin of safety.

G. Annual Standard

In the proposal, the Administrator noted that some evidence supports a link between long-term exposures to NO2 and adverse respiratory effects and that CASAC recommended in their comments prior to the proposal that, in addition to setting a new 1-hour standard to increase public health protection, the current annual standard be retained. CASAC's recommendation was based on the scientific evidence and on their conclusion that a 1-hour standard might not provide adequate protection against exposure to long-term NO2 concentrations (Samet, 2008b).

With regard to an annual standard, CASAC and a large number of public commenters (e.g., NACAA, NESCAUM; agencies from States including CA, IN, MO, NC, NY, SC, TX, VA; Tribal organizations including Fon du Lac and the National Tribal Air Organization; environmental/medical/public health groups including ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC) agreed with the proposed decision to maintain an annual standard, though their recommendations with regard to the level of that annual standard differed (see below).

As noted above, CASAC recommended ``retaining the current standard based on the annual average'' based on the ``limited evidence related to potential long-term effects of NO2 exposure and the lack of strong evidence of no effect'' and that ``the findings of the REA do not provide assurance that a short-term standard based on the one-hour maximum will necessarily protect the population from long-term exposures at levels potentially leading to adverse health effects'' (Samet, 2008b). A number of State agencies and organizations also recommended maintaining the current level of the annual standard (i.e., 53 ppb). This recommendation was based on the conclusion that, while some evidence supports a link between long-term NO2 exposures and adverse respiratory effects, that evidence is not sufficient to support a standard level either higher or lower than the current level. In addition, a number of industry groups (e.g., AAM, API, Dow, INGAA, UARG) recommended retaining the level of the current annual standard but, as described above, did so within the context of a recommendation that EPA should not set a new 1-hour standard.

In contrast, some environmental organizations and medical/public health organizations as well as a small number of States (e.g., ALA, EDF, EJ, NRDC, and organizations in CA) recommended setting a lower level for the annual standard. These commenters generally supported their recommendation by pointing to the State of California's annual standard of 30 ppb and to studies where long-term ambient NO2 concentrations have been associated with adverse respiratory effects such as impairments in lung function growth.

As discussed above (II.B.3), the evidence relating long-term NO2 exposures to adverse health effects was judged in the ISA to be either ``suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ``inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4-5.3.2.6). In the case of respiratory morbidity, the ISA (section 5.3.2.4) concluded that ``The high correlation among traffic-related pollutants made it difficult to accurately estimate the independent effects in these long-term exposure studies.'' Given these uncertainties associated with the role of long-term NO2 exposures in causing the reported effects, the Administrator concluded in the proposal that, consistent with the CASAC recommendation, existing evidence is not sufficient to justify setting an annual standard with either a higher or lower level than the current standard. Commenters have not submitted any new analyses or information that would change this conclusion. Therefore, the Administrator does not agree with the commenters who recommended a lower level for the annual standard.

The Administrator judges that her conclusions in the proposal regarding the annual standard remain appropriate. Specifically, she continues to agree with the conclusion that, though some evidence does support the need to limit long-term exposures to NO2, the existing evidence for adverse health effects following long-term NO2 exposures does not support either increasing or decreasing the level of the annual standard. In light of this and considering the recommendation from CASAC to retain the current level of the annual standard, the Administrator judges it appropriate to maintain the level of the annual standard at 53 ppb.

H. Summary of Final Decisions on the Primary NO2 Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA, the advice and recommendations of the CASAC, and public comments, the Administrator has decided to revise the existing primary NO2 standard. Specifically, the Administrator has determined that the current annual standard by itself is not requisite to protect public health with an adequate margin of safety. In order to provide protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO2 exposure, the Administrator is establishing a short-term NO2 standard defined by the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum NO2 concentrations. She is setting the level of this standard at 100 ppb, which is to reflect the maximum allowable NO2 concentration anywhere in an area. In addition to setting a new 1-hour standard, the Administrator retains the current annual standard with a level of 53 ppb. The new 1-hour standard, in combination with the annual standard, will provide protection for susceptible groups against adverse respiratory health effects associated with short-term exposures to NO2 and effects potentially associated with long-term exposures to NO2.

III. Amendments to Ambient Monitoring and Reporting Requirements

The EPA is finalizing several changes to the ambient air monitoring, reporting, and network design requirements for the NO2 NAAQS. This section discusses the changes we are finalizing which are intended to support the proposed 1-

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hour NAAQS and retention of the current annual NAAQS as discussed in Section II. Ambient NO2 monitoring data are used to determine whether an area is in violation of the NO2 NAAQS. Ambient NO2 monitoring data are collected by State, local, and Tribal monitoring agencies (``monitoring agencies'') in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58.

A. Monitoring Methods

We are finalizing the proposed changes regarding the NO2 Federal Reference Method (FRM) or Federal Equivalent Method (FEM) analyzers. Specifically, we are continuing to use the NO2 chemiluminescence FRM and are finalizing the requirement that any NO2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data. The following paragraphs provide background and rationale for the continued use of the chemiluminescence FRM and the decision to finalize the proposed changes.

1. Chemiluminescence FRM and Alternative Methods

The current monitoring method in use by most State and local monitoring agencies is the gas-phase chemiluminescence FRM (40 CFR Part 50, Appendix F), which was implemented into the NO2 monitoring network in the early 1980s. EPA did not propose to discontinue using the chemiluminescence FRM, although we received some comments from industry (Alliance of Automobile Manufacturers, Edison Electric, and the National Petrochemical and Refiners Association) raising concerns about using a method that is subject to known interferences from certain species of oxides of nitrogen known as NOZ. Important components of ambient NOZ include nitrous acid (HNO2), nitric acid (HNO3), and the peroxyacetyl nitrates (PANs).

The issue of concern in public comments is that the reduction of NO2 to NO on the MoOX converter substrate used in chemiluminescence FRMs is not specific to NO2; hence, chemiluminescence method analyzers are subject to varying interferences produced by the presence in the air sample of the NOZ species listed above and others occurring in trace amounts in ambient air. This interference is often termed a ``positive artifact'' in the reported NO2 concentration since the presence of NOZ results in an over-estimate in the reported measurement of the actual ambient NO2 concentration. This interference by NOZ compounds has long been known and evaluated (Fehsenfeld et al., 1987; Nunnermacker et al., 1998; Parrish and Fehsenfeld, 2000; McClenny et al., 2002; U.S. Environmental Protection Agency, 1993, 2006a). Further, as noted in the ISA (ISA Section 2.3), it appears that interference by NOZ on chemiluminescence FRMs is not more than 10 percent of the reported NO2 concentration during most or all of the day during winter (cold temperatures), but larger interference ranging up to 70 percent can be found during summer (warm temperatures) in the afternoon at sites away

and downwind from strong emission sources.
The EPA acknowledges that the NOZ interference in the reported NO2 concentrations collected well downwind of NOX source areas and in relatively remote areas away from concentrated point, area, or mobile sources is significantly larger than the NOZ interference in NO2 measurements taken in urban cores or other areas with fresh NOX emissions. To meet the primary objective of monitoring maximum NO2 concentrations in an area, the EPA is requiring NO2 monitors to be placed in locations of the expected highest concentrations, not in relatively remote areas away from NOX sources. The required monitors resulting from the network design discussed below in Section III.B will require monitors to be placed near fresh NOX sources or in areas of dense NOX emissions, where NO2 concentrations are expected to be at a maximum, and interference from NOZ species is at a minimum. Therefore, EPA believes that the positive artifact issue, although present, is small, relative to the actual NO2 being measured. As a result EPA believes the chemiluminescence FRM is suitable for continued use in the ambient NO2 monitoring network, as the potential positive bias from NOZ species is not significant enough to discontinue using the chemiluminescence FRM.

EPA also received support from some industry groups (e.g. Savannah River Nuclear Solutions, Teledyne API, and the Utility Air Regulatory Groups) and States (e.g., MODEQ and NCDENR) to further the development of alternative methods in determining NO2 concentrations. Such alternative methods include the photolytic- chemiluminescence method and cavity ring-down spectroscopy. As a result, EPA will continue working with commercial and industrial vendors, to identify and evaluate such new technologies. These efforts may include field testing instruments and further characterizing methods in a laboratory setting to assess their potential as future reference or equivalent methods, and their role in more directly measuring NO2.

2. Allowable FRM and FEMs for Comparison to the NAAQS

The current CFR language does not prohibit the use of any particular NO2 FRM or FEM to be used in comparison to the standard.\21\ There are designated wet chemical methods that are only able to report ambient concentration values averaged across multiple hours. With the establishment of a 1-hour NAAQS, any FRM or FEM which is a wet chemical based method would not be appropriate for use in determining compliance of the 1-hour NAAQS because they are unable to report hourly data. EPA addressed this issue by proposing and finalizing that only those methods capable of providing 1-hour measurements will be comparable to the NAAQS.

\21\ A list of approved FRM and FEMs is maintained by EPA's Office of Research and Development, and can be found at: http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-li

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a. Proposed Changes to FRM and FEMs That May Be Compared to the NAAQS

EPA proposed that only those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to the NAAQS.

b. Comments

EPA received comments from some State and industry groups (e.g. Missouri, North Carolina, and Air Quality Research and Logistics) supporting the proposed approach to only allowing those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to both the annual and 1-hour NAAQS, and did not receive any public comments that objected to the proposed approach.

c. Decisions on Allowable FRM and FEMs for Comparison to the NAAQS

Accordingly, EPA is finalizing the proposed changes to 40 CFR Part 58 Appendix C to allow only data from FRM or FEMs that are capable of providing hourly data to be used for comparison to both the annual and 1-hour NAAQS.

B. Network Design

With the establishment of a 1-hour NO2 NAAQS intended to limit exposure to maximum concentrations that may occur anywhere in an area, EPA recognizes that the data from the current NO2 network is inadequate to fully assess compliance with the revised

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NAAQS. As a result, EPA is promulgating new NO2 network design requirements. The following sections provide background, rationale, and details for the final changes to the NO2 network design requirements.

1. Two-Tiered Network Design

A two-tiered monitoring network is appropriate for the NO2 NAAQS because one tier (the near-road network) reflects the much higher NO2 concentrations that occur near-road and the second-tier (area-wide) characterizes the NO2 concentrations that occur in a larger area such as neighborhood or urban areas. The ISA (Section 2.5.4 and 4.3.6) stated that NO2 concentrations in heavy traffic or on freeways ``can be twice the residential outdoor or residential/arterial road level,'' that ``exposure in traffic can dominate personal exposure to NO2,'' and that ``NO2 levels are strongly associated with distance from major roads (i.e., the closer to a major road, the higher the NO2 concentration).'' The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). Monitoring studies suggest that NO2 concentrations near roads can be considerably higher than those in the same area but away from the road (e.g., by 30-100%, see section II.A.2), where pollutants typically display peak concentrations on or immediately adjacent to roads, producing a gradient in pollutant concentrations where concentrations decrease with increasing distance from roads. Since the intent of the revised NAAQS is to limit exposure to peak NO2 concentrations that occur anywhere in an area, monitors intended to measure the maximum allowable NO2 concentration in an area should include measurements of the peak concentrations that occur on and near roads due to on-road mobile sources. The first tier of the network design, which focuses monitoring near highly trafficked roads in urban areas where peak NO2 concentrations are likely to occur, is intended to measure maximum concentrations anywhere in an area, particularly those due to on-road mobile sources since roadway-associated exposures account for the majority of exposures to peak NO2 concentrations. The basis for the second tier of the network design is to measure the highest area-wide concentrations to characterize the wider area impact of a variety of NO2 sources on urban populations. Area-wide monitoring of NO2 also serves to maintain continuity in collecting data to inform long-term pollutant concentration trends analysis and support ongoing health and scientific research.

This section discusses the two-tier network design approach compared to the alternative network design which was also presented for comment in conjunction with a solicitation for comment on an alternative NAAQS. The alternative network design concept was based entirely on requiring only monitors that would be considered area-wide, while not requiring any near-road monitoring sites. The details of the two-tier network design, including how many monitors are required, where they are to be located, and the related siting criteria are discussed in subsequent sections.

a. Proposed Two-Tier Network Design

EPA proposed a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the highest expected NO2 concentrations at the neighborhood and larger spatial scales (also referred to as ``area-wide'' monitors). As an alternative, and in conjunction with a solicitation for comment on an alternative NAAQS, EPA solicited comment on a network comprised of only area-wide monitors.

b. Comments

EPA received many comments on the overall two-tier network design, with those who made statements with a relatively clear position on the issue generally falling into four categories: (1) Those who support the adoption of the proposed two-tier design approach, (2) those who support the adoption of the two-tier concept, but with modifications, (3) those who only supported the adoption of the alternative network design, and (4) those who encourage EPA to commit to further research of the near-road environment by monitoring near-roads, but not to use near-road data for regulatory purposes, and therefore support the alternative network design in which EPA solicited comment on a network design composed only of area-wide monitors.

Those commenters who generally supported the proposed two-tier network, included CASAC (while there was not a consensus, a majority were in support of the proposed network design), public health organizations (e.g., AACPR, ACCP, AMA, ATA, and NAMDRC), several State groups (e.g., the New York City Law Department and the Metropolitan Washington Air Quality Committee), and some industry commenters (e.g., American Chemistry Council, The Clean Energy Group, and Dow Chemical).

Those commenters who supported the adoption of the two-tier network design concept, but suggested modifications to the actual design included some health and environmental organizations (e.g., ALA, EDF, EJ, and the NRDC), some States (e.g., California, the Central Pennsylvania Clean Air Board, Harris County (Texas), Iowa, New York, San Joaquin Air Pollution Control District, Spokane Regional Clean Air Agency (SRCAA), the Texas Commission on Environmental Quality, and Wisconsin), and some industry commenters, including the American Petroleum Institute and the Utility Air Regulatory Group, who are cited by other industry commenters. We believe that although these commenters made suggestions to modify the proposed two-tier network design, they are indicating that it is an acceptable approach. Their comments and suggestions are discussed in greater detail in the following sections.

Those commenters who only supported the adoption of the alternative network design included State and industry groups (e.g., Indiana Department of Environmental Management, the New York Department of Transportation (NYSDOT), Alliance of Automobile Manufacturers, and the Engine Manufacturers Association). These commenters typically made comments on the two-tier network design, but did not do so in a way that clearly supported near-road research.

EPA received comments from some States or State organizations (e.g., National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and 10 other individual States or State groups) and industry commenters (e.g., Consumers Energy, Edison Electric, and the National Association of Manufacturers) that encouraged EPA to further research the near-road environment, opposing use of near-road monitoring data for regulatory purposes, and supported the adoption of the alternative network design for regulatory purposes. For example, with regard to implementing the two-tier network design that includes near-road regulatory monitoring, NACAA stated that ``* * *a major new network--particularly one that is inherently complicated and untried--should not be rolled out without the benefit of an effective near-road monitoring research program that can address many of the relevant data questions, and inform the specific siting requirements of the rule.'' The NAM stated that ``conducting such

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a near road [research] monitoring program would allow EPA to collect necessary data that can be used to better understand the health impacts associated with short term NO2 exposures.''

The EPA notes that the existing scientific research referenced in the proposal and throughout this final rule show that there are on- and near-road peaks of NO2 concentrations, relative to upwind or background levels, which exist due to on-road mobile source emissions. This research, as a body of evidence, also identifies the multiple local factors that affect how, where, and when peak NO2 concentrations occur on or near a particular road segment. These factors include traffic volume, fleet mix, roadway design, congestion patterns, terrain, and meteorology. The EPA and States have access to such data typically through Federal, State, and/or local departments of transportation or other government organizations, and, as a result, are in a position to implement a near-roar monitoring network that is intended to measure maximum expected NO2 concentrations resulting from on-road mobile source emissions. Further, EPA notes that near-road monitoring is not a new objective for the ambient air monitoring community as near-road carbon monoxide monitoring has been a part of ongoing, long-term, routine networks for nearly three decades. As a result, there is experience within EPA (both OAR and ORD) and State and local agencies on conducting ambient monitoring near-roads. In addition, EPA intends to develop guidance with input from all stakeholders to assist with implementation of the monitoring requirements, which is discussed in section III.B.5. EPA believes that the existing science and research provide a sufficient base of information to require a near-road monitoring network and that the collective experience that exists in the ambient monitoring community will allow for successful implementation of that network. EPA also believes that through adherence of requirements for near-road site selection and siting criteria discussed in sections III.B.6 and III.B.7, respectively, that the two-tier network design will provide a network that has a reasonable degree of similarity across the country where the required near-road monitors are targeting the maximum NO2 concentrations in an area attributable to on-road mobile sources.

Some industry commenters (e.g., Engine Manufacturers Association, the South Carolina Chamber of Commerce, and the South Carolina Manufacturers Alliance) who supported the adoption of the alternative network design suggested that monitoring in the near-road environment would not be indicative of exposure for general populations, and that EPA should not focus on the near-road environment when requiring monitoring. For example, the South Carolina Chamber of Commerce and the South Carolina Manufacturers Alliance both state that ``it appears the proposed monitoring network will result in a collection of microscale data, which is not at all representative of air quality relevant to population exposure.''

The EPA notes that the intent of a near-road monitoring is to support the revised NAAQS by assessing peak NO2 concentrations that may occur anywhere in an area. EPA recognizes that there is variability in the properties (such as traffic counts, fleet mix, and localized features) among the road segments that may exist in an area, but on the whole, roads are ubiquitous, particularly in urban environments. Consequently, a substantial fraction of the population is potentially exposed to relatively higher concentrations of NO2 that can occur in the near-road environment. The 2007 American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs07/ahs07.html) estimates that over 20 million housing units are within 300 feet (91 meters) of a 4-lane highway, airport, or railroad. Using the same survey, and considering that the average number of residential occupants in a housing unit is approximately 2.25, it is estimated that at least 45 million American citizens live near 4-lane highways, airports, or railroads. Although that survey includes airports and railroads, roads are the most pervasive of the three, indicating that a significant amount of the general population live near roads. Furthermore, the 2008 American Time Use Survey (http://www.bls.gov/tus/) reported that the average U.S. civilian spent over 70 minutes traveling per day. Accordingly, EPA concludes that monitors near major roads will address a component of exposure for a significant portion of the general population that would otherwise not be addressed.

The majority of State commenters, regardless of their position on the proposed network design, along with some industry commenters, observed that there was a need for funding the monitoring network. These comments urged EPA to provide the resources needed to implement and operate the required monitoring network. EPA notes that it has historically funded part of the cost of the installation and operation of monitors used to satisfy Federal monitoring requirements. EPA understands these concerns, although the CAA requirements from which this final rule derives (CAA sections 110, 310(a) and 319) are not contingent on EPA providing funding to States to assist in meeting monitoring requirements. However, EPA intends to work with NACAA and the State and local air agencies in identifying available State and Tribal Air Grant (STAG) funds and consider the increased resource needs that may be needed to plan, implement, and operate this revised set of minimum requirements.

c. Conclusions Regarding the Two-Tier Network Design

The EPA believes that requiring near-road monitors in urban areas as part of the network design are necessary to protect against risks associated with exposures to peak concentrations of NO2 anywhere in an area. The combination of increased mobile source emissions and increased urban population densities can lead to increased exposures and associated risks, therefore urban areas are the appropriate areas to concentrate required near-road monitoring efforts. The EPA also recognizes the need to have monitors in neighborhood and larger spatial scale locations away from roads that represent area-wide concentrations. These types of monitors serve multiple important monitoring objectives including comparison to the NAAQS, photochemical pollutant assessment, ozone forecasting, characterization of point and area source impacts, and by providing historical trends data for current and future epidemiological health research. In some situations, when coupled with data from near-road monitors, area-wide monitors may also assist in the determination of spatial variation of NO2 concentrations across a given area and provide insight to the gradients that exist between near-road or stationary source oriented

concentrations and area-wide concentration levels.
After considering the scientific data and the public comments regarding the proposed network design, the Administrator concludes that a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the maximum expected NO2 concentrations at the neighborhood and larger spatial scales (also referred to as ``area-wide'' monitors) are needed to implement the 1-hour NO2 NAAQS and

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support the annual NAAQS. The details of this two-tier network design are discussed in the following eight sections.
2. First Tier (Near-Road Monitoring Component) of the NO2 Network Design
This section provides background, rationale, and details for the final changes to the first tier of the two-tier NO2 network design. In particular, this section will focus on the thresholds that trigger monitoring requirements. Near-road site selection and siting criteria details will be discussed in subsequent sections.
a. Proposed First Tier (Near-Road Monitoring Component) of the Network Design
EPA proposed that the first tier of the two-tier NO2 monitoring network design focus monitors in locations of expected maximum 1-hour concentrations near major roads in urban areas. As noted in the previous section, the exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO2 concentrations (REA, Figures 8-17, 8-18). Since the combination of increased mobile source emissions and increased urban population densities leads to increased exposures and associated risks, the Administrator judges that urban areas are the appropriate areas in which to concentrate required near-road monitoring efforts. Therefore, we proposed that a minimum of one near-road NO2 monitor be required in Core Based Statistical Areas (CBSAs) with a population greater than or equal to 350,000 persons. Based on 2008 Census Bureau statistics, EPA estimated this would result in approximately 143 monitoring sites in as many CBSAs.
We also proposed that a second near-road monitor be required in CBSAs with a population greater than or equal to 2,500,000 persons, or in any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000. Based on 2008 Census Bureau statistics and data from the 2007 Highway Performance Monitoring System (HPMS) maintained by the U.S. Department of Transportation (DOT) Federal Highway Administration (FHWA), this particular element of the minimum monitoring requirements would have added approximately 24 \22\ sites to the approximate 143 near-road sites in CBSAs that already would have had one near-road monitor required due to the 350,000 population threshold. Overall, the first tier of the proposed network design was estimated to require 167 near-road sites in 143 CBSAs.

\22\ Of the 24 additional sites, 22 are estimated to be triggered due to a population of 2,500,000 while 2 (Las Vegas, NV and Sacramento, CA) are estimated to be triggered by the presence of one or more road segments with 250,000 AADT since they do not have a population of 2,500,000 people.

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b. Comments
The EPA received comments from some industry and public health organizations (e.g. Dow Chemical, ATS, and the AMA) supporting the proposed approach to use population thresholds for triggering minimum near-road monitoring requirements. For example, Dow Chemical Company stated that ``Dow comments that the proposed population thresholds are reasonable for implementation of the new network design and that we don't see a need to establish a threshold lower than 350,000 people for the lower bound.''
The EPA received comments from some States and State groups suggesting that a combination of population and AADT counts or just AADT counts should be used to trigger minimum near-road monitoring requirements. For example, the San Joaquin Air Pollution Control District in California suggested that we modify minimum monitoring requirements so that one near-road NO2 monitor is required for any CBSA with a population of 350,000 people which also had one or more road segments with AADT counts of 125,000 or more. In another example, Harris County Public Health and Environmental Services (HCPHES) suggested that ``* * * rather than specifying population limits for the monitoring, HCPHES supports a metric like the Annual Average Daily Traffic (AADT) as a threshold for requiring a near-road monitor. An initial focus on an AADT in excess of 250,000 is acceptable as a starting point but EPA should revisit that level and consider lowering it to 100,000 in five years.'' AASHTO \23\ and NYDOT \23\ suggested that EPA could set a threshold at 140,000 AADT for requiring near-road monitors rather than using population thresholds.

\23\ AASHTO, NESCAUM, and NYDOT did not support the two-tier network design; however they provided suggestions on how the network design might be modified if the EPA were to finalize requirements for near-road monitors. In the case of AASHTO and NYDOT, their suggestions were made with the suggestion that EPA use a separate rulemaking process to require monitors.

EPA is finalizing the population-only threshold approach to trigger near-road monitoring, as the first step in the process of establishing the first-tier of near-road monitors, and for identifying the appropriate number and locations for siting these monitors. EPA believes that the uncertainty in defining specific national AADT counts is too great to support use in this first step of the alternative approaches suggested by the commenters. EPA notes that, in general, roads with higher AADT counts have relatively higher amounts of mobile source emissions, leading to an increased potential for relatively higher on-road and roadside NO2 concentrations. This concept is supported, for example, by Gilbert et al., 2007, who state that the NO2 concentrations analyzed in their study are significantly associated with traffic counts. In part, these suggestions by commenters to include AADT counts as part of, or independently as, a threshold for requiring monitors appears to be aimed at increasing the focus of the near-road network to locations where NO2 concentrations are expected to be highest. However these suggestions would also, in effect, reduce the size of the required network compared to the network that EPA had proposed. The differences in fleet mix, roadway design, congestion patterns, terrain, and local meteorology amongst road segments that may have identical AADTs are quite variable and affect the NO2 concentrations on and near those segments. The available data and related technical and scientific quantification of what particular AADT count might be expected to contribute to some specific NO2 concentration is insufficient to establish a specific, nationally applicable AADT count threshold that could be used as part of a population-AADT combination, or a distinct AADT count, to require all near-road monitors. Therefore, EPA chose not to utilize a population-AADT or an AADT-only threshold to trigger all minimally required near-road monitoring because of the lack of a quantitative, nationally applicable relationship between a certain AADT threshold and an expected NO2 concentration. Instead, EPA is finalizing the proposed population-only threshold approach to trigger a minimum of one monitor in a CBSA. In larger CBSAs, EPA does require, at a minimum, a second monitor based on either an AADT count of 250,000 or a population threshold of 2,500,00 or more persons in a CBSA as described more fully below. EPA believes this approach for siting near-road monitoring provides a greater degree of certainty in covering a large segment of the total population (66%, which is explained below) and will provide data on exposure from geographically and spatially diverse areas where a larger number of people

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are likely to be exposed to peak NO2 concentrations.

Some commenters (e.g., AASHTO,\23\ NESCAUM,\23\ NYDEC, NYDOT \23\) suggested focusing multiple near-road monitors only in relatively larger CBSAs than those which were proposed. For example, NYDEC suggested that EPA require, at minimum, two near-road monitors in any CBSA of 2,500,000 people or more, but not in CBSAs below that population threshold. In their comments, they point out the variety of near-road environments that exist in the larger CBSAs such as New York City.

EPA notes that the larger CBSAs, such as those with a population of 2,500,000 or more persons, are more likely to have a greater number of major roads across a potentially larger geographic area, and a corresponding increase in potential for exposure in different settings (evidenced in the U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) ``Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance'' document which is discussed below). This is the primary reasoning behind the requirement for two monitors in CBSAs with more than 2,500,000 people. EPA also believes that having multiple monitors in the largest CBSAs will allow better understanding of the differences that may exist between roads in the same CBSA due to fleet mix, congestion patterns, terrain, or geographic locations. However, EPA believes that a network with substantially fewer monitors in correspondingly fewer CBSAs, as the commenters suggested, would lead to an insufficient monitoring network lacking a balanced approach needed for a regulatory network intended to support the revised NAAQS on a national basis.

On a related note to those comments that suggested focusing more near-road monitors only in the larger CBSAs, EPA proposed that any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000 must have a second monitor if they do not already have two near-road monitors because of the population threshold. Such an AADT-triggered monitor would account for situations where a relatively less populated area has a very highly trafficked road. In this case, EPA notes that because those road segments with 250,000 AADT have been identified by U.S. DOT FHWA (http://www.fhwa.dot.gov/policyinformation/tables/02.cfm) as being the top 0.03 percent of the most traveled public road segments, that they are the most heavily trafficked roads in the country. Again noting that NO2 concentrations are significantly associated with traffic counts (Gilbert et al. 2007), these roads segments likely have the greatest potential for high exposures directly connected to motor vehicle emissions in the entire country. Typically, these very highly trafficked roads are in the largest populated CBSAs, such as those with 2,500,000 people or more, and are somewhat atypical for CBSAs with less than 2,500,000 people. As a result, EPA believes it is appropriate to require a second monitor in a CBSA that has one or more road segments with 250,000 AADT counts or more if they do not already have two near-road monitors required due their population.

EPA received comments requesting that EPA explain the rationale for the selection of the population thresholds that trigger minimum monitoring requirements and also to reconsider the size of the network. For example, NYDOT suggested that this final rule explain the basis for the 350,000 and 2,500,000 population thresholds that will establish near-road monitors. In another comment, the Clean Air Council (CAC) questioned the selected population thresholds, noting that they believe that the population thresholds that were proposed were too high. Specifically, CAC stated that ``at 350,000 persons, numerous metro areas in the mid-Atlantic and Northeastern States with urban cores and highways running through will likely be exempted from the new monitors.'' The Spokane Regional Clean Air Agency stated that they ``do not believe it is necessary to require air quality monitoring for NO2 near major roadways in every metropolitan area. It is our [SRCAA's] view that EPA could establish a statistically significant number of air quality monitoring stations near roadways and develop a correlation between traffic density and ambient NO2 levels.'' Further, the EPA received many State comments suggesting reductions to the overall size of the near-road network; however the commenters did not provide very specific suggestions on how EPA should accomplish that reduction in size. For example, the Regional Air Pollution Control Agency, which represents a portion of Ohio, stated ``given the fairly standard fleet of vehicles on the nation's major highways, we urge EPA to consider the need for 142 near-roadway monitors. Perhaps a limited number of monitors across the country would suffice to sufficiently characterize near-roadway NO2 levels.'' These State commenters provided various reasons which are discussed throughout this document suggesting that the network be reduced in size, including funding concerns (section III.B.1.b), the perceived need to implement a smaller near-road research network in lieu of a regulatory network (section III.B.1.b), safety issues (section III.B.7.b), and problems with State implementation plans (section VI. D) and designation issues (section V).

EPA notes that the intent of the first tier of the network design is to support the revised NAAQS in measuring peak NO2 exposures in an area by including a minimum number of monitors resulting in a sufficiently sized national near-road monitoring network that will provide data from a geographically and spatially diverse array of areas, in terms of population, potential fleet mixes, geographic extent, and geographic setting, from across the country. The U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) ``Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance'' document (http://www.fhwa.dot.gov/policy/2006cpr/es02h.htm) states that ``while urban mileage constitutes only 24.9 percent of total (U.S.) mileage, these roads carried 64.1 percent of the 3 trillion vehicles miles (VMT) travelled in the United States in 2004.'' The document also states that ``urban interstate highways made up only 0.4 percent of total (U.S.) mileage but carried 15.5 percent of total VMT.'' These statements indicate how much more traffic volume exists on roads in urban areas versus the more rural areas that have significant amounts mileage of the total public road inventory. The basis for the selection of the proposed CBSA population level of 350,000 to trigger the requirement of one near-road monitor was chosen in an attempt to provide near-road monitoring data from a diverse array of areas, as noted above. However, in response to the significant number of comments discussed above, which in various ways encouraged at least a reduction of the size of the required near-road network or the implementation of a relatively smaller research network, EPA reconsidered the population threshold that will require one near-road NO2 monitor in a CBSA.

EPA reviewed the data, such as population, geographic, and spatial distribution, associated with particular CBSA areas that would and would not be included in particular CBSA population thresholds. According to the 2008 U.S. Census Bureau estimates (http://www.census.gov) there are 143 CBSAs with 350,000 or more persons (including territories) which contain approximately 71% of the total population (excluding territories). These

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CBSAs collectively represent territory in 44 States, the District of Columbia, and Puerto Rico. For comparison, there are 391 CBSAs with 100,000 or more persons, which contain approximately 86% of the total population (excluding territories). These particular CBSAs collectively represent territory in 49 States, the District of Columbia, and Puerto Rico. Further, there are 102 CBSAs with 500,000 or more persons, which contain approximately 66% of the total population (excluding territories). These 102 CBSAs collectively represent territory in 43 States, the District of Columbia, and Puerto Rico. Finally, there are 22 CBSAs with 2,500,000 or more persons, which contain approximately 39% of the total population, collectively representing territory in 19 States, the District of Columbia, and Puerto Rico. In comparison to the CBSA population threshold of 350,000, the 500,000 population threshold has 41 less CBSAs. However, the percentage of the total U.S. population residing in these two sets of CBSAs differs by only approximately 5 percent of the total population (e.g., 71% in CBSAs of 350,000 or more versus 66% in CBSAs of 500,000 or more persons). Also, when comparing the number of States that have some amount of their territory included in these CBSAs, the difference between the two sets of CBSAs differs by only 1 State (Alaska).

Further, EPA notes that the REA Air Quality Analysis, (REA, section 7.3.2) estimated the exceedences of health benchmark levels across the United States, including explicit consideration of on- or near- roadway exceedances in 17 urban areas associated with CBSA populations ranging from approximately 19,000,000 to 540,000. The analysis indicated that all 17 of the areas under explicit consideration were estimated to experience NO2 concentrations on or near roads that exceeded health benchmark levels.

c. Conclusions Regarding the First Tier (Near-Road Monitoring Component) of the Network Design

After consideration of public comments, and in light of the information discussed above, the Administrator has chosen to finalize the CBSA population threshold for requiring a minimum of one near-road monitor in CBSAs with a population of 500,000 or more persons. The Administrator is finalizing the other thresholds that will trigger a second near-road monitor as proposed. Accordingly, one near-road NO2 monitor is required in CBSAs with a population greater than or equal to 500,000 persons and a second near-road monitor is required in CBSAs with a population greater than or equal to 2,500,000 persons, or in any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000.

The Administrator has concluded that using a population threshold of 500,000 to require a minimum of one near-road monitor in a CBSA provides a sufficiently sized, national network of near-road monitors that will provide data from a geographically and spatially diverse set of CBSAs that supports the intent of the revised NAAQS and continues to meet the monitoring objectives of the network. Combined with the forty additional monitors that the Regional Administrators are required to site, discussed below, the monitoring network would cover an additional percentage of the total population.

EPA believes that selecting a lower population threshold, such as 100,000 or, to a lesser degree, 350,000, as discussed in the above examples, would create a much larger network of required near-road monitors but would provide diminished population coverage per monitor, compared to that provided by the 500,000 threshold. EPA notes that if a particular area, such as one with a population less than 500,000 people, might warrant a near-road monitor, the Regional Administrator has the authority to require additional monitors. The Regional Administrators' authority is discussed in section III.B.4. Further, States have the right to conduct additional monitoring above the minimum requirements on their own initiative. In the Administrator's judgment, selecting a higher threshold, such as 2,500,000, as was suggested by some commenters, does not provide a sufficient geographical and spatially diverse near-road network, compared to that provided by the 500,000 threshold. The selection of the 2,500,000 population threshold to trigger a second near-road monitor, as noted earlier in this section, is based on the fact that the larger urban areas in the country are likely to have a greater number of major roads across a potentially larger geographic area, and have a corresponding increase in potential for population exposure to elevated levels in different settings.

Changing the CBSA population threshold 350,000 to 500,000 results in a near-road monitoring network requiring approximately 126 monitors distributed within 102 CBSAs. Compared to the total number of required near-road monitors that would have resulted from the proposed CBSA population threshold of 350,000 (167 monitors), an estimated 41 fewer monitors are required. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site forty monitors in appropriate locations, focusing primarily on protecting such susceptible and vulnerable communities. This decision is discussed in detail in section III.B.4.

3. Second Tier (Area-Wide Monitoring Component) of the Network Design

The following paragraphs provide background, rationale, and details for the final changes to the second tier of the two-tier NO2 network design. In particular, this section will focus on the threshold that triggers area-wide monitoring requirements. Area-wide site selection and siting criteria details will be discussed in a subsequent section.

a. Proposed Second Tier (Area-Wide Monitoring Component) of the Network Design

As the second tier of the proposed two-tier network design, EPA proposed to require monitors to characterize the expected maximum NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in an area. This component of the two-tier network design provides information on area-wide exposures that may occur due to an individual or a group of point, area, on-road, and/or non-road sources. Further, area-wide sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, aiding in ozone forecasting, aiding in particulate matter precursor analysis and particulate matter forecasting. We proposed to require one area-wide monitoring site in each CBSA with a population greater than or equal to 1,000,000. We proposed that these area-wide sites were to be sited to represent an area of highest concentration at the neighborhood or larger spatial scales. Based on 2008 Census Bureau statistics, there are 52 CBSAs with 1,000,000 people or more, which would result in an estimated 52 area-wide monitors in as many CBSAs being minimally required. EPA also proposed to allow any current photochemical assessment monitoring station (PAMS) sites that are sited where the highest NO2 concentrations occur in an urban area

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and represent a neighborhood or urban scale to satisfy the area-wide monitoring requirement.

b. Comments

Most commenters who commented on area-wide monitoring supported the adoption of the alternative area-wide network design and did not specifically comment on the area-wide monitoring component of the proposed two-tier network design. However, EPA did receive comments from public health organizations on area-wide monitoring in the context of the proposed network design. The public health group commenters, including the ALA, EJ, EDF, and the NRDC, stated they ``oppose the proposed requirement to retain only 52 air monitors to measure area-wide concentrations of NO2.''

EPA understands the perceived concern to be that with this provision, EPA is actively reducing the number of required area-wide monitors. Prior to this rulemaking, the Ambient Air Monitoring Regulations, 71 FR 61236 (Oct. 17, 2006) (2006 monitoring rule) removed minimum monitoring requirements for NO2, and the rationale for that action is explained in that rule; however, the 2006 Monitoring rule has had a limited impact to date, evidenced by the fact that the size of the NO2 network has remained relatively steady at around 400 monitors, a majority of which are area-wide monitors, that were operating in 2008 (Watkins and Thompson, 2008). The stability of the NO2 network is due in large part to the fact that area-wide monitors serve multiple monitoring objectives, including photochemical pollutant assessment, pollutant forecasting, and in some cases, support to ongoing health research. However, considering the objective of this two-tier network design, particularly the first tier, of supporting the revised NAAQS to protect against peak NO2 exposures, some shrinkage in the area-wide network is appropriate and likely. EPA believes that the actual number of area-wide monitors that will operate in the NO2 network will be greater than the minimally required 52 sites, but likely less than the current number. States and Regional Administrators will work together on which area-wide sites may warrant retention above the minimum required if States request existing area-wide sites to be shut down or relocated.

c. Conclusions on the Second Tier (Area-Wide Monitoring Component) of the Network Design

Area-wide monitoring sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, ozone forecasting, particulate matter precursor analysis and particulate matter forecasting. EPA recognizes that a significant portion of the existing NO2 monitoring network can be characterized as area-wide monitors and that these monitoring sites serve multiple monitoring objectives, as noted above. In order to ensure that a minimum number of area-wide monitors continue operating into the future, we are finalizing the proposed minimum monitoring requirements for area-wide monitors, where one area-wide monitor is required in any CBSA with 1,000,000 people or more. Since there were no adverse comments received with regard to allowing PAMS stations that meet siting criteria to satisfy minimum monitoring requirements for area-wide monitors, we are finalizing that allowance as proposed. EPA encourages States to use the upcoming 2010 network assessment process to review existing area-wide NO2 sites to help determine what monitors might meet minimum monitoring requirements and whether or not other existing monitors warrant continued operation.

4. Regional Administrator Authority

The following paragraphs provide background, rationale, and details for the final changes to Regional Administrator authority to use discretion in requiring additional NO2 monitors beyond the minimum network requirements. The proposed rule estimated that approximately 167 near-road monitors would be required within CBSAs having populations of 350,000 or more persons. As discussed above in section III.B.2, in response to public comments, particularly from States, EPA is changing the population threshold for siting a minimum of one near-road NO2 monitor from CBSAs with 350,000 or more persons to CBSAs with 500,000 or more persons. EPA estimates that this change in the population threshold will result in a reduction in the number of minimally required near-road NO2 monitors by approximately forty monitors. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site these forty monitors in appropriate locations, focusing primarily on protecting susceptible and vulnerable communities. In addition, the Regional Administrators, working with States, may take into account other considerations described below in using their discretion to require additional monitors.

a. Proposed Regional Administrator Authority

EPA proposed that Regional Administrators have the authority to require monitoring at their discretion in particular instances. First, EPA proposed that the Regional Administrator have discretion to require monitoring above the minimum requirements as necessary to address situations where the required near-road monitors do not represent a location or locations where the expected maximum hourly NO2 concentrations exist in a CBSA. Second, EPA proposed to allow Regional Administrators the discretion to require additional near-road monitoring sites to address circumstances where minimum monitoring requirements are not sufficient to meet monitoring objectives, such as where exposures to NO2 concentrations vary across an area because of varied fleet mixes, congestion patterns, terrain, or geographic areas within a CBSA. And third, EPA proposed that Regional Administrators have the discretion to require additional area-wide NO2 monitoring sites above the minimum requirements for area-wide monitors where the minimum requirements are not sufficient to meet monitoring objectives.

b. Comments

EPA received comments from the Center on Race, Poverty and Environment expressing concern that the proposed monitoring provisions fail to consider ``disproportionately impacted communities'' which include people of color and of lower socioeconomic status. The commenter argues that this is ``a gaping hole'' in the proposed monitoring system and disproportionately impacts minority and low income populations in rural communities. In addition, the National Tribal Air Association stated that ``Indian Tribes and Alaska Natives are highly susceptible to health impacts as a result of NO2 exposure'' and ``the prevalence and severity of asthma is higher among certain ethnic or racial groups such as Indian Tribes and Alaska Natives,'' which is also discussed in section II.B.4 and the ISA (ISA, section 4.4).

The proposed rule provided the Regional Administrators with the authority to use their discretion and

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consider certain factors to require monitors above the minimum number in a CBSA. The proposal described one example where a Regional Administrator might require an additional near-road monitor where ``a particular community or neighborhood is significantly or uniquely affected by road emissions.'' EPA recognizes that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, as noted in section II.F.4.d, are at particular risk of NO2-related health effects, both because of increased exposure and because these groups have a higher prevalence of asthma and higher hospitalization rates for asthma. As noted above, in conjunction with raising the threshold for requiring one near-road NO2 monitor in CBSAs with 500,000 persons or more, EPA is requiring the Regional Administrators, under their discretionary authority, to work with States to site an additional forty monitors, nationally, focusing primarily on communities where susceptible and vulnerable populations are located. To address the risks of increased exposure to these populations, the Administrator has determined that it is appropriate and necessary, under this provision, to ensure these additional forty monitors are sited primarily in communities where susceptible and vulnerable populations are exposed to NO2 concentrations that have the potential to exceed the NAAQS (due to emissions from motor vehicles, point sources, or area sources). As a result of this action, the total number of monitors required through this rulemaking is generally equivalent to the proposed number of minimally required monitors.

EPA received comments from public health groups (e.g., ALA, Center on Race, Poverty, and the Environment, EDF, EJ, NRDC) and the Swinomish Tribe, who suggested that EPA expand monitoring coverage to address impacts from stationary sources outside of urban areas. For example, ALA, EDF, EJ, and NRDC, stated that ``EPA should require States and local offices to review inventory data to identify any potential NO2 hotspots outside of those large metropolitan areas. For instance, if a large power plant or any other source is creating elevated NO2 levels in proximity to homes, schools or other sensitive sites, in an area of less than one million people, EPA should consider requiring a monitor.''

EPA recognizes that there are major NO2 sources outside of CBSAs that have the potential to contribute to NO2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. While the proposal did not specifically state that Regional Administrators could require non-area-wide monitors outside of CBSAs, EPA believes that it is important that Regional Administrators have the authority to require NO2 monitoring in locations where NO2 concentrations may be approaching or exceeding the NAAQS, whether located inside or outside of CBSAs. Therefore, in the final rule, EPA is not limiting the Regional Administrators' discretionary authority to require NO2 monitoring only inside CBSAs; instead, the EPA is providing Regional Administrators the authority to site monitors in locations where NO2 concentrations may be approaching or exceeding the NAAQS, both inside or outside of CBSAs.

The EPA also received comments from some State groups (e.g. the New York Department of Environmental Conservation (NYSDEC), New York Department of Transportation (NYSDOT), and the New York City Law Department) and an industry group (the Council of Industrial Boiler Operators) requesting greater clarification on the way in which Regional Administrators may use their authority to require additional monitors above the minimum requirements. For example, the Council of Industrial Boiler Operators stated that ``this [Regional Administrator authority] unreasonably vests an unbounded amount of discretion in EPA to determine when ``minimum monitoring requirements are not sufficient'' and which neighborhoods are ``uniquely affected,'' and impose additional monitoring requirements where all applicable monitoring requirements are already met by the State and local agency.''

The authority of Regional Administrators to require additional monitoring above the minimum required is not unique to NO2. For example, Regional Administrators have or are proposed to have the authority to use their discretion to require additional Pb monitors (40 CFR Part 58 Appendix D section 4.5), and have the discretion to work with States or local agencies in designing and/or maintaining an appropriate ozone network, per 40 CFR Part 58 Appendix D section 4.1. EPA believes that while the NO2 monitoring network is sufficiently sized and focused, a nationally applicable network design may not account for all locations in which potentially high concentrations approaching or exceeding the NAAQS exist. Therefore, EPA believes it is important for Regional Administrators to have the ability to address possible gaps in the minimally required monitoring network, by granting them authority to require monitoring above the minimum requirements.

One case in which the Regional Administrator may exercise discretion in requiring a monitor might be a location or community affected by a stationary source where the required near-road NO2 monitor site is not the location of the maximum hourly concentration in a CBSA. For any given CBSA, there is the possibility that the maximum NO2 concentrations could be attributed to impacts from one, or a combination of, multiple sources that could include point, area, and non-road source emissions in addition to on-road mobile source emissions. As a result, the Regional Administrator may choose to require monitoring in such a location. In addition, there is the possibility that a single source or group of sources exists which may contribute to concentrations approaching or exceeding the NAAQS at locations inside or outside CBSAs, including rural communities. In such cases, Regional Administrators, working with States, may require a monitor in these locations. Further, if there are NO2 sources responsible for producing more widespread impacts on a community or relatively larger area, Regional Administrators may require an area-wide monitor to assess wider population exposures, or to support other monitor objectives served by area-wide monitors such as photochemical pollutant assessment or pollutant forecasting.

Regional Administrators may also require additional monitoring where a State or local agency is fulfilling its minimum monitoring requirements with an appropriate number of near-road monitors, but an additional location is identified where near-road population exposure exists at concentrations approaching or exceeding the NAAQS. In this case, the exposure may be due to differences in fleet mix, congestion patterns, terrain, or geographic area, relative to any minimally required monitoring site(s) in that area. We note

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that such areas might exist in CBSAs with populations less than 500,000 persons.

EPA recognizes that high concentrations of NO2 that approach or exceed the NAAQS could potentially occur in a variety of locations in an area, and we believe that Regional Administrators should have the discretion to require additional monitoring when a location is identified based on the factors discussed in the paragraph above. In such situations, State or EPA Regional staff is likely to have identified these locations through data analysis, such as the evaluation of existing ambient data and/or emissions data, or through air quality modeling. Such information may indicate that an area has NO2 concentrations that may approach or exceed the NAAQS, and that there is potential for population exposure to those high concentrations.

The Regional Administrator would use this authority in collaboration with State agencies. We expect Regional Administrators to work with State and local agencies to design and/or maintain the most appropriate NO2 network to meet the needs of a given area.

For all the situations where a Regional Administrator may require additional monitoring, including the forty additional monitors the Regional Administrators are required to site, EPA expects Regional Administrators to work on a case-by-case basis with States. Further, for the forty additional monitors that will focus primarily on protecting susceptible and vulnerable communities, EPA intends to work with States to develop criteria to guide site selection for those monitors.

c. Conclusions on Regional Administrator Authority

EPA is requiring Regional Administrators to work with States to site forty NO2 monitors, above the minimum number required in the two-tier network design, focused primarily in susceptible and vulnerable communities exposed to NO2 concentrations that have the potential to approach or exceed NAAQS. In addition, recognizing that a nationally applicable monitoring network design will not include all sites with potentially high concentrations due to variations across locations, and in response to public comments, the Administrator is providing Regional Administrators with the discretion to require additional monitors above the minimum requirements.

Regional Administrators may also use their discretionary authority to require monitoring above the minimum requirements as necessary to address situations inside or outside of CBSAs in which (1) The required near-road monitors do not represent all locations of expected maximum hourly NO2 concentrations in an area and NO2 concentrations may be approaching or exceeding the NAAQS in that area; (2) areas that are not required to have a monitor in accordance with the monitoring requirements and NO2 concentrations may be approaching or exceeding the NAAQS; or (3) the minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives. In all cases in which a Regional Administrator may consider the need for additional monitoring, EPA expects that Regional Administrators will work with the State or local agencies to evaluate evidence that suggests an area may warrant additional monitoring. EPA also notes that if additional monitoring should be required, as negotiated between the Regional Administrator and the State, the State will modify the information in its Annual Monitoring Network Plan to include any potential new sites prior to approval by the EPA Regional Administrator.

5. Monitoring Network Implementation

The following paragraphs provide background, rationale, and details for the final changes to the approach for the monitoring network implementation.

a. Proposed Monitoring Network Implementation Approach

EPA proposed that State and, when appropriate, local air monitoring agencies provide a plan for deploying monitors in accordance with the proposed network design by July 1, 2011. EPA also proposed that the proposed NO2 network be physically established no later than January 1, 2013.

b. Comments

Most environmental and public health group commenters suggested that EPA change the implementation date from the proposed January 1, 2013 to a date that would require the minimum required NO2 network to be deployed sooner than proposed. Most States and State group commenters, along with industry group commenters, recommended that EPA keep the network implementation date as January 1, 2013, or move it later than proposed. Those commenters who suggested moving it later noted that issues with monitoring site identification, site development, and overall lack of experience working in the near-road environment would make implementation difficult under the proposed implementation deadline.

EPA recognizes the challenges involved with deploying the two-tier network design by the January 1, 2013 date. We recognize the need for additional information and plan to aid State agencies in the network implementation process, particularly by developing guidance in partnership with affected stakeholders, ideally including at a minimum NACAA and the States. EPA agrees with NACAA's suggestion that the CASAC Ambient Air Monitoring and Methods subcommittee should be consulted as part of developing any guidance developed for near-road monitoring, and has already begun the process by scheduling meetings with them regarding near-road monitoring. Further, EPA believes that collaboration with the States and State groups in developing guidance will be highly beneficial to the implementation process. This would allow for those States that do have increased experience in near-road monitoring to support the guidance development process and provide a conduit for sharing experiences amongst all stakeholders.

In perspective, EPA believes that the approximate 2 years and 11 months between promulgation of this rulemaking and the mandated January 1, 2013 network implementation date includes extra time relative to what is traditionally allowed for network implementation following rulemakings. We are also cognizant of the time needed to collect complete data that would allow data from the two-tier network to be considered for designations and for use in the next NO2 NAAQS review data from the 2013, 2014, and 2015 years would provide critical information in the next NAAQS review, intended to occur on a 5-year cycle, and for use in subsequent designations. Even with complete data from 2013, 2014, and 2015 years designations would not occur until 2017, at the earliest.

c. Conclusions on Monitoring Network Implementation

EPA is finalizing the date by which State and, when appropriate, local air monitoring agencies shall establish the required NO2 monitoring network as January 1, 2013, as was proposed. We believe that the allotted time for implementation will allow for the development of guidance documentation, particularly allowing for interactions with CASAC and NACAA/States, and for the processes that will be involved in deploying this network. However, EPA recognizes that the network implementation process,

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particularly for near-road monitors, will include the assessment of road segments in CBSAs to identify locations of maximum expected hourly NO2 concentrations, identifying and working with other State and local agencies, such as transportation officials, as needed on issues regarding access and safety, and the exchange of information and feedback on potential sites with EPA, prior to any commitment to selecting and presenting new sites in an annual monitoring plan. As a result, based on feedback received through public comments, and to allow for more time to process guidance information, to carry out the deployment processes, and to allow for information exchanges to occur, we are changing the date by which State and, when appropriate, local air monitoring agencies shall provide a plan for deploying monitors in accordance with required network design, including the monitors required under the Regional Administrators' discretional authority which are to be primarily focused on providing protection to susceptible and vulnerable populations, as discussed in section III.B.4, from July 1, 2011 to July 1, 2012. EPA strongly encourages State and local air agencies to supply as much information as possible on the NO2 sites they may be considering, including possible site coordinates if available, or have possibly selected, to satisfy the minimum NO2 network monitoring requirements in their Annual Monitoring Network Plan submitted July 1, 2011.

6. Near-Road Site Selection

The following paragraphs provide background, rationale, and details for the final changes to the approach and criteria by which required near-road sites shall be selected.

a. Proposed Near-Road Site Selection Criterion

EPA proposed that the required near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments where maximum hourly NO2 concentrations are expected to be highest and siting criteria can be met in accordance with that proposed for 40 CFR Part 58 Appendix E (discussed in III.B.7). Where a State or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO2 concentrations are expected to occur, the monitoring agency should consider taking into account the potential for population exposure in the criteria utilized to select the final site location. Where one CBSA is required to have two near-road NO2 monitoring stations, we proposed that the sites shall be differentiated from each other by one or more of the following factors: Fleet mix; congestion patterns; terrain; geographic area within the CBSA; or different route, interstate, or freeway designation.

b. Comments

EPA received many comments from CASAC, public health groups, States and State groups, and industry groups on the proposed process by which States will select near-road sites. CASAC, along with some health group and State commenters questioned how States should select a site near the road with the highest ranked AADT possible, noting that EPA did not appear to require States to account for other factors. For example, one CASAC panel member noted that siting monitors based on traffic counts alone might miss locations where maximum NO2 concentrations would occur. They proceeded to recommend the use of modeling to assist in the site selection process. In another example, the ALA, EDJ, EJ, and NRDC, stated that ``Near-road monitor placement should be determined not only by the highest AADT volumes in a given CBSA, but also by the highest heavy-duty truck volumes.'' NACAA also expressed concerns on ``* * * basing monitor locations on the annual average daily traffic (AADT) without regard to vehicle mix or dispersion characteristics * * *''.

EPA does not intend for AADT counts to be the sole basis for choosing a near-road site. As noted earlier in section III.B.2, there is a general relationship between AADT and mobile source pollution, where higher traffic counts correspond to higher mobile source emissions. The use of AADT counts is intended to be a mechanism for focusing on identifying the locations of expected maximum NO2 concentrations due to mobile sources. There are other factors that can influence which road segment in a CBSA may be the actual location where the maximum NO2 concentrations could occur. These factors include vehicle fleet mix, roadway design, congestion patterns, terrain, and meteorology. When States identify their top-ranked road segments by AADT, EPA intends for States to evaluate all of the factors listed above in their site selection process, due to their influence on where the location of expected maximum NO2 concentration may occur. As a result of the comments indicating a need for clarification, EPA will specifically list the factors that must be considered by States in their site selection process once a State has identified the most heavily trafficked roads in a CBSA based on AADT counts. In addition, EPA proposed that States consider these factors when they are required to place two near-road monitors in a CBSA, i.e., CBSAs with a population of 2,500,000 persons or more. EPA notes that these factors will be used in differentiating the two monitoring sites from each other, providing further characterization of near-road environments in larger urban areas that are more likely to have a greater number of major roads across a potentially larger geographic area, and a corresponding increase in potential for exposure in different settings. Finally, EPA notes that air quality models, which were noted by the CASAC panel member to be considered for use in near-road site selection, are tools that EPA believes will be useful, and likely used by some States to inform where near-road sites need to be placed.

EPA received comments from some State and industry commenters (e.g. Iowa, NY DEC, Edison Electric Institute, and Savannah River Nuclear Solutions) who suggested that potential population exposure should be a first-level metric in the near-road monitoring site selection process, instead of a second-level metric as EPA had proposed.

EPA notes that the intent of the revised primary NO2 NAAQS is to protect against the maximum allowable NO2 concentration anywhere in an area, which includes ambient air on and around roads. This would limit exposures to peak NO2 concentrations, including those due to mobile source emissions, across locations (including those locations where population exposure near roads is greatest) in a given CBSA or area, with a relatively high degree of confidence. We also note the agency's historical practice has been to site ambient air monitors in locations of maximum concentration, at the appropriate spatial scale. If EPA were to allow population, population density, or another population weighted metric to be a primary factor in the decision on where required near-road NO2 monitors are to be located, it is possible that the required near-road monitors in a CBSA would not be located at a site of expected maximum hourly near-road NO2 concentration. By monitoring in the location of expected maximum 1-hour concentrations, near-road monitoring sites will likely represent the highest NO2 concentrations in an area directly attributable to mobile sources or a group of sources that includes mobile sources. The proposed rule did permit, and the final rule states, that States are to

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consider population in the site selection process in situations when a State identifies multiple candidate sites where maximum hourly NO2 concentrations are expected to occur.

EPA received a comment from HCPHES suggesting that required monitoring should take into consideration the location of other major mobile sources for NO2 emissions such as airports and seaports. EPA also received a comment from the South Carolina Department of Health and Environmental Control stating that a near-road network does not address ``widespread pollutants from numerous and diverse sources.''

EPA recognizes that there are major NO2 sources outside of CBSAs that have the potential to contribute to NO2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. Providing the Regional Administrators with the discretion to require additional monitors allows them to effectively address such situations, even if that area is satisfying minimum monitoring requirements. This Regional Administrator authority is discussed above in section III.B.4. EPA also notes that State and local agencies may also monitor such locations on their own initiative.

One State commenter, the Wisconsin Department of Natural Resources, requested that the term ``major road'' be defined and also requested clarification on what ``top-ranked'' means with regard to AADT counts on road segments. While the term ``major road'' is widely used in literature and can be found to be defined differently from one scientific study to another, here, EPA is using it in its commonly understood meaning as a road that is relatively heavily trafficked. EPA also does not believe it is appropriate to provide a bright-line definition for ``top-ranked''. Each CBSA will have a different distribution of total road segments and corresponding AADT counts on those segments. Further, since required near-road monitors are to be sited in locations of expected maximum concentrations, a percentile restriction on ``top ranked'' roads is unnecessary. The intent of the requirement to rank all road segments by AADT counts and select a site, considering the other local factors noted above, near a ``top-ranked'' road segment is to focus attention on the most heavily trafficked roads, around which there is higher potential for maximum NO2 concentrations to occur.

c. Conclusions on Near-Road Site Selection

We are finalizing the near-road site selection criteria as proposed, and are clarifying that the proposal intended the selection criteria to include consideration of localized factors when identifying locations of expected maximum concentrations. As a result, required near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO2 concentrations are expected to occur and siting criteria can be met in accordance with 40 CFR Part 58 Appendix E. As was noted in section III.B.5 above, EPA will work with States to assist with the near-road site selection process through the development of guidance material and through information exchanges amongst the air monitoring community.

We are also finalizing the requirement, as proposed, that when one CBSA is required to have two near-road NO2 monitoring stations, the sites shall be differentiated from each other by one or more of the following factors: fleet mix; congestion patterns; terrain; geographic area within the CBSA; or different route, interstate, or freeway designation, as was proposed.

7. Near-Road Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the siting criteria for required near-road monitoring sites.

a. Proposed Near-Road Siting Criteria

EPA proposed that near-road NO2 monitoring stations must be sited so that the NO2 monitor probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, and shall have no obstructions in the fetch between the monitor probe and roadway traffic such as noise barriers or vegetation higher than the monitor probe height. We solicited comment on, but did not propose, having near-road sites located on the predominantly downwind side of the target roadways. EPA proposed that the monitor probe shall be located within 2 to 7 meters above the ground, as is required for microscale PM2.5 and PM10 sites. We also proposed that monitor probe placement on noise barriers or buildings, where the inlet probe height is no less than 2 meters and no more than 7 meters above the target road, will be acceptable, so long as the inlet probe is at least 1 meter vertically or horizontally away (in the direction of the target road) from any supporting wall or structure, and the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer does not exceed 20 seconds.

b. Comments

EPA received comments from a number of States (e.g. Michigan, Mississippi, and Tennessee) indicating that the near-road network poses significant safety issues and a related need for increased logistical flexibility for installing a monitoring site. For example, the Mississippi Department of Environmental Quality states that ``Given the fact that these NO2 sites will be required to be housed in shelters that are within 50 meters of the road, we believe that these buildings could be large and pose a serious risk to drivers on the road.''

EPA notes that in all instances of field work, safety is a top priority. In this instance of near-road monitoring, we are dealing with the safety of the public driving on roads and the monitoring staff who may operate the near-road monitoring station as well. There are various ways to install near-road sites while ensuring worker and traffic safety, and safety is an important part of the logistical considerations that States should consider when selecting and installing near-road sites. In many cases, State and local monitoring agencies may be able to work with their State or local transportation officials during the site selection process to deal with access and safety issues. In public comments, AASHTO recommended that ``* * * State and local air monitoring agencies be required to coordinate with State and local DOTs for near-road monitoring during the establishment of the monitoring plan.'' Although EPA cannot require States to coordinate with other State or local entities, EPA believes that transportation officials would likely be able to assist in finding solutions to ensure safety while working with monitoring agencies in accommodating a new near-road monitoring station. An

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example of a step that could be taken to alleviate safety concerns might be purposefully placing a monitoring site behind existing barriers like guardrails and fencing, or possibly by installing a short distance of such barriers to protect the site workers, site infrastructure, and nearby traffic. In addition, EPA notes that the 50m distance proposed is wide enough to accommodate a site that would satisfy many setback provisions that exist for private or commercial building permits near roads, and may be viewed as a confirmation that our proposed siting criteria are safely attainable.

Some State commenters (e.g. AASHTO, NYSDOT, and Wisconsin) suggested that the allowable maximum distance a near-road monitoring probe can be from the target road be increased from 50 meters to something wider, such as 200 meters. Conversely, there were some State, environmental, and industry commenters (e.g. NESCAUM,\24\ Group Against Smog and Pollution, and Air Quality Research and Logistics) who suggested that the proposed range was appropriate, or, as suggested by both NESCAUM and the Group Against Smog and Pollution, the allowable distance should be reduced to as close as 30 or 20 meters to the nearest edge of the traffic lanes of the target road segment, respectively.

\24\ NESCAUM officially supported the alternative network design; however, they made suggestions regarding the near-road network in the event EPA finalized the proposed two-tier network design.

EPA believes that increasing the allowable distance above 50 meters would compromise the intent of near-road monitoring. As was noted in the proposal and this document, the ISA (2.5.4 and 4.3.6) and REA (7.3.2) indicate that on-road, mobile source derived NO2 exhibits a peak concentration on or very near the source road, and those concentrations decay over a variable but relatively short distance back to near area-wide or background (upwind of the target road) concentrations. Literature values indicate that the distance required for NO2 concentrations to return to near area-wide or background concentrations away from major roadways can range up to 500 meters, but the peak concentrations are occurring on or very near the source roadway. The behavior of NO2 concentrations and the actual distance over which concentrations return to near area-wide or background levels is variable, and highly dependent on topography, roadside features, meteorology, and the related photochemical reactivity conditions (Baldauf et al., 2008; Beckerman et al., 2007; Clements et al., 2008; Gilbert et al., 2003; Hagler et al., 2009; Rodes and Holland, 1980; Singer et al., 2003; Zhou and Levy, 2007). Therefore, monitor probe placement at increasing distances from a road, such as 200 meters, will correspondingly decrease the potential for sampling maximum concentrations of NO2 due to the traffic on the target road. Baldauf et al. (2009) indicate that monitoring probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

Regarding the comments suggesting required monitor probes be closer than 50 meters, EPA believes the allowable distance of 50 meters that a near-road NO2 probe can be from the target road provides enough flexibility for the logistical issues that can occur on a case-by-case basis, which is inherent in monitoring site placement, while not sacrificing the potential to monitor the peak NO2 concentrations. However, in light of the information provided here on how NO2 peak concentrations can decay over relatively short distances away from roads, EPA strongly encourages States to place near-road sites, or at least monitor probes, as close as safely possible to target roads to increase the probability of measuring the peak NO2 concentrations that occur in the near-road environment, again noting that Baldauf et al. (2009) indicate that monitor probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

EPA also proposed that required near-road NO2 monitor probes shall have no obstructions in the fetch between the monitor probe and roadway traffic such as noise barriers or vegetation higher than the monitor probe height. EPA expects that when a State makes a measurement in determining whether an NO2 inlet probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, that the measurement would likely represent a path to the monitor probe that is normal to the target road. However, EPA notes that the monitor probe will likely be influenced by various parts of the target road segment that are at a relative angle compared to the normal transect between the road and the monitor probe. EPA is not adjusting the wording of this requirement, but does intend for States to consider more than one linear pathway between the target road and the monitor probe being clear of obstructions when considering candidate site locations.

EPA received comments on the solicitation for comment on requiring near-road monitoring sites to be placed on the downwind side of the target road where the commenters (e.g. NACAA,\25\ NESCAUM, and the Clean Air Council) encouraged such a requirement. Conversely, other commenters (e.g., Air Quality and Logistics and NYSDEC suggested that such a requirement may be overly restrictive and not necessary. For example, NYSDEC stated that ``It is important to avoid making the monitor siting criteria too restrictive. It is very likely that in some CBSAs, finding suitable locations near the busiest road segments will not be possible. It is also important to remember that the NO2 monitoring instrumentation provides data continuously. Sites located downwind of sources will likely be impacted more frequently than the sites located upwind particularly when the sites are more than 50 meters from the source, and are preferred, but either side of the road will be downwind some of the time. Many of the highest NO2 concentrations are also likely to occur during inversion periods and during calm meteorological conditions when the upwind-downwind designations have little meaning.''

\25\ NACAA made a statement containing many concerns about the near-road monitoring component proposal which included a passage regarding the lack of requiring sites to be downwind. They expressed concern in ``* * * allowing upwind siting of monitors over a wide range of horizontal and vertical distances from the road * * *''.

EPA noted in its proposal that research literature indicates that in certain cases, mobile source derived pollutant concentrations, including NO2, can be detected upwind of roads, above background levels, due to a phenomenon called upwind meandering. Kalthoff et al. (2007) indicates that mobile source derived pollutants can meander upwind on the order of tens of meters, mainly due to vehicle induced turbulence. Further, Beckerman et al. (2008) note that near-road pollutant concentrations on the predominantly upwind side of their study sites dropped off to near background levels within the first 50 meters, but were above background in this short and variable upwind range, which could be due, at least in part, to vehicle induced turbulence. This upwind meandering characteristic of pollutants in the near-road environment provides an additional basis for locating near-road sites within 50 meters of target road segments, but also reduces the absolute need to be downwind of the road. EPA believes that very few, if any, near-road sites would be able to be situated in a location that was always downwind. For example, a hypothetical

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site may have winds routinely out of several different cardinal directions throughout the year, without one being a dominant direction. As a result, given variable meteorology, for some period of a year, a given near-road site may not be downwind of the target road, no matter which side of the road it is on. Therefore, EPA is not finalizing a requirement that near-road sites must be climatologically downwind of the target road segment because of the additional limitations this introduces to finding potential site candidates in exchange for what may be a small increase in the opportunity to monitor peak NO2 concentrations. However, EPA encourages States to place monitors in the climatologically downwind direction whenever possible, in an attempt to measure the peak NO2 concentrations more often than not. One way States may identify where the predominantly downwind location might be for candidate sites could be to use portable meteorological devices to characterize meteorological tendencies, in addition to evaluating other available meteorological data sources.

EPA proposed that required near-road NO2 monitor probes be located within 2 to 7 meters above the ground, as is required for microscale PM2.5 and PM10 sites. EPA also proposed that monitor probe placement on noise barriers or buildings, where the inlet probe height is no less than 2 meters and no more than 7 meters above the target road, will be acceptable, so long as the inlet probe is at least 1 meter vertically or horizontally away (in the direction of the target road) from any supporting wall or structure. NESCAUM commented that ``EPA needs to reconcile near-roadway NO2 probe height requirements with the existing micro-scale near-roadway CO probe height requirement of 2.5 to 3.5 meters above prevailing terrain. NESCAUM supports using this existing height for all near-roadway pollution monitors, as it minimizes probe height effects on measurements, and allows for proper measurement of collocated particle number concentration (which requires a very short inlet, i.e., on the order of inches) and CO.'' NYSDEC commented that ``The height requirement may not be practical for road segments in dense urban areas where existing buildings heights may exceed 7 meters. The requirement to maintain a 1 meter clearance from a supporting wall or structure may not be adequate for taller walls often found in urban areas. These walls can create down washing and street canyon effects which will make the resulting data less representative of nearby areas and will make interpretation of the resulting data difficult. However, there will need to be consistency between similar site settings.'' Finally, EPA received comments from some health groups (e.g., ALA, EJ, EDF, and NRDC) who commented that ``the lower end of the proposed height of 2 to 7 meters appears to capture the highest NO2 concentrations, and more accurately represents human exposure at the breathing zone.''

In the proposal, EPA noted that near-road monitoring sites will be adjacent to a variety of road types, where some target roads will be on an even plane with the monitoring station, while others may be cut roads (i.e., below the plane of the monitoring station) or fill and open elevated roads (i.e., where the road plane is above the monitoring station). EPA recognizes that consistency across sites with regard to probe height is desirable, and consistency with microscale, urban canyon CO sites might also be desirable. However, as was noted in the earlier discussion on ``downwind'' site placements, it is important to avoid making the monitor siting criteria too restrictive. An allowable range between 2 and 7 meters provides more flexibility in site installation, which EPA considers important because of the variety of siting situations each State may have to deal with for each individual site. While EPA agrees that a tighter allowable range such as 2.5 to 3.5 meters would reduce site to site variability and keep probes nearer the microscale siting requirements of CO, the wider range of 2 to 7 meters still provides an adequate amount of site to site consistency. EPA may also address this issue through forthcoming guidance, where an increased consistency for probe heights in similar situations such as urban canyons may be a site implementation goal, within the required 2 to 7 meter probe height range. Further, EPA believes that although certain situations, as noted by NYSDEC, may exist where the 1 meter clearance from walls or structures may be problematic near taller buildings or walls, this requirement is consistent with similar such clearance requirements for microscale CO sites in similar such situations that exist in urban canyons.

In the proposed rule, EPA proposed in the siting criteria language that the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer cannot exceed 20 seconds. EPA received comments from Air Quality Research and Logistics regarding guidelines for maximum allowable inlet length and sample residence time, where they stated that ``* * * the fast photodynamic O3-NOX equilibrium may occur in darkened sample lines at residence times of 10-20 seconds (Butcher et al. 1971; Ridley et al. 1988; Parrish et al. 1990). EPA should correct this apparent error by specifying much lower maximum residence times (e.g., 1-2 seconds) or accounting for this effect by reporting `corrected' values in error by no more than the allowed rounding convention (e.g., 1 ppb).''

EPA notes that in 40 CFR Part 58 Appendix E, paragraph (9)(c), states that sample probes for reactive gas analyzers, particularly NOY monitors, at NCore monitoring sites must have a sample residence time less than 20 seconds. EPA believes this rule is also appropriate for NO2 monitors, particularly if a monitor inlet manifold is extended away from the main monitoring shelter. EPA does agree that shorter sample residence time in the inlet manifold is desirable. Although we do not believe it appropriate to require residence times on the order of 1 to 2 seconds, and do not believe correcting values is appropriate (which was not a concept which was proposed), we do encourage States to use best practices in selecting non-reactive manifold materials, and to install sampling manifolds in an efficient manner that minimizes sample residence time. While EPA proposed this concept in the preamble to the proposed rule, we did not include it in the proposed regulatory text. The final rule includes regulatory text on this subject at 40 CFR Part 58 Appendix E, paragraph (9)(c).

c. Conclusions on Near-Road Siting Criteria

We are finalizing the near-road NO2 monitor siting criteria, as proposed, where (1) required near-road NO2 monitor probes shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment, (2) required near-road NO2 monitor probes shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment, (3) required near-road NO2 monitors are required to have sampler inlets between 2 and 7 meters above ground level, and (4) residence time of NO2 in the sample line between the

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inlet probe and the analyzer does not exceed 20 seconds.

8. Area-Wide Monitor Site Selection and Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the site selection and monitor siting criteria for required area-wide monitoring sites.

a. Proposed Area-Wide Monitor Site Selection and Siting Criteria

EPA proposed that sites required as part of the second tier of the NO2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

b. Comments

While most commenters who supported area-wide monitoring did so with regard to the adoption of the alternative area-wide network design rather than as part of the proposed approach, only a few commented on the actual sites and siting criteria. The Dow Chemical Company suggested that area-wide sites should be located at least 1,000 meters away from any major roads or intersections to ensure that the concentration of NO2 measured is representative of an area-wide concentration instead of peak near-road concentrations.

EPA notes that in order for an NO2 monitoring site to be classified as a neighborhood (or larger) spatial scale site, it must meet the roadway set-back requirements in Table E-1 of 40 CFR Part 58 Appendix E. EPA believes that this existing set-back table is appropriate to use to ensure that any NO2 site that may be intended as an area-wide site will be sufficiently distanced from any major road. For example, an NO2 monitoring site may be considered neighborhood scale if it is 10 or more meters from the edge of the nearest traffic lane of a road with 10,000 or less AADT counts.

c. Conclusions on Area-Wide Monitor Site Selection and Siting Criteria

We are finalizing the requirement that any sites required as part of the second tier of the NO2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

9. Meteorological Measurements

The following paragraphs provide background, rationale, and details for the final changes to the requirement of meteorological monitoring at near-road monitoring sites.

a. Proposed Meteorological Measurements

In further support of characterizing the peak NO2 concentrations occurring in the near-road environment, EPA proposed to require three-dimensional anemometry, providing wind vector data in the horizontal and vertical planes, along with temperature and relative humidity measurements, at all required near-road monitoring sites.

b. Comments

EPA received comments from the South Carolina Department of Health and Environmental Control commented that the recording of air turbulence data at near-road monitoring stations should be encouraged but not required. Other States (e.g., Alaska, North Carolina, and Wisconsin) provided comments that did not support the proposed meteorological measurement requirements, noting issues with costs, problems siting the probe nearer to structures and to the ground than is typically done, and that the averaging period required to better understand turbulence (through anemometry data) in the near-road environment requires a much higher frequency than what is typically reported.

EPA is removing the proposed requirements that would have required meteorological monitoring at near-road NO2 monitoring stations. However, EPA strongly encourages States to do some meteorological monitoring to better characterize the conditions under which they are acquiring NO2 data. The near-road microscale environment is complex, and understanding the turbulent dispersion that may be affecting NO2 measurements, along with having a basic understanding of from which direction the measured NO2 concentrations are coming from, which are very informative in the effort to fully understand the data being collected. At a minimum, basic anemometry data would be useful in identifying whether the site is upwind, downwind, or otherwise oriented, relative to the target road.

c. Conclusions on Meteorological Measurements

We are not finalizing the proposal to require three-dimensional anemometry, providing wind vector data in the horizontal and vertical planes, along with temperature and relative humidity measurements, at all required near-road monitoring sites.

C. Data Reporting

The following paragraphs provide background, rationale, and details for the final changes to the data reporting requirements, data quality objectives, and measurement uncertainty.

1. Proposed Data Quality Objectives and Measurement Uncertainty

In the proposal, EPA noted that State and local monitoring agencies are required to report hourly NO, NO2, and NOX data to AQS within 90 days of the end of each calendar quarter. We also noted that many agencies also voluntarily report their pre-validated data on an hourly basis to EPA's real time AIRNow data system, where the data may be used by air quality forecasters to assist in ozone forecasting. We believe these data reporting procedures are appropriate to support the revised primary NO2 NAAQS.

EPA proposed to develop data quality objectives (DQOs) for the proposed NO2 network. We proposed a goal for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

2. Comments

EPA received comments from the State of Missouri, supporting the proposed DQOs and goals for measurement uncertainty, and from North Carolina, suggesting that measurement uncertainty goals match those of the NCore multi-pollutant network.

EPA agrees that it is desirable to have measurement uncertainty goals that match that of other pollutants. EPA originally proposed the goals for precision and bias under consideration that there may be a need to account for potential increased uncertainty in 1-hour near-road NO2 data. However, we agree with the suggestion from the State of North Carolina, and are changing the goals for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent. These goals match the existing goals for NO2 and are consistent with historical measurement uncertainty goals.

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3. Conclusions on Data Quality Objectives and Measurement Uncertainty

We are finalizing the approach to develop data quality objectives, and are changing the proposed goal for measurement uncertainty, where the goals for acceptable measurement uncertainty for NO2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

IV. Appendix S--Interpretation of the Primary NAAQS for Oxides of Nitrogen and Revisions to the Exceptional Events Rule

The EPA proposed to add Appendix S, Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, to 40 CFR part 50 in order to provide data handling procedures for the proposed NO2 1-hour primary standard and for the existing NO2 annual primary standard. The proposed Appendix S detailed the computations necessary for determining when the proposed 1-hour and existing annual primary NO2 NAAQS are met. The proposed Appendix S also addressed data reporting, data completeness considerations, and rounding conventions.

Two versions of Appendix S were proposed. The first applied to a 1-hour primary standard based on the annual 4th high value form, while the second applied to a 1-hour primary standard based on the 99th percentile daily value form.

The final version of Appendix S is printed at the end of this notice and applies to an annual primary standard and a 1-hour primary standard based on the 98th percentile daily value form. Appendix S is based on the near-roadway approach to the setting the level of the 1-hour standard and to siting monitors. As such, these versions place no geographical restrictions on which monitoring sites' concentration data can and will be compared to the 1-hour standard when making nonattainment determinations and other findings related to attainment or violation of the standard.

The EPA is amending and moving the provisions of 40 CFR 50.11 related to data completeness for the existing annual primary standard to the new Appendix S, and adding provisions for the proposed 1-hour primary standard. Substantively, the data handling procedures for the annual primary standard in Appendix S are the same as the existing provisions in 40 CFR 50.11 for that standard, except for an addition of a cross-reference to the Exceptional Events Rule, the addition of Administrator discretion to consider otherwise incomplete data complete, and the addition of a provision addressing the possibility of there being multiple NO2 monitors at one site. The procedures for the 1-hour primary standard are entirely new.

The EPA is also making NO2-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines now contained in 40 CFR 50.14 are generic, and are not always appropriate for NO2 given the anticipated schedule for the designations of areas under the final NO2 NAAQS.

The purpose of a data interpretation appendix in general is to provide the practical details on how to make a comparison between multi-day and possibly multi-monitor ambient air concentration data and the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. The regulatory language for the pre-existing annual NO2 NAAQS, originally adopted in 1977, contained data interpretation instructions only for the issue of data completeness. This situation contrasts with the situations for ozone, PM2.5, PM10, and most recently Pb for which there are detailed data interpretation appendices in 40 CFR part 50 addressing more issues that can arise in comparing monitoring data to the NAAQS.

A. Interpretation of the Primary NAAQS for Oxides of Nitrogen for the Annual Primary Standard

The purpose of a data interpretation rule for the NO2 NAAQS is to give effect to the form, level, averaging time, and indicator specified in the regulatory text at 40 CFR 50.11, anticipating and resolving in advance various future situations that could occur. Appendix S provides common definitions and requirements that apply to both the annual and the 1-hour primary standards for NO2. The common requirements concern how ambient data are to be reported, what ambient data are to be considered (including the issue of which of multiple monitors' data sets will be used when more than one monitor has operated at a site), and the applicability of the Exceptional Events Rule to the primary NO2 NAAQS.

The proposed Appendix S also addressed several issues in ways which are specific to the individual primary NO2 standards, as described below.

1. Proposed Interpretation of the Annual Standard

The proposed data interpretation provisions for the annual standard are consistent with the pre-existing instructions included along with the statement of the level and form of the standard in 40 CFR 50.11. These are the following: (1) At least 75% of the hours in the year must have reported concentration data. (2) The available hourly data are arithmetically averaged, and then rounded (not truncated) to whole parts per billion. (3) The design value is this rounded annual average concentration. (4) The design value is compared with the level of the annual primary standard (expressed in parts per billion).

In the proposal, EPA noted that it would be possible to introduce additional steps for the annual primary standard which in principle could make the design value a more reliable indicator of actual annual average concentration in cases where some monitoring data have been lost. For example, averaging within a calendar quarter first and then averaging across quarters could help compensate for uneven data capture across the year. For some aspects of the data interpretation procedures for some other pollutants, the current data interpretation appendices do contain such additional steps. The proposed provisions for the proposed 1-hour NO2 standard also incorporated some such features.

2. Comments on Interpretation of the Annual Standard

We received four comments, all from State agencies, on data interpretation for the annual NO2 standard. Of the four commenters, two recommended the use of a weighted annual mean to appropriately implement the annual primary standard. Two other commenters asserted that there is no strong seasonality in NO2 concentrations, and that therefore there is no need to use a weighted annual mean or to require data completeness quarter-by-quarter.

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3. Conclusions on Interpretation of the Annual Standard

Upon investigating the issue of NO2 seasonality using data from AQS as part of considering the comments, we have found that there are notable variations in quarterly mean NO2 concentrations. It is therefore quite possible that an unweighted annual mean calculated without a quarter-by-quarter data completeness requirement might not represent the true annual mean as well as a weighted annual mean calculated with a quarter-by-quarter completeness requirement. However, the current practice of requiring 75% completeness of all of the hours in the year and calculating the annual mean without weighting has been retained in the final rule, because of its simplicity and because we believe it will not interfere with effective implementation of the annual NAAQS. No area presently is nonattainment for or comes close to violating the annual standard. Therefore, the choice between the two approaches can only have a practical effect, if any, on whether at some time in the future an area is determined to be newly violating the annual standard. If a monitor has a complete and valid design value below the standard using the unweighted mean approach (with only an annual data completeness requirement) but the design value would be considered incomplete and invalid under a hypothetical weighted mean approach (with a quarterly completeness requirement), the monitor would in either case be considered not to be violating and its data would not be the basis for a nonattainment designation. If a monitor has a design value above the standard using the unweighted annual mean approach but is incomplete with respect to a hypothetical quarterly completeness requirement, then the two approaches would have different implications for the determination of a violation. A quarterly completeness requirement would make a finding of violation impossible, unless the Administrator chose to treat the data as if complete under another provision of the final rule. The unweighted annual mean approach would allow but not force a finding of violation, because the Administrator will have discretion to make any such findings because there will be no mandatory round of designations for the annual standard given that the annual standard has not been revised in this review. The Administrator will be able to consider the representativeness of the unweighted annual mean when deciding whether to make a discretionary nonattainment redesignation. Given that the annual standard requires only one year of monitoring data for the calculation of a design value, little time will be lost if the Administrator chooses to work with a State to obtain a new design value based on more complete and/or seasonally balanced monitoring data.

B. Interpretation of the Primary NAAQS for Oxides of Nitrogen 1-Hour Primary Standard

1. Proposed Interpretation of the 1-Hour Standard

With regard to data completeness for the 1-hour primary standard with a 4th highest daily value form, the proposed Appendix followed past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the 1-hour primary NO2 NAAQS, the key air quality statistics are the daily maximum 1-hour concentrations in three successive years. It is important that sampling within a day encompass the period when concentrations are likely to be highest and that all seasons of the year are well represented. Hence, the 75% requirement was proposed to be applied at the daily and quarterly levels.

Recognizing that there may be years with incomplete data, the proposed text provided that a design value derived from incomplete data would nevertheless be considered valid in either of two situations.

First, if the design value calculated from at least four days of monitoring observations in each of these years exceeds the level of the 1-hour primary standard, it would be valid. This situation could arise if monitoring was intermittent but high NO2 levels were measured on enough hours and days for the mean of the three annual 4th high values to exceed the standard. In this situation, more complete monitoring could not possibly have indicated that the standard was actually met.

Second, we proposed a diagnostic data substitution test which was intended to identify those cases with incomplete data in which it nevertheless is very likely, if not virtually certain, that the daily 1-hour design value would have been observed to be below the level of the NAAQS if monitoring data had been minimally complete.

It should be noted that one possible outcome of applying the proposed substitution test is that a year with incomplete data may nevertheless be determined to not have a valid design value and thus to be unusable in making 1-hour primary NAAQS compliance determinations for that 3-year period.

Also, we proposed that the Administrator have general discretion to use incomplete data based on case-specific factors, either at the request of a State or at her own initiative. Similar provisions exist already for some other NAAQS.

The second version of the proposed Appendix S contained proposed interpretation procedures for a 1-hour primary standard based on the 99th percentile daily value form. The 4th high daily value form and the 99th percentile daily value form would yield the same design value in a situation in which every hour and day of the year has reported monitoring data, since the 99th percentile of 365 daily values is the 4th highest value. However, the two forms diverge if data completeness is 82% or less, because in that case the 99th percentile value is the 3rd highest (or higher) value, to compensate for the lack of monitoring data on days when concentrations could also have been high.

Logically, provisions to address possible data incompleteness under the 99th percentile daily value form should be somewhat different from those for the 4th highest form. With a 4th highest form, incompleteness should not invalidate a design value that exceeds the standard, for reasons explained above. With the 99th percentile form, however, a design value exceeding the standard stemming from incomplete data should not automatically be considered valid, because concentrations on the unmonitored days could have been relatively low, such that the actual 99th percentile value for the year could have been lower, and the design value could have been below the standard. The second proposed version of Appendix S accordingly had somewhat different provisions for dealing with data incompleteness. One difference was the addition of another diagnostic test based on data substitution, which in some cases can validate a design value based on incomplete data that exceeds the standard.

The second version of the proposed Appendix S provided a table for determining which day's maximum 1-hour concentration will be used as the 99th percentile concentration for the year. The proposed table is similar to one used now for the 24-hour PM2.5 NAAQS, which is based on a 98th percentile form, but adjusted to reflect

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a 99th percentile form for the 1-hour primary NO2 standard. The proposed Appendix S also provided instructions for rounding (not truncating) the average of three annual 99th percentile hourly concentrations before comparison to the level of the primary NAAQS.

2. Comments on Interpretation of the 1-Hour Standard

Three commenters expressed the view that the 75% completion per quarter requirement should apply with respect to the 1-hour standard. A fourth commenter recommended that the requirement be increased to 82%. Another person commented that the requirement of 75% of the hours in a day is too stringent. The commenter noted that it would be inappropriate not to count the day if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS. A comment was received that the substitution test should not be included, on the grounds that nonattainment should not be declared without irrefutable proof. This commenter also said that the same completeness requirement as used for nonattainment should be used for attainment. We received one comment that the computation of design values where multiple monitors are present at a site should be averaged and not taken from a designated primary monitor.

3. Conclusions on Interpretation of the 1-Hour Standard

Consistent with the Administrator's decision to adopt a 98th percentile form for the 1-hour NAAQS, the final version of Appendix S is based on that form. Table 1 has been revised from the version that was proposed, so that it results in the selection of the 98th percentile value rather than the 99th percentile value.

We agree with the three comments expressing the view that the requirement for 75% data completeness per quarter should apply with respect to the 1-hour standard. A fourth comment recommended that the requirement be increased to 82%. We believe 82% is too stringent because of the number of monitors that would not achieve such a requirement and we believe that 75% captures the season. We agree that an incomplete day should be counted if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS, and we have accounted for that in section 3.2.c.i by validating the design value if it is above the level of the primary 1-hour standard when at least 75 percent of the days in each quarter have at least one reported hourly value. We agree that substitution should not be used for the establishment of attainment/nonattainment. The commenter who remarked on this issue appears not to have understood that the specific proposed substitution tests have essentially zero probability of making a clean area fail the NAAQS, or vice versa, because the substituted values are chosen to be conservative against such an outcome. As noted in section 3.2(c)(i), when substitution is used, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

In the course of considering the above comment regarding data substitution tests to be used in cases of data incompleteness, EPA has realized that there could be some cases of data incompleteness in which the proposed procedure for calculating the 1-honr design value might result in an in appropriately low design value. As proposed, only days with measurements for at least 75% of the hours in the day would be considered in any way when identifying the 99th percentile value (99th for purposes of the adopted NAAQS). However, there could be individual hours in other, incompletely monitored days that had measured concentrations higher than the identified 98th percentile value from the complete days. It would be inappropriate not to consider those hours and days in some way. However, if all days with at least one hourly concentration were used to identify the 99th percentile value without any regard to their incompleteness, this could also result in a design value that is biased low because the extra days could increase the number of ``annual number of days with valid data'' enough to affect which row of Table 1 of Appendix S is used. It could, for example, result in the 8th highest ranked daily maximum concentration being identified as the 98th percentile value (based on Table 1 of Appendix S) rather than a higher ranked concentration; this would also be inappropriate because days which were not monitored intensively enough to give a reasonable likelihood of catching the maximum hourly concentration would in effect be treated as if they had such a likelihood. For example, 50 days with only one hourly measurement during a time of day with lower concentrations would ``earn'' the State the right to drop one notch lower in the ranking of days when identifying the 98th percentile day, inappropriately. The final version of Appendix S solves this problem by providing that two procedures be used to identifying the 98th percentile value, the first based only on days with 75% data completeness and the second based on all days with at least one hourly measurement. The final design value is the higher of the two values that result from these two procedures.

With regard to situations with multiple monitors operating at one site, we think as discussed in the proposal, that designation of a primary monitor is preferable to averaging the data from multiple monitors based on administrative simplicity and transparency for the public, and is unbiased with respect to compliance outcome provided the State is able to make the designation only before any data has been collected.

Finally, as proposed, the final version of Appendix S has a cross reference to the Exceptional Events Rule (40 CFR 50.14) with regard to the exclusion of data affected by exceptional events. In addition, the specific steps for including such data in completeness calculations while excluding such data from actual design value calculations is clarified in Appendix S.

C. Exceptional Events Information Submission Schedule

The Exceptional Events Rule at 40 CFR 50.14 contains generic deadlines for a State to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A State must initially notify EPA that data has been affected by an event by July 1 of the year after the data are collected; this is done by flagging the data in AQS and providing an initial event description. The State must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review is foreshortened, and all information must be submitted to EPA no later than one year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a newly revised NAAQS. One problem is

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that some of the deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the revised NAAQS is promulgated. Until the level and form of the NAAQS have been promulgated a State does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day. The only way a State could guard against this possibility is to flag all data that could possibly be eligible for exclusion under a future NAAQS. This could result in flagging far more data than will eventually be eligible for exclusion. EPA believes this is an inefficient use of State and EPA resources, and is potentially confusing and misleading to the public and regulated entities. Another problem is that it may not be feasible for information on some exceptional events that may affect final designations to be collected and submitted to EPA at least one year in advance of the final designation decision. This could have the unintended consequence of EPA designating an area nonattainment as a result of uncontrollable natural or other qualified exceptional events.

When Section 50.14 was revised in March 2007, EPA was mindful that designations were needed under the recently revised PM2.5 NAAQS, so exceptions to the generic deadline were included for PM2.5. The EPA was also mindful that similar issues would arise for subsequent new or revised NAAQS. The Exceptional Events Rule at section 50.14(c)(2)(v) indicates ``when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those NAAQS.''

EPA proposed revised exceptional event data flagging and documentation deadlines in FR 34404 [Federal Register/Vol. 74, No. 134/ Wednesday, July 15, 2009/Proposed Rules] and invited comments from the public. The Agency received no comments related to the revised proposed schedule for NO2 exceptional event data flagging and documentation deadlines.

For the specific case of NO2, EPA anticipates that initial designations under the revised NAAQS may be made by January 22, 2012 based on air quality data from the years 2008-2010. (See Section VI below for more detailed discussion of the designation schedule and what data EPA intends to use.) If final designations are made by January 22, 2012, all events to be considered during the designations process must be flagged and fully documented by States one year prior to designations, by January 22, 2011. This date also coincides with the Clean Air Act deadline for Governors to submit to EPA their recommendations for designating all areas of their States.

The final rule text at the end of this notice shows the changes that will apply if a revised NO2 NAAQS is promulgated by January 22, 2010, and designations are made two years after promulgation of a NO2 NAAQS revision.

Table 1 below summarizes the data flagging and documentation deadlines corresponding to the two year designation schedule discussed in this section. If the promulgation date for a revised NO2 NAAQS occurs on a different date than January 22, 2010, EPA will revise the final NO2 exceptional event flagging and documentation submission deadlines accordingly to provide States with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS.

Table 1--Schedule for Exceptional Event Flagging and Documentation Submission for Data To Be Used in Designations Decisions for New or Revised NAAQS

NAAQS pollutant/standard/(level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
NO2/1-Hour Standard (100 PPB)........	2008	July 1, 2010 \a\........	January 22, 2011.
	2009	July 1, 2010...........	January 22, 2011.
	2010	April 1, 2011\a\........	July 1, 2011.\a\

\a\ Indicates change from general schedule in 40 CFR 50.14.

Note: EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

V. Designation of Areas

A. Proposed Process

The CAA requires EPA and the States to take steps to ensure that the new or revised NAAQS are met following promulgation. The first step is to identify areas of the country that do not meet the new or revised NAAQS. Section 107(d)(1) provides that, ``By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under section 109, the Governor of each State shall * * * submit to the Administrator a list of all areas (or portions thereof) in the State'' that should be designated as nonattainment, attainment, or unclassifiable for the new NAAQS. Section 107(d)(1)(B)(i) further provides, ``Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation.''

No later than 120 days prior to promulgating designations, EPA is required to notify States of any intended modifications to their designations as EPA may deem necessary. States then have an opportunity to comment on EPA's tentative decision. Whether or not a State provides a recommendation, the EPA must promulgate the designation that it deems appropriate.

Accordingly, Governors must submit their initial NO2 designation recommendations to EPA no later than January 2011. If the Administrator intends to modify any State's recommendation, the EPA will notify the Governor no later than 120 days prior to designations in January 2012. States that believe the Administrator's modification is inappropriate will have an opportunity to demonstrate why they believe their recommendation is more appropriate before designations are finalized.

B. Public Comments

Several industry commenters requested that EPA slow the timeline for implementing a near-roadway monitoring network and designating roadway areas because they believe EPA lacks significant information about the implementation and performance of a national, near-roadway monitoring network. Two commenters also requested that if a near-roadway monitoring network is deployed, that 1-hour NO2 standards be made more

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lenient until the next review period so that more information will be available about near-roadway NO2 concentrations before a stringent standard is selected.

A response to commenters' requests that EPA slow the monitoring implementation schedule and the request that EPA make the 1-hour NO2 standard more lenient until the next review period are addressed in sections III.B.5 and II.F.4.D, respectively.

Section 110(d)(1)(B) requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS (i.e., by January 2012). While the CAA provides the Agency an additional third year from promulgation of a NAAQS to complete designations in the event that there is insufficient information to make NAAQS compliance determinations, we anticipate that delaying designations for an additional year would not result in significant new data to inform the initial designations. A near-roadway monitoring network is not expected to be fully deployed until January 2013 therefore, EPA must proceed with initial designations using air quality data from the existing NO2 monitoring network. Because none of the current NO2 monitors are sited to measure near-roadway ambient air, we expect that most areas in the country with current NO2 monitors will not violate the new NO2 NAAQS. In the event that a current NO2 monitor indicates a violation of the revised standards, EPA intends to designate such areas ``nonattainment'' no later than 2 years following promulgation of the revised standards. We intend to designate the rest of the country as ``unclassifiable'' for the revised NO2 NAAQS until sufficient air quality data is collected from a near-roadway monitoring network. Once the near-roadway network is fully deployed and 3 years of air quality data are available, the EPA has authority under the CAA to redesignate areas as appropriate from ``unclassifiable'' to ``attainment'' or ``nonattainment.'' We anticipate that sufficient data to conduct designations would be available after 2015.

A number of commenters, largely from industry groups, focused on the concern that a near-roadway monitoring network would lead to regional nonattainment on the basis of high NO2 concentrations found near roadways. These commenters requested that any future nonattainment areas be limited to the area directly surrounding roadways found to have above-standard NO2 concentrations.

The CAA requires that any area that does not meet a NAAQS or that contributes to a violation in a nearby area that does not meet the NAAQS be designated ``nonattainment.'' States and EPA will need to determine which sources and activities contribute to a NAAQS violation in each area. Depending on the circumstances in each area this may include sources and activities in areas beyond the area directly surrounding a major roadway. EPA intends to issue nonattainment area boundary guidance after additional information is gathered on the probable contributors to violating near-roadway NO2 monitors.

C. Final Designations Process

The EPA intends to promulgate initial NO2 designations by January 2012 (2 years after promulgation of the revised NAAQS). Along with today's action EPA is also promulgating new monitoring rules that focus on roadways. As noted in section III, States must site required NO2 near-roadway monitors and have them operational by January 1, 2013. States will need an additional 3 years thereafter to collect air quality data in order to determine compliance with the revised NAAQS. This means that a full set of air quality data from the new network will not be available until after 2015. Since we anticipate that data from the new network will not be available prior to the CAA designation deadlines discussed above, the EPA intends to complete initial NO2 designations by January 2012 using the 3 most recent years of quality-assured air quality data from the current monitoring network, which would be for the years 2008-2010. The EPA will designate as ``nonattainment'' any areas with NO2 monitors recording violations of the revised NO2 NAAQS. We intend to designate all other areas of the country as ``unclassifiable'' to indicate that there is insufficient data to determine whether or not they are attaining the revised NO2 NAAQS.

Once the NO2 monitors are positioned in locations meeting the near-roadway siting requirements and monitoring data become available, the Agency has authority under section 107(d)(3) of the CAA to redesignate areas as appropriate from ``unclassifiable'' to ``attainment'' or ``nonattainment.'' The EPA intends to issue guidance on the factors that States should consider when determining nonattainment boundaries after additional information is gathered on the probable contributors to violating near-roadway NO2 monitors.

VI. Clean Air Act Implementation Requirements

This section of the preamble discusses the Clean Air Act (CAA) requirements that States and emissions sources must address when implementing new or revised NO2 NAAQS based on the structure outlined in the CAA and existing rules.\26\ EPA may provide additional guidance in the future, as necessary, to assist States and emissions sources to comply with the CAA requirements for implementing new or revised NO2 NAAQS.

\26\ Since EPA is retaining the annual standard without revision, the discussion in this section relates to implementation of the proposed 1-hour standard, rather than the annual standard.

The CAA assigns important roles to EPA, States, and, in specified circumstances, Tribal governments to achieve the NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain State measures necessary to achieve the air quality standards in each area. EPA provides assistance to States by providing technical tools, assistance, and guidance, including information on the potential control measures that may help areas meet the standards.

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once they have been established by EPA. Under section 110 of the CAA, 42 U.S.C. 7410, and related provisions, States are required to submit, for EPA approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed at sources of NO2 emissions. If a State fails to adopt and implement the required SIPs by the time periods provided in the CAA, the EPA has responsibility under the CAA to adopt a Federal Implementation Plan (FIP) to assure that areas attain the NAAQS in an expeditious manner.

The States, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program for NO2 and nonattainment new source review (NSR). See sections 160-169 of the CAA. In addition, Federal programs provide for nationwide reductions in emissions of NO2 and other air pollutants under Title II of the Act, 42 U.S.C. 7521-7574, which involves controls for automobiles, trucks, buses, motorcycles, nonroad engines, and aircraft emissions; the new source performance standards (NSPS) for stationary sources under section 111 of the CAA, 42 U.S.C. 7411.

CAA Section 301(d) authorizes EPA to treat eligible Indian Tribes in the same manner as States (TAS) under the CAA and requires EPA to promulgate regulations specifying the provisions of the statute for which such treatment is appropriate. EPA has promulgated these

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regulations--known as the Tribal Authority Rule or TAR--at 40 CFR Part 49. See 63 FR 7254 (February 12, 1998). The TAR establishes the process for Indian Tribes to seek TAS eligibility and sets forth the CAA functions for which TAS will be available. Under the TAR, eligible Tribes may seek approval for all CAA and regulatory purposes other than a small number of functions enumerated at section 49.4. Implementation plans under section 110 are included within the scope of CAA functions for which eligible Tribes may obtain approval. Section 110(o) also specifically describes Tribal roles in submitting implementation plans. Eligible Indian Tribes may thus submit implementation plans covering their reservations and other areas under their jurisdiction.

Under the CAA and TAR, Tribes are not, however, required to apply for TAS or implement any CAA program. In promulgating the TAR EPA explicitly determined that it was not appropriate to treat Tribes similarly to States for purposes of, among other things, specific plan submittal and implementation deadlines for NAAQS-related requirements. 40 CFR 49.4(a). In addition, where Tribes do seek approval of CAA programs, including section 110 implementation plans, the TAR provides flexibility and allows them to submit partial program elements, so long as such elements are reasonably severable--i.e., ``not integrally related to program elements that are not included in the plan submittal, and are consistent with applicable statutory and regulatory requirements.'' 40 CFR 49.7.

To date, very few Tribes have sought TAS for purposes of section 110 implementation plans. However, some Tribes may be interested in pursuing such plans to implement today's proposed standard. As noted above, such Tribes may seek approval of partial, reasonably severable plan elements, or they may seek to implement all relevant components of an air quality program for purposes of meeting the requirements of the Act. In several sections of this preamble, EPA describes the various roles and requirements States will address in implementing today's proposed standard. Such references to States are generally intended to include eligible Indian Tribes to the extent consistent with the flexibility provided to Tribes under the TAR. Where Tribes do not seek TAS for section 110 implementation plans, EPA will promulgate Federal implementation plans as ``necessary or appropriate to protect air quality.'' 40 CFR 49.11(a). EPA also notes that some Tribes operate air quality monitoring networks in their areas. For such monitors to be used to measure attainment with this primary NAAQS for NO2, the criteria and procedures identified in this rule would apply.

A. Classifications

1. Proposal

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purpose of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify NO2 nonattainment areas, but is not required to do so. The primary reason to establish classifications is to set different deadlines for each class of nonattainment area to complete the planning process and to provide for different attainment dates based upon the severity of the nonattainment problem for the affected area. However, the CAA separately establishes specific planning and attainment deadlines for certain pollutants including NO2 in sections 191 and 192: 18 months from nonattainment designation for the submittal of an attainment plan, and as expeditiously as possible, but no later than 5 years from nonattainment designation for areas to attain the standard. In the proposal, EPA stated its belief that classifications are unnecessary in light of these relatively short deadlines.

2. Public Comments

One commenter stated that they disagree with EPA's decision not to impose non-attainment classifications on areas with measured near-road NO2 concentrations in excess of the new NO2 standard, and urged EPA to provide a graduated non-attainment

classification system for the new standard. According to the commenter, ``a classification system defining higher levels of non-attainment with increasingly stringent requirements at those levels is one that allows for finer calibration of air quality regulatory response defined at the Federal level.''

As stated in the proposed rule, Section 192(a), of part D, of the CAA specifically provides an attainment date for areas designated as nonattainment for the NO2 NAAQS. Therefore, EPA has legal authority to classify NO2 nonattainment areas, but the 5-year attainment date addressed under section 192(a) cannot be extended pursuant to section 172(a)(2)(D). Based on this limitation, EPA proposed not to establish classifications within the 5- year interval for attaining any new or revised NO2 NAAQS. It is also EPA's belief that given the short deadlines that States have to develop and submit SIP's and for areas to achieve emissions reductions in order to attain the standard within the 5 year attainment period, a graduated classifications system would not be appropriate. Therefore, EPA is using it's discretion under the CAA not to establish classifications.

3. Final

EPA is not making any changes to the discussion on classifications in the proposed rule. Therefore, there will be no classifications for the revised NO2 NAAQS.

B. Attainment Dates

The maximum deadline by which an area is required to attain the NO2 NAAQS is determined from the effective date of the nonattainment designation for the affected area. For areas designated nonattainment for the revised NO2 NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). The EPA will determine whether an area has demonstrated attainment of the NO2 NAAQS by evaluating air quality monitoring data consistent with the form of the NAAQS for NO2 if revised, which will be codified at 40 CFR part 50, Appendix F.

1. Attaining the NAAQS

a. Proposal

In order for an area to be redesignated as attainment, the State must comply with the five requirements as provided under section 107(d)(3)(E) of the CAA. This section requires that:

--EPA must have determined that the area has met the NO2 NAAQS;
--EPA has fully approved the State's implementation plan;
--The improvement in air quality in the affected area is due to permanent and enforceable reductions in emissions;
--EPA has fully approved a maintenance plan for the area; and
--The State(s) containing the area have met all applicable requirements under section 110 and part D.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the

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discussion on attaining the NAAQS in the proposed rule.

2. Consequences of Failing To Attain by the Statutory Attainment Date

a. Proposal

Any NO2 nonattainment area that fails to attain by its statutory attainment date would be subject to the requirements of sections 179(c) and (d) of the CAA. EPA is required to make a finding of failure to attain no later than 6 months after the specified attainment date and publish a notice in the Federal Register. The State would be required to submit an implementation plan revision, no later than one year following the effective date of the Federal Register notice making the determination of the area's failure to attain, which demonstrates that the standard will be attained as expeditiously as practicable, but no later than 5 years from the effective date of EPA's finding that the area failed to attain. In addition, section 179(d)(2) provides that the SIP revision must include any specific additional measures as may be reasonably prescribed by EPA, including ``all measures that can be feasibly implemented in the area in light of technological achievability, costs, and any nonair quality and other air quality-related health and environmental impacts.''

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on consequences of failing to attain by the statutory attainment date in the proposed rule.

C. Section 110(a)(2) NAAQS Infrastructure Requirements

1. Proposal

Section 110(a)(2) of the CAA requires all States to develop and maintain a solid air quality management infrastructure, including enforceable emission limitations, an ambient monitoring program, an enforcement program, air quality modeling, and adequate personnel, resources, and legal authority. Section 110(a)(2)(D) also requires State plans to prohibit emissions from within the State which contribute significantly to nonattainment or maintenance areas in any other State, or which interfere with programs under part C to prevent significant deterioration of air quality or to achieve reasonable progress toward the national visibility goal for Federal class I areas (national parks and wilderness areas).

Under section 110(a)(1) and (2) of the CAA, all States are required to submit SIPs to EPA which demonstrate that basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) listed below, set forth the elements that a State's program must contain in the SIP.\27\ The list of section 110(a)(2) NAAQS implementation requirements are the following:

\27\ Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

Ambient air quality monitoring/data system: Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.

Program for enforcement of control measures: Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation and permitting of new/modified sources.

Interstate transport: Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in the State from contributing significantly to nonattainment in another State or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.

Adequate resources: Section 110(a)(2)(E) requires States to provide assurances of adequate funding, personnel and legal authority for implementation of their SIPs.

Stationary source monitoring system: Section 110(a)(2)(F) requires States to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.

Emergency power: Section 110(a)(2)(G) requires States to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.

Provisions for SIP revision due to NAAQS changes or findings of inadequacies: Section 110(a)(2)(H) requires States to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.

Consultation with local and Federal government officials: Section 110(a)(2)(J) requires States to meet applicable local and Federal government consultation requirements when developing SIP and reviewing preconstruction permits.

Public notification of NAAQS exceedances: Section 110(a)(2)(J) requires States to adopt measures to notify the public of instances or areas in which a NAAQS is exceeded.

PSD and visibility protection: Section 110(a)(2)(J) also requires States to adopt emissions limitations, and such other measures, as may be necessary to prevent significant deterioration of air quality in attainment areas and protect visibility in Federal Class I areas in accordance with the requirements of CAA Title I, part C.

Air quality modeling/data: Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.

Permitting fees: Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.

Consultation and participation by affected local government: Section 110(a)(2)(M) requires States to provide for consultation and participation by local political subdivisions affected by the SIP.

2. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on section 110(a)(2) NAAQS infrastructure requirements in the proposed rule.

D. Attainment Planning Requirements

1. Nonattainment Area SIPs

a. Proposal

Any State containing an area designated as nonattainment with respect to the NO2 NAAQS must develop for submission a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable statutory attainment date (see sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the NO2 part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment.

Section 172 of the CAA includes general requirements for all designated nonattainment areas. Section 172(c)(1)

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requires that each nonattainment area plan ``provide for the implementation of all reasonably available control measures (RACM) as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of Reasonably Available Control Technology (RACT)), and shall provide for attainment of the national primary ambient air quality standards.'' States are required to implement RACM and RACT in order to attain ``as expeditiously as practicable''.

Section 172(c) requires States with nonattainment areas to submit a SIP for these areas which contains an attainment demonstration that shows that the affected area will attain the standard by the applicable statutory attainment date. The State must also show that the area will attain the standards as expeditiously as practicable, and it must include an analysis of whether implementation of reasonably available measures will advance the attainment date for the area.

Part D SIPs must also provide for reasonable further progress (RFP) (see section 172(c)(2) of the CAA). The CAA defines RFP as ``such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date.'' (See section 171 of the CAA.) Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions sufficient to maintain generally linear progress toward attainment by the applicable attainment date.

All NO2 nonattainment area SIPs must include contingency measures which must be implemented in the event that an area fails to meet RFP or fails to attain the standards by its attainment date. (See section 172(c)(9).) These contingency measures must be fully adopted rules or control measures that take effect without further action by the State or the Administrator. The EPA interprets this requirement to mean that the contingency measures must be implemented with only minimal further action by the State or the affected sources with no additional rulemaking actions such as public hearings or legislative review.

Emission inventories are also critical for the efforts of State, local, and Federal agencies to attain and maintain the NAAQS that EPA has established for criteria pollutants including NO2.
Section 191(a) in conjunction with section 172(c) requires that areas designated as nonattainment for NO2 submit an emission inventory to EPA no later than 18 months after designation as nonattainment. In the case of NO2, sections 191(a) and 172(c) also require that States submit periodic emission inventories for nonattainment areas. The periodic inventory must include emissions of NO2 for point, nonpoint, mobile (on-road and non-road), and area sources.

b. Public Comments

Several commenters indicated that EPA should take steps to ensure that States actually require mobile source emissions reductions in order to attain the NO2 NAAQS as opposed to controlling point sources. Another commenter went further and stated that States be required to control on-road emissions as opposed to emissions from stationary sources and in particular EGUs. This commenter also indicated that EPA should delay nonattainment designations until States had a cost effective means of reducing on-road emissions of NO2.

EPA cannot require States to develop a SIP that only addresses one type of source, in this case on-road mobile sources. States may select appropriate control measures to attain the NAAQS and EPA must approve them if they otherwise meet all applicable requirements of the Act. See CAA 116. EPA expects that States will evaluate a range of control measures that will reduce NO2 emissions within the time allowed to attain the standard. This would include the emissions reductions attributable to Federal controls on on-road and non-road mobile sources, and controls that they have put in place to reduce NOX emissions in order to attain the 8-hour ozone NAAQS and/ or the PM2.5 NAAQS. If these existing controls are not sufficient for an area to reach attainment with the NO2 NAAQS, EPA would expect the State to implement additional control measures that would bring the area into attainment by the deadline. For a designation based on data from a near roadway monitor EPA would expect the States to give primary consideration to controlling emissions from on-road sources; however, it is likely that other types of sources contribute to the concentrations that are measured at a near roadway monitor and a State may decide to implement controls on these other contributing sources.

The Clean Air Act requires that EPA finalize designations within two years after a NAAQS is revised unless the available air quality data is insufficient to make designations by that time. In that case, EPA must finalize designations within three years after the NAAQS is revised. As discussed elsewhere in today's final rule, EPA believes that it has sufficient data to make designations within two years and that most areas will be designated as unclassifiable at that time. Taking the additional year provided by the CAA would not allow additional data from the new near roadway monitors to be factored into the designations process in any event. Therefore, it is EPA's intention to designate areas within two years as required by the Act. EPA intends to redesignate areas once it has sufficient data from the new monitoring network to designate areas as clearly attaining or not attaining the standard.

c. Final

The EPA is not making any changes to the discussion on nonattainment area SIPs in the proposed rule.

2. New Source Review and Prevention of Significant Deterioration Requirements

a. Proposal

The Prevention of Significant Deterioration (PSD) and nonattainment New Source Review (NSR) programs contained in parts C and D of Title I of the CAA govern preconstruction review of any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator.\28\ The EPA rules addressing these programs can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S. States which have areas designated as nonattainment for the NO2 NAAQS must submit, as a part of the SIP due 18 months after an area is designated as nonattainment, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area. SIPs that address the PSD requirements related to attainment areas are due no later than 3 years after the promulgation of a revised NAAQS for NO2.

\28\ The terms ``major'' and ``minor'' define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not ``major.'' ``Major'' is defined by the applicable regulations--PSD or nonattainment NSR.

The NSR program is composed of three different permit programs:
Prevention of Significant Deterioration (PSD).
Nonattainment NSR (NA NSR).
Minor NSR.

The PSD program applies when a major source, that is located in an area that is designated as attainment or

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unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.\29\ The nonattainment NSR program applies on a pollutant-specific basis when a major source constructs or modifies in an area that is designated as nonattainment for that pollutant. The minor source NSR program addresses both major and minor sources which undergo construction or modification activities that do not qualify as major, and it applies, as necessary to assure attainment, regardless of the designation of the area in which a source is located.

\29\ In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

The PSD requirements include but are not limited to the following:
Installation of Best Available Control Technology (BACT);
Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
Notification of Federal Land Manager of nearby Class I areas; and
Public comment on permit.

Nonattainment NSR requirements include but are not limited to:
Installation of Lowest Achievable Emissions Rate (LAER) control technology;
Offsetting new emissions with creditable emissions reductions;
A certification that all major sources owned and operated in the State by the same owner are in compliance with all applicable requirements under the CAA;
An alternative siting analysis demonstrating that the benefits of a proposed source significantly outweigh the environmentai and social costs imposed as a result of its location, construction, or modification; and
Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires ``* * * regulation of the modification and construction of any stationary source * * * as necessary to assure that the [NAAQS] are achieved.'' Areas which are newly designated as nonattainment for the NO2 NAAQS as a result of any changes made to the NAAQS will be required to adopt a nonattainment NSR program to address major sources of NO2 where the program does not currently exist for the NO2 NAAQS and may need to amend their minor source program as well. Prior to adoption of the SIP revision addressing major source nonattainment NSR for NO2 nonattainment areas, the requirements of 40 CFR part 51, appendix S may apply.

b. Public Comments

One commenter claimed that EPA's setting of a more stringent standard, i.e., short-term NO2 NAAQS, could have important implications for NSR and PSD and title V permits. Another commenter indicated that the promulgation of a new 1-hr NO2 short-term standard could create the need for a short-term PSD increment. Another commenter stated that a 1-hr NO2 Significant Impact Level (SIL) should be developed.

The EPA acknowledges that a decision to promulgate a new short-term NO2 NAAQS will clearly have implications for the air permitting process. The full extent of how a new short-term NO2 NAAAQS will affect the NSR process will need to be carefully evaluated. First, major new and modified sources applying for NSR/PSD permits will initially be required to demonstrate that their proposed emissions increases of NOX will not cause or contribute to a violation of either the annual or 1-hour NO2 NAAQS and the annual PSD increment. In addition, we believe that section 166 of the CAA authorizes us to consider the need to promulgate a new 1-hour increment. Historically, EPA has developed increments for each applicable averaging period for which a NAAQS has been promulgated. However, increments for a particular pollutant do not necessarily need to match the averaging periods that have been established for NAAQS for the same pollutant. Environmental Defense Fund, Inc. v. EPA, 898 F.2d 183, 189-190 (DC Cir. 1990) (`` * * * the `goals and purposes' of the PSD program, set forth in 160, are not identical to the criteria on which the ambient standards are based.'') Thus, we would need to evaluate the need for a new 1-hour NO2 increment in association with the goals and purposes of the statutory PSD program requirements.

We also believe that there may be a need to revise the screening tools currently used under the NSR/PSD program for completing NO2 analyses. These screening tools include the significant impact levels (SILs), as mentioned by one commenter, but also include the significant emissions rate for emissions of NOX and the significant monitoring concentration (SMC) for NO2. EPA intends to evaluate the need for possible changes or additions to each of these important screening tools for NOX/NO2 due to the addition of a 1-hour NO2 NAAQS. If changes or additions are deemed necessary, EPA will propose any such changes for public notice and comment in a separate action.

c. Final

The EPA is not making any changes to the discussion concerning the requirements for NSR and PSD as stated in the proposed rule.

3. General Conformity

a. Proposal

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 et seq.), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. The EPA rules, developed under the authority of section 176(c) of the CAA, prescribe the criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. Each Federal agency must determine that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment areas and those areas redesignated attainment since 1990 (``maintenance areas'') with respect to the criteria pollutants under the CAA: \30\ carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO2), ozone (O3), particulate matter (PM2.5 and PM10), and sulfur dioxide (SO2). The general conformity rules apply one year following the effective date of designations for any new or revised NAAQS.

\30\ Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. The general conformity rule also requires that notices of draft and final general conformity determinations be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion concerning general conformity stated in the proposed rule.

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4. Transportation Conformity

a. Proposal

Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that transportation plans, transportation improvement programs (TIPs) and Federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: Carbon monoxide (CO), ozone (O3), nitrogen dioxide (NO2), and particulate matter (PM2.5 and PM10). Transportation conformity for a revised NO2 NAAQS does not apply until one year after the effective date of a nonattainment designation. (See CAA section 176(c)(6) and 40 CFR 93.102(d)).

EPA's Transportation Conformity Rule (40 CFR 51.390, and Part 93, Subpart A establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not making changes to the Transportation Conformity rule in this rulemaking. However, in the future, EPA will review the need to conduct a rulemaking to establish any new or revised transportation conformity tests that would apply under a revision to the NO2 NAAQS for transportation plans, TIPs, and applicable highway and transit projects.

b. Public Comments

Several commenters stated that transportation conformity could stop the funding of highway and transit projects in NO2 nonattainment areas. These commenters stated that if an area fails to demonstrate conformity, it enters a conformity lapse and only certain types of projects can be funded during a lapse. The commenters further stated that the NO2 NAAQS will require more areas to determine conformity for the first time. The commenters also expressed concern that the NO2 NAAQS proposal did not contain sufficient information to understand to what extent revisions to the NAAQS, and the NO2 monitoring requirements, will result in transportation conformity requirements for individual transportation projects such as the need for a hot-spot analysis. The commenters further stated that hot-spot analyses could result in needless delays for transportation improvement projects.

With regard to the comment that more areas will have to demonstrate conformity for the first time due to the revisions to the NO2 NAAQS, given that today's final rule is requiring that near roadway monitoring be carried out in urban areas with populations greater than 350K, EPA believes that most areas with such populations that would be designated nonattainment for NO2 are already designated nonattainment or maintenance for one or more of the other transportation-related criteria pollutants (ozone, PM2.5, PM10 and carbon monoxide). As such, these areas would have experience in making transportation conformity determinations. If areas with no conformity experience are designated nonattainment for the NO2 NAAQS, EPA and U.S. DOT would be available to assist areas in implementing the transportation conformity requirements.

The commenter expressed concern that transportation conformity could stop highway and transit funding because areas could experience a conformity lapse and in such cases only certain types of projects could be funded. A conformity lapse occurs when an area misses a deadline for a required conformity determination. A new nonattainment area must demonstrate conformity within one year after the effective date of its designation. For any areas designated nonattainment for the revised NO2 NAAQS in early-2012, they would have to determine conformity within one year of the effective date of that designation which would be in early-2013. If that date was missed, a lapse would occur and only projects exempt from conformity such as safety projects, transportation control measures in an approved SIP for the area and projects or project phases that were approved by U.S. DOT before the lapse began can proceed during the lapse. EPA's experience in implementing the 1997 ozone and PM2.5 NAAQS shows that nearly all areas make their initial conformity determinations within the one-year grace period. Areas can also lapse if they fail to determine conformity by an applicable deadline such as determining conformity within two years after motor vehicle emissions budgets are found adequate. However, areas that miss one of these conformity deadlines have a one-year grace period before the lapse goes into effect. During the grace period, the area can continue to advance projects from the transportation plan and transportation improvement program. EPA's experience is that areas generally are able to make a conformity determination before the end of the grace period.

The commenter expressed concern that the NO2 NAAQS proposal did not contain sufficient detail concerning possible project-level requirements for transportation projects and that any requirements for hot-spot analyses could needlessly delay transportation projects. As EPA indicated in the NPRM, EPA is considering whether to revise the transportation conformity rule to establish requirements that would apply to transportation plans, transportation improvement programs and/or transportation projects in NO2 nonattainment and maintenance areas. If EPA concludes that the conformity rule must be revised in light of the final NO2 NAAQS, we will conduct notice and comment rulemaking to accomplish the revisions. At that time interested parties will have the opportunity to comment on any transportation conformity NPRM. This is the same course of action that EPA has taken with respect to revising the transportation conformity rule for the ozone and PM2.5 NAAQS.

With regard to the commenter's assertion that a requirement for hot-spot analyses for individual projects would needlessly delay transportation projects, EPA disagrees. First, CAA section 176(c)(1)(B) requires that transportation projects not cause new violations or make existing violations worse, or delay timely attainment or cause an interim milestone to be missed. EPA would only impose a hot-spot requirement for projects in NO2 nonattainment and maintenance areas if they are necessary to comply with CAA conformity requirements and therefore are needed to protect public health by reducing exposures to unhealthy levels of NO2 that could be created by the implementation of a proposed highway or transit project. The public would be exposed to unhealthy levels of NO2 if a highway or transit project caused a new violation of the NO2 NAAQS, made an existing violation worse, or delayed timely attainment or delayed achieving an interim emissions milestone. If any delay in the project did occur, it would not be viewed as needless as it occurred for the important purpose of protecting the exposed public's health. Second, EPA does not agree that requiring a hot-spot analysis would needlessly delay projects in NO2 nonattainment areas. Such hot-spot analyses, if they are eventually required, generally would be done as part of the NEPA process, which these projects are already subject to; therefore, conducting an NO2 hot-spot analysis would not be introducing a new step to a project's approval process, but rather would add one additional analysis which must be completed as part of an existing project approval process.

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c. Final

EPA is not making any changes to the discussion concerning transportation conformity as stated in the proposed rule.

VII. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. This section describes the conforming changes that were proposed, major comments received on these changes, EPA's responses to these comments and final decisions on the AQI breakpoints. Recognizing the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS, EPA proposed conforming changes to the AQI in connection with the final decision on the NO2 NAAQS if revisions to the primary standard were promulgated. Conforming changes would include setting the 100 level of the AQI at the same level as the revised primary NO2 NAAQS and also setting the other AQI breakpoints at the lower end of the AQI scale (i.e., AQI values of 50 and 150). EPA did not propose to change breakpoints at the higher end of the AQI scale (from 200 to 500), which would apply to State contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this review does not inform decisions about breakpoints at those higher levels.

With regard to an AQI value of 50, the breakpoint between the good and moderate categories, EPA proposed to set this value to be between 0.040 and 0.053 ppm NO2, 1-hour average. EPA proposed that the figure towards the lower end of this range would be appropriate if the standard is set towards the lower end of the proposed range for the standard (e.g. 80 ppb), while figures towards the higher end of the range would be more appropriate for standards set at the higher end of the range for the standard (e.g., 100 ppb). EPA noted that historically this value is set at the level of the annual NAAQS, if there is one, or one-half the level of the short-term NAAQS in the absence of an annual NAAQS, and solicited comments on this range for an AQI of 50 and the appropriate basis for selecting an AQI of 50 within this range.

With regard to an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, the range of 0.360 to 0.370 ppm NO2, 1-hour average, represents the midpoint between the proposed range for the short-term standard and the level of an AQI value of 200 (0.64 ppm NO2, 1-hour average). Therefore, EPA proposed to set the AQI value of 150 to be between 0.360 and 0.370 ppm NO2, 1-hour average.

EPA received comments from several State environmental agencies and organizations of State and local agencies that generally expressed the view that the AQI was designed to provide the public with information about regional air quality and therefore it should be based on community-wide monitors. These commenters went on to state that using near-road NO2 monitors for the AQI would present problems because they would not represent regional NO2 concentrations and it would be difficult to communicate this type of information to the public using the AQI. Some expressed concern that NO2 measured at near-roadway monitors could be the critical pollutant and could drive the AQI even though it may not represent air quality across the area. Other agencies expressed concern that there is currently no way to forecast ambient NO2 levels near roadways. One State agency commented that the AQI is intended to represent air quality where people live, work and play.

EPA agrees with commenters that the AQI should represent regional air quality, and that measurements that apply to a limited area should not be used to characterize air quality across the region. Community-wide NO2 monitors should be used to characterize air quality across the region. However, the AQI reporting requirements encourage, but do not require, the reporting of index values of sub-areas of an MSA. We agree with the commenter that stated the view that the AQI is intended to represent air quality where people live, work and play. To the extent that near-roadway monitoring occurs in areas where people live, work or play, EPA encourages reporting of the AQI for that specific sub-area of the MSA (64 FR 42548, August 4, 1999). We also agree that it may be difficult to communicate this type of information and we plan to work with State and local air agencies to figure out the best way to present this information to the public using the AQI. Air quality forecasting is recommended but not required (64 FR 42548, August 4, 1999). EPA will work with State agencies that want to develop a forecasting program.

With regard to the proposed breakpoints, EPA received few comments. The National Association of Clean Air Agencies commented that it would be confusing to the public to have an AQI value of 50 set below the level of the annual NO2 standard. We agree with this comment, and therefore have decided that it is appropriate to set the AQI value of 50, the breakpoint between the good and moderate ranges, set at the numerical level of the annual standard, 53 ppb NO2, 1-hour average. The AQI value of 100, the breakpoint between the moderate and unhealthy for sensitive groups category, is set at 100 ppb, 1-hour average, the level of the primary NO2 NAAQS. EPA is setting an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, at 0.360 ppm NO2, 1-hour average.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ``significant regulatory action'' because it was deemed to ``raise novel legal or policy issues.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in developing this final rule.

B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The information collection requirements are not enforceable until OMB approves them.

The Information Collection Request (ICR) document prepared by EPA for these revisions to part 58 has been assigned EPA ICR number 2358.02.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet

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the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). We do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with NO2 FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 2358.01). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The amendments would revise the technical requirements for NO2 monitoring sites, require the siting and operation of additional NO2 ambient air monitors, and the reporting of the collected ambient NO2 monitoring data to EPA's Air Quality System (AQS). The annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) is $3,261,007. Burden is defined at 5 CFR 1320.3(b). State, local, and Tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of NO2 in ambient air as required by section 109 of the CAA. American Trucking Ass'ns v. EPA, 175 F.3d 1027, 1044-45 (DC cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities.

D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The revisions to the NO2 NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed $100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the NO2 NAAQS. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the NO2 NAAQS. In this final rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Tribes. The rule does not alter the relationship between the

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Federal government and Tribes as established in the CAA and the TAR. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, this rule does not infringe existing Tribal authorities to regulate air quality under their own programs or under programs submitted to EPA for approval. Furthermore, this rule does not affect the flexibility afforded to Tribes in seeking to implement CAA programs consistent with the TAR, nor does it impose any new obligation on Tribes to adopt or implement any NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The final rule will establish uniform national ambient air quality standards for NO2; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. The protection offered by these standards may be especially important for asthmatics, including asthmatic children, because respiratory effects in asthmatics are among the most sensitive health endpoints for NO2 exposure. Because asthmatic children are considered a sensitive population, we have evaluated the potential health effects of exposure to NO2 pollution among asthmatic children. These effects and the size of the population affected are discussed in chapters 3 and 4 of the ISA; chapters 3, 4, and 8 of the REA, and sections II.A through II.E of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ``significant energy action'' as defined in Executive Order 13211, ``Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for NO2. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rulemaking involves technical standards. Therefore the Agency conducted a search to identify potential applicable voluntary consensus standards. However, we identified no such standards, and none were brought to our attention in comments. Therefore, EPA has decided to use the technical standard described in Section III.A of the preamble.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health effects on any population, including any minority or low-income population. The final rule will establish uniform national standards for NO2 in ambient air.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A Major rule cannot take effect until 60 days after it is published in the Federal Register. This action is a ``major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective on April 12, 2010.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 22, 2010.
Lisa P. Jackson,
Administrator.

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For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 50--NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

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1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

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2. Section 50.11 is revised to read as follows:

Sec. 50.11 National primary and secondary ambient air quality standards for oxides of nitrogen (with nitrogen dioxide as the indicator).

(a) The level of the national primary annual ambient air quality standard for oxides of nitrogen is 53 parts per billion (ppb, which is 1 part in 1,000,000,000), annual average concentration, measured in the ambient air as nitrogen dioxide.
(b) The level of the national primary 1-hour ambient air quality standard for oxides of nitrogen is 100 ppb, 1-hour average concentration, measured in the ambient air as nitrogen dioxide.
(c) The level of the national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.
(d) The levels of the standards shall be measured by:
(1) A reference method based on appendix F to this part; or
(2) By a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter.
(e) The annual primary standard is met when the annual average concentration in a calendar year is less than or equal to 53 ppb, as determined in accordance with Appendix S of this part for the annual standard.
(f) The 1-hour primary standard is met when the three-year average of the annual 98th percentile of the daily maximum 1-hour average concentration is less than or equal to 100 ppb, as determined in accordance with Appendix S of this part for the 1-hour standard.
(g) The secondary standard is attained when the annual arithmetic mean concentration in a calendar year is less than or equal to 0.053 ppm, rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm must be rounded up). To demonstrate attainment, an annual mean must be based upon hourly data that are at least 75 percent complete or upon data derived from manual methods that are at least 75 percent complete for the scheduled sampling days in each calendar quarter.

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3. Section 50.14 is amended by adding an entry to the end of table in paragraph (c)(2)(vi) to read as follows:

Sec. 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *
(c) * * *
(2) * * *
(vi) * * *

Table 1--Schedule for Exceptional Event Flagging and Documentation Submission for Data To Be Used in Designations Decisions for New or Revised NAAQS

NAAQS pollutant/ standard/ (level)/ promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
	* * * * * * *		
NO2/1-Hour Standard (100 PPB)........	2008	July 1, 2010 \a\........	January 22, 2011.
	2009	July 1, 2010...........	January 22, 2011.
	2010	April 1, 2011 \a\.......	July 1, 2011 \a\.

\a\ Indicates change from general schedule in 40 CFR 50.14.
Note: EPA notes that the table of revised deadlines only applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

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4. Appendix S to Part 50 is added to read as follows:

Appendix S to Part 50--Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen (Nitrogen Dioxide)

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for oxides of nitrogen as measured by nitrogen dioxide (``NO2 NAAQS'') specified in 50.11 are met. Nitrogen dioxide (NO2) is measured in the ambient air by a Federal reference method (FRM) based on appendix F to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported NO2 concentrations and the levels of the NO2 NAAQS are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to the annual average of all of the 1-hour concentration values as defined in section 5.1 of this appendix.

Daily maximum 1-hour values for NO2 refers to the maximum 1-hour NO2 concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.

Design values are the metrics (i.e., statistics) that are compared to the NAAQS levels to determine compliance, calculated as specified in section 5 of this appendix. The design values for the primary NAAQS are:

(1) The annual mean value for a monitoring site for one year (referred to as the ``annual primary standard design value'').

(2) The 3-year average of annual 98th percentile daily maximum 1-hour values for a monitoring site (referred to as the ``1-hour primary standard design value'').

98th percentile daily maximum 1-hour value is the value below which nominally 98 percent of all daily maximum 1-hour concentration values fall, using the ranking and selection method specified in section 5.2 of this appendix.

Quarter refers to a calendar quarter.

Year refers to a calendar year.

2. Requirements for Data Used for Comparisons With the NO2 NAAQS and Data Reporting Considerations

(a) All valid FRM/FEM NO2 hourly data required to be submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.

(b) When two or more NO2 monitors are operated at a site, the State may in advance designate one of them as the primary monitor. If the State has not made this designation, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the State has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

3. Comparisons With the NO2 NAAQS

3.1 The Annual Primary NO2 NAAQS

(a) The annual primary NO2 NAAQS is met at a site when the valid annual primary standard design value is less than or equal to 53 parts per billion (ppb).

(b) An annual primary standard design value is valid when at least 75 percent of the hours in the year are reported.

(c) An annual primary standard design value based on data that do not meet the completeness criteria stated in section 3.1(b) may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(d) The procedures for calculating the annual primary standard design values are given in section 5.1 of this appendix.

3.2 The 1-hour Primary NO2 NAAQS

(a) The 1-hour primary NO2 NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to 100 parts per billion (ppb).

(b) An NO2 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if one of the following conditions is true.

(i) At least 75 percent of the days in each quarter of each of three consecutive years have at least one reported hourly value, and the design value calculated according to the procedures specified in section 5.2 is above the level of the primary 1-hour standard.

(ii)(A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3.2(c)(ii)(B) results in a ``test design value'' that is below the level of the NAAQS. The test substitutes actual ``high'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same calendar quarter) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the ``test design value'', as defined in section 3.2(c)(ii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator; if any quarter has less than 50 percent data capture then this substitution test cannot be used. Identify for each quarter (e.g., January-March) the highest reported daily maximum 1-hour value for that quarter, excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than

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75 percent data capture. If after substituting the highest non-excluded reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ``test design value'' below the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been met in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

(iii)(A) A 1-hour primary standard design value that is above the level of the NAAQS can be validated if the substitution test in section 3.2(c)(iii)(B) results in a ``test design value'' that is above the level of the NAAQS. The test substitutes actual ``low'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same three months of the calendar) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true above-NAAQS-level status for that 3-year period; the result of this data substitution test (the ``test design value'', as defined in section 3.2(c)(iii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are a minimum number of available daily data points from which to identify the low quarter-specific daily maximum 1-hour values, specifically if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. Only days with at least 75 percent of the hours reported shall be considered in identifying the low value to be used for substitution.

(B) The substitution test is as follows: Data substitution will be performed in all quarter periods that have less than 75 percent data capture. Identify for each quarter (e.g., January-March) the lowest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days with at least 75 percent capture in the quarter period shall be considered when identifying this lowest value. If after substituting the lowest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 75 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ``test design value'' above the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been exceeded in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ``test design value'', shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in 3.2(b) and also do not satisfy section 3.2(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5.2 of this appendix.

4. Rounding Conventions

4.1 Rounding Conventions for the Annual Primary NO2 NAAQS

(a) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) The annual primary standard design value is calculated pursuant to section 5.1 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.2 Rounding Conventions for the 1-hour Primary NO2 NAAQS

(a) Hourly NO2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5.2 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the Primary NO2 NAAQS

5.1 Procedures for the Annual Primary NO2 NAAQS

(a) When the data for a site and year meet the data completeness requirements in section 3.1(b) of this appendix, or if the Administrator exercises the discretionary authority in section 3.1(c), the annual mean is simply the arithmetic average of all of the reported 1-hour values.

(b) The annual primary standard design value for a site is the valid annual mean rounded according to the conventions in section 4.1.

5.2 Calculation Procedures for the 1-hour Primary NO2 NAAQS

(a) Procedure for identifying annual 98th percentile values. When the data for a particular site and year meet the data completeness requirements in section 3.2(b), or if one of the conditions of section 3.2(c) is met, or if the Administrator exercises the discretionary authority in section 3.2(d), identification of annual 98th percentile value is accomplished as follows.

(i) The annual 98th percentile value for a year is the higher of the two values resulting from the following two procedures.

(1) Procedure 1.

(A) For the year, determine the number of days with at least 75 percent of the hourly values reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum hourly values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cny) as determined from step (A). The corresponding ``n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, P0.98, y = the nth largest value.

(2) Procedure 2.

(A) For the year, determine the number of days with at least one hourly value reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from all the days with at least one hourly value reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 98th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (i.e., row) for the annual number of days with valid data for year y (cny) as determined from step (A). The corresponding ``n'' value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, P0.98, y = the nth largest value.

(b) The 1-hour primary standard design value for a site is mean of the three annual 98th percentile values, rounded according to the conventions in section 4.

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Table 1

Annual number of days with valid data for year ``y'' (cny)	P0.98, y is the nth maximum value of the year, where n is the listed number
1-50	1
51-100	2
101-150	3
151-200	4
201-250	5
251-300	6
301-350	7
351-366	8

PART 58--AMBIENT AIR QUALITY SURVEILLANCE

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5. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart A--[Amended]

0

6. Section 58.1, is amended by adding the definitions for ``AADT'' and ``Near-road NO2 Monitor'' in alphabetical order to read as follows:

Sec. 58.1 Definitions

* * * * *
AADT means the annual average daily traffic.
* * *
Near-road NO2 Monitor means any NO2 monitor meeting the specifications in 4.3.2 of Appendix D and paragraphs 2, 4(d), 6.1, and 6.4 of Appendix E of this part.
* * * * *

Subpart B [Amended]

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7. Section 58.10, is amended by adding paragraphs (a)(5) and (b)(12) to read as follows:

Sec. 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *
(5) A plan for establishing NO2 monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the Administrator by July 1, 2012. The plan shall provide for all required monitoring stations to be operational by January 1, 2013.
* * * * *
(b) * * *
(12) The identification of required NO2 monitors as either near-road or area-wide sites in accordance with Appendix D, Section 4.3 of this part.
* * * * *

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8. Section 58.13 is amended by adding paragraph (c) to read as follows:

Sec. 58.13 Monitoring network completion.

* * * * *
(c) The network of NO2 monitors must be physically established no later than January 1, 2013, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, and E to this part.

0
9. Section 58.16 is amended by revising paragraph (a) to read as follows:

Sec. 58.16 Data submittal and archiving requirements.

* * * * *
(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO2; CO; O3; NO2; NO; NOY; NOX; Pb-TSP mass concentration; Pb-PM10 mass concentration; PM10 mass concentration; PM2.5mass concentration; for filter-based PM2.5FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated PM2.5 mass concentration data; PM10-2.5 mass concentration; chemically speciated PM10-2.5 mass concentration data; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm). The State, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.
* * * * *

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10. Appendix A to Part 58 is amended by adding paragraph 2.3.1.5 to read as follows:

Appendix A to Part 58--Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *
2.3.1.5 Measurement Uncertainty for NO2. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.
* * * * *

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11. Appendix C to Part 58 is amended by adding paragraph 2.1.1 to read as follows:

Appendix C to Part 58--Ambient Air Quality Monitoring Methodology

* * * * *

2.1.1 Any NO2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data.

* * * * *

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12. Appendix D to Part 58 is amended by revising paragraph 4.3 to read as follows:

Appendix D to Part 58--Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.3 Nitrogen Dioxide (NO2) Design Criteria

4.3.1 General Requirements

(a) State and, where appropriate, local agencies must operate a minimum number of required NO2 monitoring sites as described below.

4.3.2 Requirement for Near-road NO2 Monitors

(a) Within the NO2 network, there must be one microscale near-road NO2 monitoring station in each CBSA with a population of 500,000 or more persons to monitor a location of expected maximum hourly concentrations sited near a major road with high AADT counts as specified in paragraph 4.3.2(a)(1) of this appendix. An additional near-road NO2 monitoring station is required for any CBSA with a population of 2,500,000 persons or more, or in any CBSA with a population of 500,000 or more persons that has one or more roadway segments with 250,000 or greater AADT counts to monitor a second location of expected maximum hourly concentrations. CBSA populations shall be based on the latest available census figures.

(1) The near-road NO2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO2 concentrations are expected to occur and siting criteria can be met in accordance with appendix E of this part. Where a State or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO2 concentrations are expected to occur, the monitoring agency shall consider the potential for population exposure in the criteria utilized to select the final site location. Where one CBSA is required to have two near-road NO2 monitoring stations, the sites shall be differentiated from each other by one or more of the following factors: fleet mix; congestion patterns; terrain; geographic area within the

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CBSA; or different route, interstate, or freeway designation.

(b) Measurements at required near-road NO2 monitor sites utilizing chemiluminescence FRMs must include at a minimum: NO, NO2, and NOX.

4.3.3 Requirement for Area-wide NO2 Monitoring

(a) Within the NO2 network, there must be one monitoring station in each CBSA with a population of 1,000,000 or more persons to monitor a location of expected highest NO2 concentrations representing the neighborhood or larger spatial scales. PAMS sites collecting NO2 data that are situated in an area of expected high NO2 concentrations at the neighborhood or larger spatial scale may be used to satisfy this minimum monitoring requirement when the NO2 monitor is operated year round. Emission inventories and meteorological analysis should be used to identify the appropriate locations within a CBSA for locating required area-wide NO2 monitoring stations. CBSA populations shall be based on the latest available census figures.

4.3.4 Regional Administrator Required Monitoring

(a) The Regional Administrators, in collaboration with States, must require a minimum of forty additional NO2 monitoring stations nationwide in any area, inside or outside of CBSAs, above the minimum monitoring requirements, with a primary focus on siting these monitors in locations to protect susceptible and vulnerable populations. The Regional Administrators, working with States, may also consider additional factors described in paragraph (b) below to require monitors beyond the minimum network requirement.

(b) The Regional Administrators may require monitors to be sited inside or outside of CBSAs in which:

(i) The required near-road monitors do not represent all locations of expected maximum hourly NO2 concentrations in an area and NO2 concentrations may be approaching or exceeding the NAAQS in that area;

(ii) Areas that are not required to have a monitor in accordance with the monitoring requirements and NO2 concentrations may be approaching or exceeding the NAAQS; or

(iii) The minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives.

(c) The Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO2 network to address the data needs for an area, and include all monitors under this provision in the annual monitoring network plan.

4.3.5 NO2 Monitoring Spatial Scales

(a) The most important spatial scale for near-road NO2 monitoring stations to effectively characterize the maximum expected hourly NO2 concentration due to mobile source emissions on major roadways is the microscale. The most important spatial scales for other monitoring stations characterizing maximum expected hourly NO2 concentrations are the microscale and middle scale. The most important spatial scale for area-wide monitoring of high NO2 concentrations is the neighborhood scale.

(1) Microscale--This scale represents areas in close proximity to major roadways or point and area sources. Emissions from roadways result in high ground level NO2 concentrations at the microscale, where concentration gradients generally exhibit a marked decrease with increasing downwind distance from major roads. As noted in appendix E of this part, near-road NO2 monitoring stations are required to be within 50 meters of target road segments in order to measure expected peak concentrations. Emissions from stationary point and area sources, and non-road sources may, under certain plume conditions, result in high ground level concentrations at the microscale. The microscale typically represents an area impacted by the plume with dimensions extending up to approximately 100 meters.

(2) Middle scale--This scale generally represents air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may include locations of expected maximum hourly concentrations due to proximity to major NO2 point, area, and/or non-road sources.

(3) Neighborhood scale--The neighborhood scale represents air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Emissions from stationary point and area sources may, under certain plume conditions, result in high NO2 concentrations at the neighborhood scale. Where a neighborhood site is located away from immediate NO2 sources, the site may be useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(4) Urban scale--Measurements in this scale would be used to estimate concentrations over large portions of an urban area with dimensions from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Urban scale sites may also support other monitoring objectives of the NO2 monitoring network identified in paragraph 4.3.4 above.

4.3.6 NOy Monitoring

(a) NO/NOy measurements are included within the NCore multi-pollutant site requirements and the PAMS program. These NO/NOy measurements will produce conservative estimates for NO2 that can be used to ensure tracking continued compliance with the NO2 NAAQS. NO/NOy monitors are used at these sites because it is important to collect data on total reactive nitrogen species for understanding O3 photochemistry.

* * * * *

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13. Appendix E to Part 58 is amended as follows:
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a. By revising paragraphs 2, and 6.1.
0
b. By adding paragraphs 4(d) and 6.4.
0
c. By revising paragraphs 9(c), 11 and Table E-4.

Appendix E to Part 58--Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

2. Horizontal and Vertical Placement

The probe or at least 80 percent of the monitoring path must be located between 2 and 15 meters above ground level for all ozone and sulfur dioxide monitoring sites, and for neighborhood or larger spatial scale Pb, PM10, PM10-2.5, PM2.5, NO2 and carbon monoxide sites. Middle scale PM10-2.5 sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale Pb, PM10, PM10-2.5 and PM2.5 sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale near-road NO2 monitoring sites are required to have sampler inlets between 2 and 7 meters above ground level. The inlet probes for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be 3\1/2\ meters above ground level. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building or wall, then it should be located on the windward side of the building relative to the

prevailing wind direction during the season of highest concentration potential for the pollutant being measured.
* * * * *

4. * * *

(d) For near-road NO2 monitoring stations, the monitor probe shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment.
* * * * *

6. * * *

6.1 Spacing for Ozone Probes and Monitoring Paths

In siting an O3 analyzer, it is important to minimize destructive interferences form sources of NO, since NO readily reacts with O3. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as microscale or middle scale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent the middle scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring

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path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from the Table E-1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.
* * * * *

6.4 Spacing for Nitrogen Dioxide (NO2) Probes and Monitoring Paths

(a) In siting near-road NO2 monitors as required in paragraph 4.3.2 of appendix D of this part, the monitor probe shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment.

(b) In siting NO2 monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E-1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E-1 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference form automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined form the Table E-1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.
* * * * *

9. * * *

(c) No matter how nonreactive the sampling probe material is initially, after a period of use reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is also critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses even in the most inert probe material when the residence time exceeds 20 seconds.\26\ Other studies \27-28\ indicate that a 10 second or less residence time is easily achievable. Therefore, sampling probes for reactive gas monitors at NCore and at NO2 sites must have a sample residence time less than 20 seconds.
* * * * *

11. Summary

Table E-4 of this appendix presents a summary of the general requirements for probe and monitoring path siting criteria with respect to distances and heights. It is apparent from Table E-4 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor, probe, or monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For CO and near-road NO2 monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a single manifold or monitoring path for monitoring more than one pollutant.

Table E-4 of Appendix E to Part 58. Summary of Probe and Monitoring Path Siting Criteria

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path \1\	Horizontal and vertical distance from supporting structures\2\ to probe, inlet or 90% of monitoring path\1\ (meters)	Distance from trees to probe, inlet or 90% of monitoring path\1\ (meters)	Dista roadway inlet or path\1
SO2 3,4,5,6	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2-15	>1	>10	N/A
CO 4,5,7	Micro, middle (300 m), Neighborhood (1 km).	3\1/2\: 2-15	>1	>10	2-10; see of this middle a neighbor
O3 3,4,5	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2-15	>1	>10	See Table appendix scales.
NO2 3,4,5	Micro (Near-road [50-300]).	2-7 (micro);	>1	>10	<=50 mete road mic
	Middle (300m)	2-15 (all other scales).	...	...	
	Neighborhood, Urban, and Regional (1 km).	...	...	...	See Table appendix other sc
Ozone precursors (for PAMS) 3 4 5	Neighborhood and Urban (1 km).	2-15	>1	>10	See Table appendix scales.
PM, Pb 3,4,5,6,8	Micro: Middle, Neighborhood, Urban and Regional.	2-7 (micro); 2-7 (middle PM10 2.5); 2-15 (all other scales).	>2 (all scales, horizontal distance only).	>10 (all scales)	2-10 (mic Fig appendix other sc

N/A--Not applicable.
\1\ Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, a scale NO2 monitoring, and all applicable scales for monitoring SO2,O3, and O3 precursors.
\2\ When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.
\3\ Should be >20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.
\4\ Distance from sampler, probe, or 90% of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (see text).
\5\ Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.

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\6\ The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fu ash, or lead content). This criterion is designed to avoid undue influences from minor sources.
\7\ For microscale CO monitoring sites, the probe must be >10 meters from a street intersection and preferably at a midblock location.
\8\ Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at 1 apart for samplers having flow rates less than 200 liters/min to preclude airflow interference.

* * * * *

14. Appendix G to Part 58 is amended as by revising paragraph 9 and Table 2 to read as follows:

Appendix G to Part 58--Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How Does the AQI Relate to Air Pollution Levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term (i.e., averaging time of 24-hours or less) standard for each pollutant. The index value of 50 is associated with one of the following: the numerical level of the annual standard for a pollutant, if there is one; one-half the level of the short-term standard for the pollutant; or the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects that affect increasing proportions of the population. An index value is calculated each day for each pollutant (as described in section 12 of this appendix), unless that pollutant is specifically excluded (see section 8 of this appendix). The pollutant with the highest index value for the day is the ``critical'' pollutant, and must be included in the daily AQI report. As a result, the AQI for any given day is equal to the index value of the critical pollutant for that day. For the purposes of reporting the AQI, the indexes for PM10 and PM2.5 are to be considered separately.
* * * * *

Table 2--Breakpoints for the AQI

These breakpoints	Equal these AQIs

O3 (ppm) 8-hour	O3 (ppm) 1-hour\1\	PM2.5 ([micro]g/m\3\)	PM10 ([micro]g/m\3\)	CO (ppm)	SO2 (ppm)	NO2 (ppm) 1-hour	AQI	Category
0.000-0.059	....	0.0-15.4	0-54	0.0-4.4	0.000-0.034	0-0.053	0-50	Good.
0.060-0.075	....	15.5-40.4	55-154	4.5-9.4	0.035-0.144	0.054-0.100	51-100	Moderate.
0.076-0.095	0.125-0.164	40.5-65.4	155-254	9.5-12.4	0.145-0.224	0.101-0.360	101-150	Unhealthy for Sensitive Groups.
0.096-0.115	0.165-0.204	\3\ 65.5-150.4	255-354	12.5-15.4	0.225-0.304	0.361-0.64	151-200	Unhealthy.
0.116-0.374	0.205-0.404	\3\ 150.5-250.4	355-424	15.5-30.4	0.305-0.604	0.65-1.24	201-300	Very Unhealthy.
(\2\)	0.405-0.504	\3\ 250.5-350.4	425-504	30.5-40.4	0.605-0.804	1.25-1.64	301-400	Hazardous.
(\2\)	0.505-0.604	\3\ 350.5-500.4	505-604	40.5-50.4	0.805-1.004	1.65-2.04	401-500	Hazardous.

\1\ Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI bas ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index calculated, and the maximum of the two values reported.

\2\ 8-hours O3 values do not define higher AQI values (>=301). AQI values of 301 or greater are calculated with 1-hour O3 concentrations.

\3\ If a different SHL for PM2.5 is promulgated, these numbers will change accordingly.

[FR Doc. 2010-1990 Filed 2-8-10; 8:45 am]
BILLING CODE 6560-50-P

APP. P

Supplemental Statement of Basis
PSD Permit Application for Avenal Energy Project
March 2011

EPA is supplementing its Statement of Basis for this application for a Clean Air Act Prevention of Significant Deterioration (PSD) permit to address several considerations that have arisen since the close of the comment period on this permit. Due to the fact that Avenal's permit application was complete and a proposed permit issued in advance of EPA's proposal of certain recently-promulgated regulations establishing new and additional requirements and other compelling factors, EPA has tentatively determined that it should grandfather this permit from those requirements, i.e., not require a demonstration of compliance with those requirements for this permit. Furthermore, EPA has determined that it is appropriate to provide a detailed Environmental Justice Analysis regarding its proposed PSD permit action for this facility for public comment. The proposed facility, called the Avenal Energy Project (Project) by the permit applicant, Avenal Power Center, LLP (APC), will be located in Kings County, California, and consists of two GE 7FA combustion turbine generators, two heat recovery steam generators, one steam turbine generator, and associated equipment. The proposed location for the Project constitutes the majority of the northeast quarter of Section 19, Township 21 South, Range 18 East, Mt. Diablo Base and Meridian. The Kings County Assessor's Parcel Number (APN) for this location is 36-170-035. The geographic coordinates for the proposed location are Latitude 36.088394° N and Longitude 120.061141° W. The proposed location is currently in agricultural production, is zoned industrial by the City of Avenal and is owned by the applicant. The City of Avenal has informed the EPA that the unofficial address for this location's APN is 33119 Avenal Cutoff Road, Avenal, California 93204. EPA Region 9 first received the application for this permit in February 2008 and notified the applicant on March 19, 2008 that its permit application was complete,[1] in accordance with the procedure described in EPA regulations. 40 CFR 124.3(c).

On June 16, 2009, EPA Region 9 issued for public comment a proposed permit for the Project, which would grant conditional approval, in accordance with the PSD regulations, to APC to construct and operate a 600 MW (net) electric generating facility, along with a statement of basis and ambient air quality impact report describing the basis for the permit conditions and other related information. The proposed PSD permit requires the use of Best Available Control Technology (BACT) to limit emissions to the greatest extent feasible of carbon monoxide (CO), oxides of nitrogen (NO_x), particulate matter (PM), and particulate matter less than 10 micrometers in diameter (PM_{10}). The area in which this facility will be located is in attainment with the National Ambient Air Quality Standards (NAAQS) for these pollutants, as well as sulfur dioxide (SO2) and lead. We note that the area where this facility will be located is not meeting the NAAQS for ozone and particulate matter less than 2.5 micrometers in diameter ($PM_{2.5}$). The emissions from the proposed project of the air pollutants (including precursors to the formation of these pollutants) for which the relevant area is not attaining the NAAQS are regulated under the Nonattainment New Source Review permitting program administered by the San Joaquin Valley Air Pollution Control District (District).

[1] Under 40 CFR 52.21(b)(22), "[c]omplete means, in reference to an application for a permit, that the application contains all of the information necessary for processing the application."

EPA provided public notices requesting public comment on the proposed permit for the Project on June 16, 2009, August 27, 2009 through August 29, 2009, and September 11, 2009. The August and September 2009 notices announced that EPA would extend the public comment period and hold a public information meeting and two public hearings in conjunction with its proposed PSD permit for the Project. The public information meeting and two public hearings were held as scheduled, and the public comment period for the proposed permit closed on October 15, 2009.

In parallel with this process required under the Clean Air Act, EPA has taken the steps necessary to ensure its action on this permit application complies with section 7 of the Endangered Species Act. EPA requested initiation of consultation with the U.S. Fish and Wildlife Service under section 7 of the ESA on July 10, 2008, and provided additional information requested by the Service on October 22, 2008. The U.S. Fish and Wildlife Service completed its biological opinion concluding the formal consultation process in August 2010.

At this point, the APC permit application has been pending well beyond the one-year deadline by which the Clean Air Act requires EPA to take action to grant or deny this application. The permit applicant has filed a suit in federal District Court to compel EPA to reach a final decision on this permit application. EPA has represented to the Court that it would be able to issue a final permit decision in accordance with 40 CFR 124.15 by May 27, 2011 after taking comment on this supplemental statement of basis.

EPA is providing an additional public hearing and opportunity to comment on this supplemental statement of basis, as described in the associated public notice.

I. Grandfathering From Requirements Established by Recently Promulgated Rules

EPA has determined that it is not appropriate or equitable under the circumstances present here to require this permit applicant to meet certain recently promulgated requirements that have taken effect while EPA has been in the process of reviewing this application. For the reasons discussed below, EPA believes it is authorized to issue a PSD permit to this applicant without requiring a demonstration that the source will not cause or contribute to a violation of the nitrogen dioxide (NO2) or sulfur dioxide (SO2) NAAQS for the one-hour averaging time or a showing that this source will meet the BACT requirement for greenhouse gases.

In 2010, EPA completed a series of regulations that established additional standards and criteria applicable to the review and issuance of permits to construct or modify major stationary sources of air pollution under the PSD program. The relevant regulations include NAAQS for hourly concentrations of NO2 and SO2 and limitations on greenhouse gas emissions from light duty vehicles. EPA first proposed these regulations in July 2009, December 2009, and September 2009 respectively. Under EPA's interpretation of applicable statutes and regulations, these new regulations created additional standards and criteria that became applicable to the review and issuance of PSD permits when the new regulations became effective. This is because the criteria for issuance of PSD permits include requirements that a source demonstrate it will not cause or contribute to a violation of any NAAQS and that the proposed source will meet emissions limitations achievable through application of BACT for each pollutant subject to regulation under the Clean Air Act ("the Act"). 42 U.S.C. 7475(a)(3)-(4); 40 C.F.R. 52.21(k); 40 C.F.R. 52.21(b)(12); 75 Fed. Reg. 17004 (April 2, 2010). When completing the regulations to establish NAAQS for hourly NO2 and SO2 concentrations and the limitations on greenhouse gas emissions from light duty vehicles, EPA did not adopt transitional provisions in the PSD regulations to grandfather any permit applications that were pending at the time the new requirements took effect.

Nevertheless, EPA has determined in this case that it should not apply the criteria and standards described in the preceding paragraph to the APC permit application under the circumstances that are presented here. EPA first proposed the hourly NO2 standard more than a year after the time that EPA determined APC's PSD permit application was complete. Indeed, EPA had issued a proposed PSD permit for the project prior to the proposal date of the NAAQS standard. At this point, the APC permit application has been pending for nearly two years beyond the statutory deadline by which EPA was required to make a decision to grant or deny this application. This delay has been exacerbated by the need for APC to conduct an analysis to show that the proposed APC facility will not cause a violation of the hourly NO2 NAAQS, in accordance with EPA previously announced interpretation of the PSD regulations. In consideration of EPA's statutory obligation to take action on this permit application in a timely manner, the nature of the source APC seeks to construct, and the factors that have contributed to the extended delay in this case, EPA does not believe it is appropriate or equitable at this point to require that APC demonstrate compliance with the hourly NO2 NAAQS or additional requirements that have taken effect during the extended delay that has resulted from EPA's prior interpretation that APC should make such a showing before EPA could grant the permit application.

A. Substantive and Procedural Requirements Applicable to PSD Permitting

Section 165 of the Act (42 U.S.C. § 7475) and EPA's implementing regulations (40 C.F.R. § 52.21; 40 C.F.R. Part 124) contain both substantive and procedural requirements that must be satisfied before a PSD permit may be issued to authorize construction or modification of a major stationary source of air pollutants. When EPA promulgates a new NAAQS and completes rules that make an additional pollutant subject to regulation under the Act,[2] the Agency must take care to ensure that PSD permit decisions are made in accordance with both the substantive and procedural requirements of the Act and EPA's implementing regulations.

NAAQS Compliance

Among the substantive requirements, the Clean Air Act and PSD regulations provide that a permit may not be issued unless the applicant demonstrates that the source will not cause or contribute to a violation of "any NAAQS." 42 U.S.C. § 7475(a)(3); 40 C.F.R. 52.21(k). This requirement does not apply to any NAAQS for which the area in which the source proposes to locate is designated non-attainment. 40 C.F.R. 52.21(i)(2). EPA has previously explained that, as a general matter, each decision to issue a PSD permit should be supported by a record

[2] Such pollutants are defined in EPA regulations as a "regulated NSR pollutant." 40 C.F.R. § 52.21(b)(50).

showing that the applicant will not cause or contribute to a violation of any NAAQS (except one for which the area is designated nonattainment) that is effective on or before the date that the permit is issued. On April 1, 2010, the Director of EPA's Office of Air Quality Planning and Standards issued a memorandum reminding Regional Offices that EPA interprets the phrase "any NAAQS" contained in the PSD provisions of the Act and EPA regulations to cover any NAAQS in effect at the time of a final permit decision. The memorandum cited prior instances where EPA has applied this interpretation, including one where EPA also issued a rule to grandfather some pending applications from the requirement to show the source would not violate the NAAQS for PM10. 52 Fed. Reg. 24672 (July 1, 1987). The April 2010 memorandum said the following:

> [P]ermits issued under 40 CFR 52.21 on or after April 12, 2010, must contain a demonstration that the source's allowable emissions will not cause or contribute to a violation of the new 1-hour NO2 NAAQS. ... There are no exceptions under 40 CFR 52.21 in this case because as noted above, EPA has not adopted a grandfathering provision applicable to the 1-hour NO2 NAAQS that would enable the required permit to be issued to a prospective source.

One day later, EPA also addressed this subject in the context of a final decision published in the Federal Register on the topic of the pollutants subject to the requirements of the PSD program. 75 Fed. Reg. 17004 (April 2, 2010). This document said the following:

> EPA generally interprets a revised NAAQS that establishes either a lower level for the standard or a new averaging time for a pollutant already regulated to apply upon the effective date of the revised NAAQS. Thus, unless EPA promulgates a grandfathering provision that allows pending applications to apply standards in effect when the application is complete, a final permit decision issued after the effective date of a NAAQS must consider such a NAAQS.

Id. at 17008.

Best Available Control Technology

PSD permit applicants must also show that the proposed source will meet an emissions limitation based on application of BACT for each pollutant subject to regulation under the Act. 42 U.S.C. 7475(a)(4). As discussed in EPA's final action entitled "Reconsideration of Interpretation of Regulations that Determine Pollutants Covered by Clean Air Act Permitting Programs," EPA construes the BACT requirement to apply to each pollutant that is subject to regulation under the Act at the time a PSD permit is issued. 75 Fed. Reg. 17004 (April 2, 2010). In this April 2010 action explaining EPA's decision to continue following a legal interpretation established in a December 2008 memorandum from the Administrator ("PSD Interpretive Memo"), EPA identified January 2, 2011 as the date when greenhouse gases would first became subject to regulation under the Act. January 2, 2011 is the date when the first regulatory requirement to control emissions of greenhouse gases under the Clean Air Act takes effect under the Light Duty Vehicle Rule that EPA completed on May 7, 2010. 75 Fed. Reg. 25324. EPA proposed the vehicle rule on September 28, 2009.

EPA also explained in the April 2, 2010 final action described above that the Agency did not "see any grounds to establish a transition period for permit applications that are pending before GHGs become subject to regulation." Id. at 17021. EPA did not see a basis to promulgate a grandfathering provision for greenhouse gases because permit applications pending prior to April 2, 2010 already had a transition period of nine months in which the permit could be issued without addressing the BACT requirement for greenhouse gases. For permits that could not be issued in that nine-month period, EPA believed that it would be feasible to begin incorporating greenhouse gas considerations into permit reviews in parallel with completion of work on other pollutants. EPA also observed that permit applicants had notice that greenhouse gases would become subject to regulation for purposes of the PSD program upon completion of the light duty vehicle standards. Thus, the Agency said in April 2010 that "EPA does not intend to promulgate a transition or grandfathering provision that exempts pending permit applications from the onset of GHG requirements in the PSD program." EPA also explained that "in the absence of such a provision, PSD permits that are issued on or after January 2, 2011 ... will be required to contain the provisions that fulfill the applicable program requirements for GHGs." Id. at 17022. In June 2010, EPA affirmed that it did not intend to adopt a grandfathering provision for greenhouse gases when the Agency completed the PSD and Title V Greenhouse Gas Tailoring Rule. 75 Fed. Reg. 31514, 31592-93 (June 3, 2010).

Timely Permit Review

The Act also requires that permitting authorities complete review of PSD permit applications in a timely manner. Section 165(c) of the Act specifies that "[a]ny completed permit application under section 7410 of this title for a major emitting facility in any area to which this part applies shall be granted or denied not later than one year after the date of filing of such completed application." 42 U.S.C. § 7475(c). EPA should be mindful of this obligation when establishing new regulations that affect the requirements applicable to PSD permit applications, especially applications that are in process at the time additional requirements become effective.

Under certain circumstances EPA has previously established transition provisions which relieved persons proposing new major sources and major modifications that have submitted a complete PSD permit application from having to amend applications to demonstrate compliance with the new PSD requirements. For example, EPA adopted such a provision to address the transition from the TSP NAAQS to the PM_{10} NAAQS. See, 40 CFR 52.21(i)(1)(x). EPA adopted similar provisions pertaining to new or revised PSD increments for NO2 and particulate matter. 40 CFR 52.21(i)(9)-(10). Permit applicants meeting the eligibility criteria in these provisions were grandfathered from the new PSD requirements that otherwise would have applied to them.

B. <u>Grounds for Grandfathering this Permit Application from New Requirements</u>

In order to balance EPA's statutory obligations to issue permits in a timely manner and in accordance with the substantive requirements of the Act, EPA is proposing to issue a PSD permit to APC without requiring a showing that this source will not cause or contribute to a violation of the hourly NO2 and SO2 NAAQS or establishing emissions limitations for greenhouse gases in the permit. This determination is based on the following factors that are discussed in more detail below:

(1) The facility that APC proposes to construct will be a well-controlled, natural-gas fired electric generating facility that will apply BACT for NO2 and not cause or contribute to a violation of the NAAQS that were in place before promulgation of the hourly standards;

(2) APC's permit application was deemed complete by EPA more than a year before, and EPA had issued a proposed permit for the project one month before, the date on which EPA proposed the hourly NO2 NAAQS.

(3) Unanticipated challenges with the preparation and review of sufficient information to predict the impact of proposed sources on hourly NO2 concentrations were not apparent when EPA determined there was no need to establish a grandfathering provision for this requirement and others that followed.

(4) The challenges encountered in supplementing the APC permit application to address the hourly NO2 NAAQS caused additional delay beyond the dates when the hourly SO2 NAAQS and greenhouse gas requirements became applicable to PSD permit applications.

(5) Court decisions recognize an exception, in cases of significant delay by the administrative agency, to the general rule that an administrative agency should apply the law in effect at the time its issues a permit or license.

Considering these factors and EPA's statutory obligations to complete action on this permit in a timely manner, EPA believes there is cause to grandfather this permit application from the identified requirements in order to reconcile competing obligations under the Clean Air Act and achieve an equitable outcome.

Projected Emissions from the APC Facility

The facility that APC seeks authorization to construct is a state-of-the-art natural-gas fired electric generating facility that will achieve the lowest levels of air pollutant emissions achievable in this instance. The proposed PSD permit requires the use of BACT to limit emissions of carbon monoxide (CO), oxides of nitrogen (NO_x), particulate matter (PM), and particulate matter less than 10 micrometers in diameter (PM_{10}). *See,* Statement of Basis and Ambient Air Quality Impact Report, Section 7, pp. 15-23 (June 2009)

The record for this permit demonstrates that the source will not cause or contribute to a violation of any NAAQS regulated under the permit that was in effect at the time EPA issued a proposed permit for this project. EPA has determined from the modeled results for the facility that the Project impacts are well below (in all cases, less than 6 percent of) the applicable NAAQS for the PSD pollutants addressed in the PSD permit. The maximum modeled impact of NO2 for the annual averaging period is 0.5 µg/m3, less than 1 percent of the NAAQS of 100 μg/m3. The modeled PM10 impact (24-hour averaging period) is 2.9 μg/m3, approximately 2 percent of the PM10 24-hour NAAQS of 150 μg/m3. The modeled CO impact for the 8-hour averaging period is 337 μg/m3, less than 4 percent of the NAAQS of 10,000 μg/m3, and the modeled CO impact for the 1-hour averaging period is 2,175 μg/m3, less than 6 percent of the NAAQS of 40,000 μg/m3. *See,* Statement of Basis and Ambient Air Quality Impact Report, Section 8, pp. 24-27 (June 2009); 40 C.F.R Part 50.

Proposal of Hourly NO2 NAAQS After Application Completed

At the time its permit application was deemed complete, Avenal did not have notice of the potential for the hourly NO2 NAAQS requirement to become applicable when its permit application was completed. EPA declared the Avenal PSD permit application complete in March 2008. EPA proposed the hourly NO2 NAAQS over a year later on July 15, 2009.

Complications with Implementation of Hourly NO2 NAAQS

EPA issued the hourly NO2 NAAQS on February 9, 2010 and established that this standard would become effective on April 12, 2010. At that time, EPA did not consider adopting a transitional provision for pending permit applications completed prior to this date. EPA expected that permit applicants would readily be able to determine, based on existing EPA modeling guidelines, how to expeditiously complete the analysis necessary to show that stationary source construction would not cause or contribute to violations of the hourly NO2 NAAQS. However, some PSD permit applicants have experienced unforeseen challenges with the preparation of sufficient information to predict the impact of the proposed source on hourly NO2 concentrations in accordance with PSD modeling guidelines.

EPA has approved the air quality dispersion model known as AERMOD for use in several regulatory applications, including use by permit applicants to demonstrate that the sources they propose to build will not cause or contribute to violations of the hourly NO2 standard. On February 25, 2010, before the hourly NO2 standard became effective, EPA issued a Notice Regarding Modeling for New Hourly NO2 NAAQS, which explained that the current AERMOD model should be used in accordance with established guidelines on the application of this and other air quality models contained in 40 C.F.R. Part 51, Appendix W. In addition, after the hourly NO2 NAAQS became effective, EPA issued two additional guidance memoranda on June 28, 2010. One of those memoranda, entitled "*Applicability of Appendix W Modeling Guidance for the 1-hour NO2 National Ambient Air Quality Standard*," provided additional technical guidance on using AERMOD to demonstrate that proposed construction of a stationary source will not cause or contribute to a violation of the hourly NO2 standard. EPA believed these actions would be sufficient to enable all permit applicants, including those with applications pending on April 12, 2010 when the NO2 NAAQS became effective, to complete appropriate modeling of hourly NO2 concentrations.

Despite these actions by EPA, some applicants seeking PSD permits to construct or modify stationary sources of air pollution have experienced unforeseen challenges with the timely preparation of sufficient information to demonstrate that the proposed construction will not cause or contribute to violations of the hourly NO2 NAAQS. These challenges have resulted from the fact that to address the hourly NO2 NAAQS, many permit applicants need to conduct a cumulative air quality impact assessment. This has also necessitated the application of modeling techniques that are more refined than those that have previously been adequate to demonstrate compliance with the annual NO2 standard. These refined modeling techniques require consideration of the chemical transformation of NOx emissions through the Ozone Limiting Method or Plume Volume Molar Ratio Method under the third and most-refined Tier of EPA's modeling guidelines applicable to NO2. Additional refinements in the determination of background concentrations based on modeling of nearby sources and ambient monitoring data may also be necessary in many cases. This level of refinement requires acquisition and analysis of additional data inputs that are available but not as readily accessible to permit applicants as has been the case with other data used in air quality modeling for annual NO2 concentrations. Permit applicants and permitting authorities have needed more time than EPA expected to develop familiarity with these refined approaches and to obtain and analyze the necessary data.

Due in part to these complications, APC's efforts to complete a sufficient modeling demonstration to show this source will not cause or contribute to violations of the hourly NO2 standard has produced unanticipated delays in the review of the PSD permit application submitted by APC. This has exacerbated EPA's failure to comply with the statutory deadline for action on this permit application. The potential for such a circumstance to arise was not apparent when EPA completed the hourly NO2 NAAQS without grandfathering pending PSD permit applications at that time.

Greenhouse Gas Requirements

When EPA completed the reconsideration of the PSD Interpretive Memo in April 2010 and identified the date on which greenhouse gases would become subject to regulation, the Agency's conclusion that it would not be necessary to establish a transitional provision for the PSD requirements applicable to greenhouse gases was informed by the assumption that permits pending as of April 2010 would reasonably be expected to be issued within the next nine months. Thus, when EPA concluded that the approximately nine months remaining until January 2, 2011 was a sufficient transition period for completing action on most pending permit applications without having to address the greenhouse gas requirements, EPA had not considered the potential delays that would result for long-pending complete permit applications such as APC's from completion of modeling to address the hourly NO2 NAAQS. Since these delays have prevented EPA from issuing a final decision on the APC permit application by January 2, 2011, EPA believes it is appropriate to grandfather this permit from the greenhouse gas requirements. If not for the delays associated with addressing the hourly NO2 NAAQS requirements, EPA would have completed action on the APC permit application prior to January 2, 2011 and the application would not have been subject to the greenhouse gas requirements. The limited grandfather from the GHG requirements that EPA is applying in this case is justified to provide this permit applicant with the benefit of the 9-month transitional period EPA identified in April 2010 before the complications associated with implementing the hourly NO2 NAAQS in the PSD permitting program became apparent.

Hourly SO2 NAAQS

On June 22, 2010, EPA published a final rule establishing a primary SO2 NAAQS based on a 1-hour averaging time. 75 Fed. Reg. 35,520 (Jun. 22, 2010). That rule became effective on August 23, 2010. EPA first proposed this standard on December 8, 2009, more than 20 months after EPA determined Avenal's application was complete. As with the greenhouse gas requirement, the Agency's decision not to establish a transitional provision for the hourly SO2 NAAQS was informed by the assumption that an hourly NO2 NAAQS modeling demonstration could be completed more expeditiously than has proven to be the case for the APC permit. EPA did not anticipate that delays in completing modeling for the hourly NO2 NAAQS would impede EPA's ability to complete action on the long-pending complete permit applications such as APC's before the hourly SO2 NAAQS became effective on August 23, 2010. Similar to the situation described above with respect to greenhouse gases, EPA would have been able to complete action on this permit application before August 23, 2010 if it had not requested additional information from Avenal to address the hourly NO2 NAAQS and experienced the complications described.

Although these considerations support grandfathering this permit application from the hourly SO2 NAAQS, we note that because of the low SO2 emissions from this facility, EPA regulations do not require additional analysis to demonstrate that this source will not cause a violation of the hourly SO2 NAAQS. The Project's SO2 emissions are estimated to be 16.7 tons per year. Since this is well below the 40 tons per year significant emissions rate for SO2, additional analysis is not required from APC. *See* 40 C.F.R. §§ 52.21(m)(1) and 52.21(b)(23)(i). Sources with emissions below these levels are considered to have a negligible or "de minimis" impact on air quality that would not cause or contribute to violation of the NAAQS for the pollutant in question. Thus, further analysis is not required under EPA regulations.

Judicial Decisions Support Grandfathering the Permit Application from New Requirements in this Case

EPA's proposed action to grandfather this permit application that has been pending for well beyond the statutory deadline for action is supported by judicial opinions that have addressed analogous circumstances involving a change in legal requirements while action on an application for a government approval was unduly delayed. In the April 2010 interpretive statements described above, EPA relied on judicial opinions supporting the general principle that a decision on an application for a government license, permit, or other type of authorization must be based on the law in effect at the time of the decision of the reviewing authority. See *Ziffrin, Inc. v. United States*, 318 U.S. 73, 78 (1943); *State of Alabama v. EPA*, 557 F.2d 1101, 1108 (5th Cir. 1977). However, some courts have also recognized an exception to this principle in circumstances where there has been a significant and prejudicial delay by the government agency reviewing an application. These courts have extended to actions by government agencies a principle that courts sometimes apply when they themselves are unable for various reasons to issue decisions in a timely manner. The judicial principle has been expressed by the Supreme Court as follows:

> where the delay in rendering a judgment or a decree arises from the act of the court, that is, where the delay has been caused either by the convenience, or by the multiplicity or press of business, either the intricacy of the questions involved, or of any other cause not attributable to the laches of the parties, the judgment or decree may be entered retrospectively, as of a time it should or might have been entered up.

Mitchell v. Overman, 103 U.S. 62, 64-65 (1880). This principle is sometimes identified by the Latin maxim *actus curiae neminem gravabit.*

In one such case applying this principle to action by a government agency, an individual had applied for U.S. citizenship under a statute that expired before the government acted on his application. The court held that the individual was entitled to have his petition for naturalization granted under the expired law because of the government's delay in the approval of his application. *Application of Martini*, 184 F.Supp. 395, 401-402 (S.D.N.Y. 1960). That court opinion applies the judicial principle described above "to the delay caused by administrative inaction." 184 F.Supp. at 401-402. The United States Court of Appeals for the Second Circuit later observed that the above case and others had applied this principle to "situations involving prejudicial delays in the administrative proceedings." *Fassilis v. Esperdy*, 301 F.2d 429, 434 (2d Cir. 1962). However, the Second Circuit actually declined to reach the same result in the absence of a similar showing of delay. *Id.* This opinion of the Second Circuit followed the general principle described in *Ziffrin Inc. v. United States*, 318 U.S. 73 (1943) that an administrative agency should apply the law in effect at the time of its final decision on an application. Nevertheless, the Second Circuit case did not question the earlier decisions that applied an exception to this principle where there has been a meaningful delay by an administrative agency. *Id.* at 434. Although the Second Circuit upheld several denials of applications for permanent residency status based in part on a change in law that occurred during administrative appeals of the denials, this result was based on the court's conclusion that there were "no substantial delays on the part of the administrative agency which operated to deprive the applicants of any right to which any of them was entitled." *Id.* Thus, the *Fassilis* opinion appears to confirm the viability of the principle applied in the *Martini* case where there has been a significant delay by an administrative agency.

Together, the above cases support the view that an administrative agency has the power in limited and compelling circumstances to issue a permit decision based on the legal requirements that were applicable at the time the Agency should have taken action.

Conclusion Regarding Grandfathering

Notwithstanding these considerations, EPA must also ensure compliance with the substantive requirements of the Clean Air Act. The Act does not expressly authorize EPA to waive the substantive permitting criteria when a permit application has not been granted or denied within the one-year deadline. Thus, EPA must consider how to reconcile what have now become conflicting statutory obligations because of the delays in processing this permit application. Given the ambiguity in the Act on this point, EPA has the discretion to apply a permissible interpretation of the Act that balances the requirements in the Act to make a decision on a permit application within one year and to ensure that new and modified sources will only be authorized to construct after showing they can meet the substantive permitting criteria. Given the nature of the facility APC proposes to construct, the fact that EPA proposed the hourly NO2 NAAQS more than a year after Avenal's application was complete and after EPA had proposed to approve it, the delay in processing this application that resulted from promulgation of this standard, and the judicial precedent described above, EPA believes it is appropriate to reconcile these competing legal obligations by not requiring that APC show it will not cause or contribute to a violation of the one-hour NAAQS for NO2 and SO2 or that this facility will be capable of meeting emissions limitations for greenhouse gases based on the BACT requirement.

Although EPA previously issued interpretive statements that suggest grandfathering is not permissible in any circumstance absent an express grandfathering provision in the regulations, this previous interpretation should not apply to the circumstances present here. In making those prior statements, EPA had not sufficiently considered the judicial decisions described above and the present circumstances where several factors have combined to cause a delay of EPA's action on the APC permit nearly two years beyond the statutory deadline. In light of these circumstances and the extended delay of EPA's action on the APC permit application attributable to the challenges experienced in attempting to address the hourly NO2 NAAQS, EPA reads the law to allow EPA to issue this permit application based on the criteria and standards applicable to PSD permit decisions prior to the effective date of the hourly NO2 NAAQS.

The previous interpretive statements discussed above were reflected in actions of officials from EPA's headquarters offices. In order to effectuate the refinement of the previous Agency interpretations described above and to facilitate issuance of this permit, EPA's Assistant Administrator for Air and Radiation is issuing this statement of basis and intends to issue the final permit decision for the APC permit application after consideration of any public comment that may be submitted on this action. This action is authorized under a special delegation from the EPA Administrator contained in the administrative record.

II. Environmental Justice Analysis

Introduction

Executive Order 12898 entitled "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations" states in relevant part that "each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." Section 1-101 of Exec. Order 12898, 59 Fed. Reg. 7629, (Feb. 16, 1994) "Federal agencies are required to implement this order consistent with, and to the extent permitted by, existing law."*Id.* at 7632. Based on this Executive Order, the EPA's Environmental Appeals Board (EAB) has held that environmental justice issues must be considered in connection with the issuance of federal Prevention of Significant Deterioration (PSD) permits issued by EPA Regional Offices and states acting under delegations of Federal authority. *See, e.g.,* In *re Prairie State Generating Company*, 13 E.A.D. 1, 123 (EAB 2006); *In re Knauf Fiber Glass, GmbH*, 8 E.A.D. 121, 174-75 (EAB 1999) ("Knauf I"). EPA Regional Offices or their delegates in the states have for several years incorporated environmental justice considerations into their review of applications for PSD permits. The EAB reinforced the importance of completing an environmental justice analysis in a recent opinion discussed further below. *See, , In re: Shell Gulf of Mexico, Inc. and Shell Offshore, Inc.*, OCS Appeal Nos. 10-1 to 10-4, Slip Op. at 63-4, (EAB December 30, 2010) ("Shell II").

During the extended public comment period that EPA provided in 2009 regarding the proposed PSD permit for the Avenal Energy Project (Project), EPA received a number of comments concerning potential impacts on the surrounding communities, and we will respond to those in the Response to Comments that will accompany our final permit decision. For reasons we discuss in detail below, we have prepared this separate Environmental Justice Analysis to address the question of potential impacts of emissions of the air pollutants addressed in EPA's PSD permit action, and in particular short-term NO2 exposures. Another environmental justice analysis was conducted, as part of the state permitting and certification process for this Project, that addresses certain other air pollutants, namely ozone and fine particles, and we have summarized the results of that analysis in this document. We note that the local air district permit and the California Energy Commission (CEC)'s certification are the subject of a complaint submitted to EPA under Title VI of the Civil Rights Act.

For purposes of the Executive Order on environmental justice, EPA has recognized that compliance with the applicable NAAQS is emblematic of achieving a level of public health protection that demonstrates that EPA's issuance of a PSD permit for a proposed facility will not have disproportionately high and adverse human health or environmental effects on minority populations and low-income populations. See e.g., *Shell II.* slip op. 74; *In re Shell Offshore Inc.*, 13 E.A.D. 357, 404-5 (EAB 2007) ("Shell I"); *In re Knauf Fiber Glass, GmbH*, 9 E.A.D 1, 15-17 (EAB 2000) ("Knauf II"); *In re AES Puerto Rico*, L.P., 8 E.A.D. 324, 351 (EAB 1999). This is because the NAAQS are health-based standards, designed to protect public health with an adequate margin of safety, including sensitive populations such as children, the elderly, and asthmatics. As the EAB recently observed, "[i]n the context of an environmental justice analysis, compliance with the NAAQS is emblematic of achieving a level of public health protection that, based on the level of protection afforded by the NAAQS, demonstrates that minority or low-income populations will not experience disproportionately high and adverse human health or environmental effects due to exposure to relevant criteria pollutants." Shell, Slip Op. at 73. This is supported by the fact that "[t]he Agency sets the NAAQS using technical and scientific expertise, ensuring that the primary NAAQS protects the public health with an adequate margin of safety." *Shell II*, Slip Op. at 73.

The studies assessed by EPA in setting NAAQS and the integration of the scientific evidence presented therein have undergone extensive critical review by EPA, the Clean Air Scientific Advisory Committee (CASAC), and the public. Final Rule, 75 Fed. Reg. 6474, 6478 Feb. 9, 2010. "The rigor of the review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS." Id. When setting the NAAQS, "[t]he Administrator's final decisions draw upon scientific information and analysis related to health effects, population exposures, and risks; judgments about the appropriate response to the range of uncertainties that are inherent in scientific evidence and analyses; and comment received from CASAC and the public." Id. at 6483. In light of these characteristics of the process for setting the standards, the EAB generally "relies on and defers to the Agency's cumulative expertise when upholding a permit issuer's environmental justice analysis based on a proposed facility's compliance with the relevant NAAQS in a PSD appeal." *Shell II*, Slip. Op. at 74. The NAAQS are also the underpinning for the State Implementation Plan process, which requires states to adopt rules and programs that will reduce emissions causing air pollution.

Pursuant to Clean Air Act section 165(a)(3), construction of a major emitting facility may not commence until the owner or operator of such facility demonstrates, among other things, that the facility will not cause or contribute to air pollution in excess of any NAAQS applicable to the permit decision. 42 U.S.C. § 7475(a)(3); see also 40 C.F.R. §§ 52.21(k), 52.21(i)(2). EPA proposes to regulate emissions affecting the following NAAQS under the PSD permit: NO2 (annual average), CO (1-hr and 8-hr average), and PM10 (24-hr). The proposed permit does not contain emission limitations for SO2 because, as noted above, the Project's SO2 emissions are estimated to be 16.7 tons per year, which is well below the 40 tons per year significant emissions rate for SO2. *See* 40 C.F.R. §§ 52.21(b)(23)(i); 52.21(j)(2); 52.21(m)(1). EPA has determined that the proposed facility's projected emissions will not cause or contribute to a violation of the applicable NAAQS, and are, in fact, well below the NAAQS. Indeed, EPA estimated that the projected emissions would be very low – i.e., less than 6% of the applicable NAAQS. Using that information for its environmental justice analysis, EPA has determined that compliance with the applicable NAAQS is indeed sufficient to satisfy the Executive Order as to those regulated pollutants.

Furthermore, Section 165(a) (2) of the CAA provides that a PSD permit may be issued only after "a public hearing has been held with opportunity for interested persons including representatives of the Administrator to appear and provide written or oral presentations on the air quality impact of [the proposed] source, alternatives thereto, control technology requirements, and other appropriate considerations." In light of the Agency's proposed determination that it should grandfather this permit application from the 1-hour

NO2 NAAQS, EPA's environmental justice analysis considers "other appropriate considerations" that extend beyond the impacts of the pollutants and NAAQS for those pollutants that are addressed in the PSD permit.

In this case, EPA's environmental justice analysis will consider not only the annual NO2 NAAQS, which was applicable at the time of the permit application and when EPA issued a proposed permit for the project, but also the potential impacts of the facility on short-term NO2 concentrations. EPA is examining short-term NO2 concentrations – even though EPA is proposing not to apply the new one-hour NO2 NAAQS to this permit application – because the Agency recently determined that the annual NO2 standard alone is not sufficient to protect public health with an adequate margin of safety against adverse respiratory effects associated with short-term exposures to NO2. Final Rule, 75 Fed. Reg. 6474, (Feb. 9, 2010) Therefore, EPA's environmental justice analysis considers whether short-term exposures to NO2 emissions from the Project may result in disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

The Project is also subject to an air permit issued on November 4, 2008 by the San Joaquin Valley Air Pollution Control District (District), which includes conditions necessary to satisfy the requirements of the Non-attainment New Source Review (NSR) Program under sections 172(c)(5) and 173 of the Clean Air Act. This permit addresses ozone, one of the two air pollutants for which the San Joaquin Valley (Valley) has been designated non-attainment.[3] The facility's projected emissions are below the threshold that would trigger non-attainment new source review of the other non-attainment pollutant – PM2.5. The California Energy Commission, in reviewing the permit applicant's Application for Certification relating to the aforementioned District permit, analyzed environmental justice considerations pertaining to, among other things, the proposed siting and emissions profile of the facility. This analysis is contained in the California Energy Commission's Final Commission Decision (08-AFC-1) (December 2009).

The District's action in issuing an NSR permit for this facility and the CEC's action in certifying the Project are the subject of a pending administrative complaint under Title VI of the Civil Rights Act. This complaint, submitted to EPA on October 15, 2009 by Greenaction for Health and Environmental Justice, alleges that the District discriminated against Avenal and Kettleman City residents of color and Spanish-speakers by failing to notify or involve residents during the decision-making process. In addition, the complaint alleges that operation of the proposed Avenal power plant will result in adverse health impacts on the residents of color of Avenal and Kettleman City, who are already impacted by multiple sources of pollution. EPA's Office of Civil Rights has accepted both of these allegations for investigation[4]. By letter dated

[3] New source review in non-attainment areas is different from PSD review. Because the area already has air quality that does not meet national health standards, and yet to preserve the ability for economic development to occur in those areas without exacerbating air quality and public health concerns, the Clean Air Act requires that sources seeking to build or expand in a non-attainment area must meet the Lowest Achievable Emissions Rate (LAER) and offset their anticipated new emissions by eliminating emissions of an equal, or depending on the severity of the non-attainment, greater amount. LAER requires a level of emissions reduction, through the use of control technology or other approaches, that is as or more stringent than Best Available Control Technology (BACT), which is required in attainment areas.

[4] EPA also referred to the US Department of Energy the second allegation as it relates to the actions of the CEC.

August 6, 2010, EPA notified the complainant that it is holding its investigation of the second allegation described above in abeyance because it is not ripe for review while EPA is still considering the PSD permit application.

Project Description and Regulatory Framework

As discussed above, the Avenal Power Center, LLC has applied to EPA for a PSD permit for the Project, a new natural gas fired power plant to be located in Kings County, California, within the San Joaquin Valley Air Pollution Control District, which covers 25,000 square miles and is about 250 miles long from the northern tip of San Joaquin County to the southern tip of Kern County.

Under the Clean Air Act, new sources of pollutants for an area that has been designated attainment or unclassifiable are regulated under the PSD program. In the San Joaquin Valley, these pollutants include NO2, PM10, SO2, lead, and CO, and therefore EPA's proposed PSD permit for the Project regulates those pollutants that the facility has the potential to emit in significant amounts. In addition, the facility will emit pollutants for which the San Joaquin Valley has been designated non-attainment. Specifically, the Valley is designated as an extreme non-attainment area for ozone and a non-attainment area for PM2.5. Thus, the non-attainment pollutants subject to NSR permitting by the District include NOx and VOC as ozone precursors, and PM2.5.[5] In addition, for power plants over 50 MW, the California Energy Commission (CEC) must issue a license to authorize construction of a proposed power plant. The District issued the non-attainment NSR permit for the facility on October 30, 2008 and the CEC completed its licensing process on December 16, 2009.

The Project is expected to produce approximately 600 megawatts (MW, nominal) net electrical output from natural gas-fired combined-cycle generating equipment. The facility will be operated in combined-cycle mode. Two combustion turbine generators (CTGs) will connect to a dedicated heat recovery steam generator (HRSG), where hot combustion exhaust gas will flow through a heat exchanger to generate steam. The facility will be equipped with natural gas-fired duct burners to augment steam production during peaking operation. Electrical power will be generated from the combustion of natural gas in two 180 MW (nominal) CTGs. Exhaust from each gas turbine will flow through the dedicated HRSG to produce steam to power a shared 300 MW (nominal) Steam Turbine Generator (STG).

The Project will be equipped with state-of-the-art control technology and will be one of the lowest emitting power plants of its kind. Each of the Project's CTGs will be equipped with dry low-NOx (DLN) combustors. The facility will install selective catalytic reduction (SCR) and oxidation catalyst (Ox-Cat) systems. SCR will be used to reduce NO_x emissions from the combustion turbine generators and the Ox-Cat to reduce emissions of carbon monoxide and volatile organic compounds. Additional equipment includes a natural gas-fired auxiliary boiler equipped with an ultra low-NOx burner, a natural gas-fired emergency generator equipped with a non-selective catalytic reduction (NSCR) system, and a diesel-fired emergency firewater pump

[5] The projected PM2.5 emissions from the Avenal facility fall below the regulatory threshold for new source review and there are no PM2.5 requirements in the District's permit.

engine with a turbo-charger and an inter-cooler/after-cooler. These pollution control technologies are required to meet the Best Available Control Technology (BACT) and Lowest Achievable Emissions Rate (LAER) requirements under the PSD and non-attainment NSR permitting programs.

The facility is expected to have emissions as shown in the following table[6].

Pollutant	Estimated Annual Emissions (tons/year)	Major Source Threshold (tons/year)	Significant Emission Rate (tons/year)	Does PSD apply?
CO	602.7	100	100	Yes
NO2	144.3	100	40	Yes
PM/PM10	80.7	100	25/15	Yes
SO_x	16.7	100	40	No

EPA's proposed permit includes, among other requirements, 1-hour emissions limits for NO2, CO, and PM/PM10 on a mass basis as well as 1-hour emissions limits for NO2 and CO on a concentration basis that meet PSD Best Available Control Technology requirements. Based on the BACT analysis EPA has conducted, the proposed permit requires the most stringent control technology available to reduce NO2 emissions.

Demographics, Health Data, and Air Quality in the Avenal Area

Description of Local Area

The project would be located on industrial zoned lands administered by the City of Avenal. Currently, the site is in agricultural use. This area is about 6 miles (~9.7 km) from the residential and business centers of the City of Avenal. The topography of the Kettleman Hills divides the populated areas of the City of Avenal from the project site. The City of Huron is located approximately 8 miles (~12.9 km) north of the site and Kettleman City is located approximately 10 miles (~16 km) southeast of the site[7].

Avenal has a population of 16,236, including 7,000 inmates at Avenal State Prison. Many of the remaining residents either work at the prison or in the agriculture or oil industries. The City of Huron in Fresno County is 9 miles (14.5 km) east of Interstate 5 (I-5) and 3 miles (4.8 km) south of Highway 198. Huron is home to over 7,400 residents and during the harvest season, from April to November, the city's population increases to over 9,000 with an influx of migrant laborers. The local economy is based on agriculture. Kettleman City is a small community with a population of approximately 1,620. The community is located in southern

[6] The facility is not expected to emit lead.
[7] Avenal Energy Application to California Energy Commission, Section 6-9, Land Use.

Kings County adjacent to the Interstate 5 freeway and surrounded by agricultural fields, and defunct oil and natural gas extraction operations. A hazardous waste landfill operated by Waste Management, Inc. is located in the Kettleman Hills about 3.5 miles (~5.6 km) southwest of Kettleman City.

Demographic Information

EPA believes an area encompassed by a 25 km radius from the proposed facility is appropriate for this environmental justice analysis as this includes populations of interest in the area that may be impacted by emissions from the Project. Demographic information for areas of 15 and 50 km radii are also provided for comparison. These areas include portions of Kings and Fresno counties. Thus, for health information EPA will present metrics for both Kings and Fresno counties. Relevant areas of comparison include the 8-county area of the San Joaquin Valley and the State of California as a whole.

Demographic information[8] is captured within three radii surrounding the proposed Avenal Energy Project at 50, 25 and 15km (see Appendix 1).

Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
25	32,244	82	25	3	30	50	27,771
50	162,723	62	29	7	11	35	36,843
Kings County	129,461	59	29	7	9	31	35,749
Fresno County	799,407	60	32	10	10	32	34,725
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493

All three radii capture populations above the state average for percent minority and below the state average for median household income. As the area decreases in size relative to the proposed facility, the percent minority increases. The median household income captured in the 15 km radius is more than $20,000 below the state average.

EPA's Final Report *Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (ISA)*[9] discussed below specifically identified children[10] (defined here as under 18 years

[8] US Census Bureau, 2000 Data, Summary File 3

old) and older adults (65+ years) as being particularly vulnerable to NO2 impacts. The percentages of children under 18 within the three radii are close to the state average. The percentages of older adults living within the three radii are lower than the state average.

Linguistic isolation[11] limits a household's capacity for civic engagement in the regulatory process. All three radii capture households that are above the state average for linguistic isolation. The percent of linguistically isolated households in the State of California is 10% and the percent of households in the 25km radius is 30%.

Education level is another factor that may influence susceptibility and vulnerability to air pollution. Limited formal education is a barrier to employment, health care and social resources, and can increase the risk of poverty, stress, and impacts from environmental stressors. The percent of population without a high school diploma increases the smaller the radius around the facility. Compared to the state average of 23%, the percent of population over 25 years of age without a high school diploma in the 25km radius is 50%. See Appendix 1 for block group maps of each demographic variable described above.

Status of Air Quality in the Area

The San Joaquin Valley is an extreme ozone non-attainment area and a non-attainment area for PM2.5. The area is designated as attainment or unclassifiable for PM10, NO2, CO, SO2, and lead. The San Joaquin Valley has some of the highest PM2.5 levels in the country.

As discussed in more detail below, EPA recently promulgated a 1-hour NO2 NAAQS of 100 ppb. EPA has not yet made attainment designations for this new standard. There is limited 1-hour NO2 monitoring data in California from EPA-approved monitoring network sites. The NO2 data for the monitoring network for California for 2006-2009 are presented in Appendix 2. The data in the table indicate that the 1 -hour NO2 monitored design values for 2007-2009 range from 5.1 ppb to 85.5 ppb. The ambient monitoring sites nearest to the Project are the Hanford monitoring site which is 28 miles from the facility, and the Visalia monitoring site which is 46 miles from the facility[12]. The NO2 design value monitored at the Visalia site is 61.3 ppb and for

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[9] Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (Final Report), Section 4.3, U.S. Environmental Protection Agency, Washington DC, EPA/600/R-08/071, 2008.

[10] Children are particularly vulnerable to adverse health effects from air pollution because:

- Children's lungs are still developing. This period of growth and development of the lungs is a critical time period for health effects from exposure to air pollution. Exposures to air pollutants during this time can have life-long effects on the lungs, including lung capacity, the diameter of the airways, and the number and types of cells that line the airways. It is important to note that airways develop through adolescence.
- Children breathe in more air than adults compared to their body weight, leading to a higher dose of air pollution.
- Children's airways are narrower than adults, making them more susceptible to air pollution.

[11] A linguistically isolated household is defined by the US Census Bureau as a household in which no member 14 years old and over (1) speaks only English or (2) speaks a non-English language and speaks English "very well." In other words, all members 14 years old and over have at least some difficulty with English.

[12] The Hanford and Visalia monitors are "neighborhood scale," which means that they represent conditions throughout some reasonably homogeneous urban subregion, with dimensions of a few kilometers. These data are useful to the understanding and definition of processes that take periods of hours to occur and hence involve considerable mixing and transport. The monitors therefore do not represent source-specific or peak concentrations.

the Hanford site, 50.0 ppb (61% and 50% of the 1-hour NO2 NAAQS, respectively). This indicates that background levels at the monitors closest to the facility are on par with measured levels of NO2 statewide, and that background levels of 1-hour NO2 in the general area surrounding the facility are not disproportionately high as compared with communities elsewhere in the State.

1-Hour NO2 National Ambient Air Quality Standard

EPA periodically conducts comprehensive reviews of the scientific literature on health effects associated with exposure to the criteria air pollutants. The NAAQS are set at a level that protects public health with an adequate margin of safety, including sensitive populations such as children, the elderly, and asthmatics. On January 22, 2010, EPA promulgated a new 1-hour standard for NO2 to provide increased public health protection from short-term NO2 exposures that have been linked to respiratory illnesses that lead to emergency room visits and hospital admissions, particularly in at-risk populations such as children, the elderly, and asthmatics. The standard became effective on April 12, 2010.

Sources of NO2

As noted in the record that accompanied the promulgation of the 1-hour NO2 standard, NO2 is emitted by stationary sources such as utilities, industry and other combustion sources. The largest contributor, however, is motor vehicles, and the greatest concern identified in the review of the NAAQS for NO2 was exposure to short term NO2 spikes associated with motor vehicle emissions. Nationwide, mobile sources account for 61% of NOx emissions. In Kings County, the percentage of NOx emission attributable to mobile sources is 91%.[13] NO2 concentrations on or near major roads are appreciably higher than those measured at monitors in the current network. In-vehicle concentrations can be 2-3 times higher than measured at nearby community-wide monitors and near-roadway concentrations have been measured to be approximately 30 to 100% higher than those measured away from major roads. Individuals who spend time on or near major roads can experience short-term NO2 exposures considerably higher than measured by the current network, which are of particular concern for at-risk populations, including people with asthma, children, and the elderly. As a result, the final NO2 NAAQS required that new monitors be located near roadways in addition to community scale monitors. Final Rule, 75 Fed. Reg. 6474 (Feb. 9, 2010); 40 CFR Part 58, Appendix D, Section 43.

EPA anticipates NOx, including NO2,concentrations, will continue to decrease as a result of state and federal mobile source engine and fuel standards already in effect and being phased in as new vehicles replace older ones. Heavy-duty trucks contributed more than half of the NOx emissions in Kings County in 2010. The new standards for on-road heavy-duty trucks, which were fully effective with the 2007 and 2010 model years, are anticipated to result in NOx emissions reductions of almost 60% from these trucks in Kings County by 2020 (see Appendix

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Reference: EPA's QA Handbook, Volume II, Appendix E (http://www.epa.gov/ttnamti1/files/ambient/pm25/qa/vol2appe.pdf).

[13] ARB, CEPAM-2009 Almanac - 2/6/2011), Appendix 1, Table 1: NOx Emissions Projections - Kings County California.

3). California's in-use truck rule will further reduce emissions from heavy-duty trucks. In addition, new national emissions standards covering many non-road diesel engine categories, including construction and farm equipment, will be fully effective by 2015.

Health Effects Associated with NO2

EPA's ISA concluded that recent studies provided scientific evidence that NO2 is associated with a range of respiratory effects. Specifically, these studies provided evidence sufficient to infer a likely causal relationship between short-term NO2 exposure and adverse effects on the respiratory system.

Evidence from epidemiologic studies shows an association between NO2 exposure and children's hospital admissions, emergency department visits, and calls to doctors for asthma. NO2 exposure is associated with aggravation of asthma, including symptoms, medication use, and lung function. Effects of NO2 on asthma are most evident with a lag of 2-6 days after exposure, rather than same-day levels of NO2. The relationship in children between hospital admissions or emergency department visits for asthma and NO2 exposure holds even after adjusting for co-pollutants such as particulate matter and carbon monoxide.

In addition, the ISA concluded that the available evidence on the effects of short-term exposure to NO2 on cardiovascular health effects is inadequate to infer the presence or absence of a causal relationship at this time. The ISA concluded that the epidemiologic evidence is suggestive but not sufficient to infer a causal relationship of short-term exposure to NO2 with all cause and cardiopulmonary-related mortality[14].

Impacts of NO2 on Susceptible and Vulnerable Populations

The NAAQS are intended to provide an adequate margin of safety for both general populations and sensitive subpopulations, for those subgroups potentially at increased risk for ambient air pollution health effects. The term susceptibility generally encompasses innate or acquired factors that make individuals more likely to experience effects with exposure to pollutants.

As stated in the NO2 ISA at page 4-12:

> Persons with preexisting respiratory disease, children, and older adults may be more susceptible to the effects of NO2 exposure. Individuals in sensitive groups may be

[14] Results from several large U.S. and European multicity studies and a meta-analysis study indicated positive associations between ambient NO2 concentrations and the risk of all-cause (non-accidental) mortality, with effect estimates ranging from 0.5 to 3.6% excess risk in mortality per standardized increment. In general, the NO2 effect estimates were robust to adjust for co-pollutants. Both cardiovascular and respiratory mortality were associated with increased NO2 concentrations in epidemiologic studies; however, similar associations were observed for other pollutants, including PM and SO2. The range of risk estimates for excess mortality was generally smaller than that for other pollutants such as PM. While NO2 exposure, alone or in conjunction with other pollutants, may contribute to increased mortality, evaluation of the specificity of this effect was difficult. U.S. EPA. Integrated Science Assessment for Oxides of Nitrogen – Health Criteria (Final Report), Section 4.3. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-08/071, 2008.
Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=194645#Download

affected by lower levels of NO2 than the general population or experience a greater impact with the same level of exposure. A number of factors may increase susceptibility to the effects of NO2. Studies generally reported a positive excess risk for asthmatics, and there was emerging evidence that [cardiovascular disease] may cause persons to be more susceptible, though it is difficult to distinguish the effect of NO2 from other traffic pollutants. Children and older adults (65+ years) may be more susceptible than adults, possibly due to physiological changes occurring among these age groups. In addition to intrinsically susceptible groups, a portion of the population may be at increased vulnerability due to higher exposures, generally people living and working near roadways. A considerable fraction of the population resides, works, or attends school near major roadways and likely include a disproportionate number of individuals in groups with higher prevalence of asthma and higher hospitalization rates for asthma (e.g., ethnic or racial minorities and individuals of low socio-economic status). Of this population, those with physiological susceptibility will have even greater risks of health effects related to NO2.

Next Steps for New NO2 Health Standard

The 1-hour NO2 standard became effective on April 12, 2010. As required by the CAA, states will submit recommendations to EPA on which areas do and do not meet the standard, based on air quality monitoring data, and will also identify areas for which sufficient data are not yet available. EPA will review the states' recommendations and finalize designations by January 2012. Concurrently, EPA and the states will enhance the ambient monitoring network to ensure it provides adequate coverage, including for exposure near roadways. This monitoring network is to be in place by January 2013. For areas designated non-attainment, states will be required to develop plans to reduce emissions that are contributing to the high levels, and more stringent new source review will apply. New sources will be required to control emissions to meet the Lowest Achievable Emission Rate and offset any new emissions so that there will be no net increase in emissions in the non-attainment area.

Health Metrics Related to Asthma

The NO2 ISA specifically identifies persons with preexisting respiratory disease as being at increased risk from NO2 related adverse impacts. This section presents data on health metrics in Kings and Fresno Counties in California that may be associated with exposures to NO2.

Respiratory diseases can greatly impair a child's ability to function, and are an important cause of missed school days and limitations to activities. Important respiratory diseases in children include asthma, bronchitis, and upper respiratory infections. In 1994-96, on a national basis, 24 percent of children with asthma had to limit their activities due to their asthma, and the disease caused children to miss 14 million days of school. Studies have shown that outdoor and indoor air pollution causes some respiratory symptoms and increases the frequency or severity of asthma attacks.[15] As noted above, NO2 exposure is associated with aggravation of asthma.

[15] http://www.epa.gov/economics/children/child_illness/ci-background.html

Asthma Disparities and Income

In California as a whole, asthma disparities exist on the basis of race and ethnicity, age, and income. According to the California Breathing (California Department of Public Health) Report: The Burden of Asthma: A Surveillance Report (2007) [16], lower income is associated with more frequent asthma symptoms and higher asthma hospitalization rates, but slightly lower rates of lifetime asthma prevalence. The report states:

> Prevalence of severe symptoms is almost seven times higher among adults with household incomes below $20,000 compared to adults with household incomes over $100,000. The rate of asthma hospitalizations is three times higher among people living in areas where the median income is less than $20,000 compared to people living in areas where the median income is greater than $50,000. Additionally, people with more repeat asthma hospitalizations come from areas with a lower median income.

Hospitalizations and Emergency Department Visits

The tables below compare the age-adjusted rates for asthma hospitalizations and asthma related emergency department visits in Kings and Fresno Counties versus the State of California and are tracked by the California Environmental Health Tracking Program[17].

2009 Asthma Hospitalizations by Race and Ethnicity

The rate of asthma hospitalizations for children in Fresno and Kings Counties aged 0 – 4 is significantly higher than the rate for California as a whole. Hospitalizations due to asthma for non-Hispanic white children age 0 – 4 in California number 19 per 10,000, compared to 42 and 28, respectively, for non-Hispanic white children in Fresno and Kings Counties. Hospitalizations due to asthma for African-American children age 0 – 4 in California number 55 per 10,000, compared to 75 for African-American children in the same age group in Fresno County (data not available for Kings County). Hospitalizations due to asthma for Latino children age 0 – 4 in California number 21 per 10,000, compared to and 45 and 29 (similar to non-Hispanic white children) for Latino children in Fresno and Kings Counties, respectively.

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[16] http://www.californiabreathing.org/phocadownload/asthmaburdenreport.pdf

[17] The California Environmental Health Tracking Program provides data for two asthma indicators: asthma hospitalizations and asthma-related emergency department visits. A careful evaluation of asthma in a particular community requires review of both asthma-related emergency department (ED) visits and asthma-related hospital admissions because when a patient goes to the emergency room with asthma, sometimes they are treated in the emergency department and discharged and sometimes they are admitted to the hospital. An asthma-related hospital admission is identified by looking at hospitalization data and selecting the admissions that had an asthma diagnosis. Hospitalization represents people with severe asthma who end up being hospitalized for their asthma. An asthma-related emergency department (ED) visit is measured by examining hospital records on ED visits and identifying the visits that had an asthma diagnosis. Some ED visits may result in a hospitalization. Emergency department visits represent people with asthma who end up at the emergency department (ED) or utilize urgent care services for treatment of asthma symptoms. This may be because they have been unable to manage their asthma properly or they lack access to a primary health care provider. California Environmental Health Tracking Program, http://www.ehib.org/project.jsp?project_key=ehss01

Age Adj Rate, per 10,000 persons 2009[b]	Total		Black		Hispanic[a]		White		Asian/ Pacific Islander	
	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]
U.S.	Comparable national data for emergency department visits are not readily available, however the *California Breathing Report* notes that California hospitalization rates are consistently around 1.5 times lower than overall U.S. rates.									
CA	9.42	22.71	29.65	55.38	9.31	20.82	7.90	19.15	6.56	17.73
Fresno County	12.5[d]	49.34[d]	31.91	75.48	11.44[d]	45.28[d]	11.60[d]	42.47[d]	8.91[d]	48.79[d]
Kings County	10.78[d]	31.22[d]	18.54	NA	12.77[d]	29.56[d]	8.93[d]	28.17[d]	NA	NA

a. Includes Puerto Ricans
b. 2009 Data, from California Environmental Health Tracking Program, http://www.ehib.org/
c. Children 0-4 years old
d. This rate is statistically significantly higher than the rate for the State of California for the same ethnic/age group

2009 Asthma Emergency Department Visits by Race and Ethnicity

For asthma-related Emergency Department visits, the rates for Fresno and Kings Counties are higher than the rate for the State of California, and the difference is statistically significant when compared across any of the following: the entire population, the Latino population, children under 4, and adults aged 65 and older. Latino children age 0 – 4 in Fresno and Kings Counties, as compared to all Latino children age 0-4 in the State of California have almost double the rate of emergency department visits: 200 and 193, respectively, per 10,000, versus 107. For African–American children in the same age group, the difference is similarly striking: 409 and 536 for Fresno and Kings Counties, respectively, per 10,000 visits, versus 333 for all African American children age 0-4 in the State.

Age Adj Rate, per 10,000 persons 2009[b]	Total		Black		Hispanic[a]		White		Asian/ Pacific Islander	
	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]	All Ages	Children[c]
U.S.	Comparable national data for emergency department visits are not readily available.									
CA	47.99	109.92	163.05	332.95	44.53	107.66	40.36	79.52	18.68	50.93
Fresno County	68.04[d]	216.14[d]	180.02[d]	409.06[d]	61.62[d]	200.06[d]	65.90[d]	167.17[d]	25.44[d]	123.86[d]
Kings County	71.24[d]	196.01[d]	146.99	536.51[d]	73.28[d]	193.35[d]	61.98[d]	133.80[d]	NA	NA
Avenal	26.3[e]	NA	NA	NA	NA	NA	NA	NA	NA	NA

Kettle-man City	35.75[e]	NA	NA	NA	NA	NA	NA	NA	NA	NA

a. Includes Puerto Ricans
b. 2009 Data, from California Environmental Health Tracking Program, http://www.ehib.org/
c. Children 0-4 years old
d. This rate is higher than the rate for the State of California for the same ethnic/age group.
e. Data from 2005-2007 California Office of Statewide Health Planning and Development (OSHPD) Patient ED Database. Numerator for rates is ED visits with a principal diagnosis using ICD-9 code 493. Denominator for Kettleman City and Avenal rates is the estimated number of residents from the ESRI Community Sourcebook of Zip Code Demographics.[18]

Asthma Prevalence in Kings and Fresno Counties

Data from the California Department of Public Health's "California Breathing" program are based on 2007 information. These data show a lifetime prevalence of 24% among Kings County children age 0-17, second highest in the State, and a prevalence of 19.2% for Fresno County, as compared to the statewide prevalence for the same age group of 15.4%[19]. In addition, according to the Kings County Health Status Report,[20] asthma prevalence has been increasing in recent years.

2007 Lifetime Asthma Prevalence by Race and Ethnicity

In Percents	**Total**		**Black**		**Hispanic**[a]		**White**		**Asian/ Pacific Islander**		**Family Income Below Poverty Level**	
	All Ages	Children[b]	All Ages	Children	All Ages	Children	All Ages	Children	All Ages	Children	All Ages	Children
U.S.[c]	11.5	13.1	13.2	19.7	10.2	12.6	11.5	11.2	Comparable data not available		14.4	15.7
CA[d]	13.6[f]	15.4[f]	18.2	25.9[e]	10.7	13[e]	14.1	20[e]	9.9	17[e]	11.9	NA

[18]Of the three population centers within the project area, data for two of the areas, Kettleman City and Avenal, are available as the result of a study conducted by the California Environmental Protection Agency and the California Department of Public Health (DPH). Although the asthma ED visit rate appears lower for Avenal and Kettleman City as compared with the SJV and California rates, because the population in these two areas is relatively small (15,000 and 1620 respectively) there is a high degree of variability in these rates. It is important to note that the study reached the conclusion that for most of the health metrics examined, Kettleman City was not appreciably different than any other community in the Valley. The Department of Public Health did note, however, an excess in the number of children with birth defects born to mothers who had lived in Kettleman City. Investigation of Birth Defects and Community Exposures in Kettleman City, California, California EPA and California Department of Public Health, page 60, December 2010. Available at http://www.calepa.ca.gov/envjustice/Documents/2010/KCDocs/ReportFinal/FinalReport.pdf

[19] http://www.californiabreathing.org/asthma-data/county-comparisons/lifetime-asthma-prevalence-children-2007

[20] http://www.countyofkings.com/health/forms/Community%20Health%20Status%20Report%202008-2009.pdf (page 34)

In Percents	Total		Black	Hispanic[a]	White	Asian/ Pacific Islander	Family Income Below Poverty Level
Fresno County[f]	18.3[g]	19.2[g]	Prevalence data are not available at the county level by racial / ethnic population.				
Kings County[f]	17.9	24.0[g]	Prevalence data are not available at the county level by racial / ethnic population.				

a. Includes Puerto Ricans (National asthma prevalence of 20.3% for all ages, 17.8% for children)
b. Children <18 years old
c. 2007 CDC data, available at: http://www.cdc.gov/asthma/nhis/07/table2-1.htm
d. California Breathing (California Department of Public Health) Report: The Burden of Asthma: A Surveillance Report (2007), based on 2003 data, except where noted
e. Data available only for adolescents. Prevalence among all CA adolescents is 18%.
f. County Comparisons based on 2007 data from California Department of Public Health, California Breathing program. Available at: http://www.californiabreathing.org/
g. The prevalence is statistically significantly higher than the rate for the State of California for the same ethnic/age group.

Access to Health Care in Kings and Fresno Counties

Medically Underserved Areas or Populations have been designated in portions of all eight San Joaquin Valley counties, including Kings and Fresno Counties[21]. According to California Health Interview Survey (CHIS) data, 16.4% of the Kings County population and 14.2% of the Fresno County population was not insured as of the date of the last survey (2007) compared to 13.2% of the entire California population surveyed.[22]

Health Impacts Associated with Air Pollution in the Area

The San Joaquin Valley, which includes Kings County, is an extreme ozone non-attainment area with some of the highest levels of PM2.5 in the country. The poor air quality creates an adverse health impact for all its residents. Children, people older than 65, and minorities living in Kings and nearby Fresno County suffer from higher rates of asthma-related hospitalizations and emergency department visits than similar groups living elsewhere in the State. The residents living within 25 km of the proposed project are disproportionately low income and minority compared with the rest of the State. While we have only county-level statistics, we anticipate that these statistics would also represent local conditions.

[21] http://hpsafind.hrsa.gov/
[22] http://www.askchis.com/

Impact of Project's Emissions on the NAAQS Applicable to the PSD Permit Application

The first part of EPA's environmental justice analysis concerns the potential effects on minority or low income populations from emissions that may affect the NAAQS EPA proposes to apply to this permit application. Those are emissions affecting the NAAQS for NO2 (annual average), CO (1-hr and 8-hr average), and PM10 (24-hr average and annual). As noted earlier, since the potential emissions of the Project are below significance levels for SO2, the project is not expected to have a significant impact on the applicable SO2 NAAQS.

EPA has determined from the modeled results for the facility that the Project impacts are well below (in all cases, less than 6% of) the applicable NAAQS for the PSD pollutants regulated under the PSD permit, including the annual NO2 standard. The modeled impact of NO2 for the annual averaging period is 0.5 $\mu g/m^3$, less than 1% of the NAAQS of 100 $\mu g/m^3$. The modeled PM10 impact (24-hour averaging period) is 2.9 $\mu g/m^3$, approximately 2% of the PM10 24-hour NAAQS of 150 $\mu g/m^3$. The modeled CO impact for the 8-hour averaging period is 337 µg/m3, less than 4% of the NAAQS of 10,000 $\mu g/m^3$, and the modeled CO impact for the 1-hour averaging period is 2,175 $\mu g/m^3$, less than 6% of the NAAQS of 40,000 $\mu g/m^3$. As stated elsewhere, the NAAQS are health based standards and are designed to protect public health with an adequate margin of safety, including sensitive populations. Taking into account these modeled results in light of the health-based nature of the applicable NAAQS, EPA has determined that proposed emissions limits for these pollutants will not result in disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Review of Modeled Short-Term NO2 Impacts from Avenal Energy Project's Emissions

The second part of EPA's environmental justice analysis for this permit concerns the short-term impacts of NO2. For the reasons stated in the Revised Statement of Basis, EPA is proposing to grandfather the Project from demonstrating that this source will not cause or contribute to a violation of the recently promulgated 1-hour NO2 NAAQS. EPA nevertheless is performing an analysis of impacts from short-term NO2 concentrations because the Agency recently determined that the annual NO2 standard alone is not sufficient to protect public health with an adequate margin of safety against adverse respiratory effects associated with short-term exposures to NO2. Final Rule, 75 Fed. Reg. 6474 (Feb. 9, 2010). We note that because emissions of SO2 from the project are below significance levels and thus have no more than a de minimis impact, we do not anticipate any significant or disproportionate impacts associated with these emissions. Therefore, further analysis of short-term impacts on SO2 is not necessary.

The Agency currently has limited data as to the impacts of NO2 emissions from the project or existing sources on the communities of interest. As previously discussed, there is limited hourly NO2 monitoring data in California from EPA-approved monitoring network sites, and the closest monitoring sites are 28 miles and 46 miles from the proposed Project. The limited data indicate that background levels at the monitors closest to the facility are on par with measured levels of NO2 statewide, and that background levels of 1-hour NO2 in the general area surrounding the facility are not disproportionately high as compared with communities elsewhere in the State.

In addition, the District conducted an assessment of the 1-hour NO2 emissions from the Project on June 14, 2010.[23] The results of this analysis indicate that the operational emissions from the facility result in a maximum 1-hour NO2 impact of 82.43 $\mu g/m^3$ (44 ppb), which represents 44% of the standard (188 $\mu g/m^3$ or 100 ppb). This value represents the highest modeled impact at any location resulting from the facility's emissions alone; all other locations would have a lower impact from the facility. The modeled impact is based on the average of the five yearly maximum 8th high values, consistent with EPA's *Notice Regarding Modeling for New Hourly NO2 NAAQS, Updated - 02/25/2010,* which discusses procedures for calculating NO2 modeled values suitable for comparison to the 1-hour NO2 NAAQS.[24]

This is the best information available to EPA at this time regarding the potential impacts of the facility's NO2 emissions on short-term NO2 levels. We do not have an acceptable analysis prepared for PSD purposes that provides a detailed comparison of the facility's emissions, as well as background and nearby sources, with the 1-hour NO2 NAAQS.

In light of the limited data available, EPA cannot reach any definitive conclusion about the specific human health or environmental impacts of short-term exposure to NO2 emissions from the facility on minority and low-income populations.

Emissions of Pollutants for Which Area Exceeds Air Quality Standards

The California Energy Commission analyzed environmental justice considerations before approval of Avenal's Application for Certification. Final Commission Decision, Application for Certification (08-AFC-1), pp. 328-332 (December 2009). The Commission concluded based on the evidentiary record that the fully mitigated project would not result in any significant adverse environmental or public health impacts to any population, including farm workers in the region. Id. at 331. EPA presents here a summary of the State's environmental justice analysis, as set forth in the Final Commission Decision, in order to provide further information about the

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[23] See Memorandum of June 14, 2010 to Derek Fukuda, AQE-Permit Services, from Leland Villalvazo. SAQS-Technical Services, Subject: Revised NO2 1-hour NAAQA Assessment for Avenal Power Center. This memorandum was prepared in support of the Revised Preliminary Determination of Compliance Evaluation for the Avenal Power Center Project, which proposed to limit the annual facility wide NOx and CO emissions for the source, resulting in a minor source permit for PSD purposes. However, as noted in EPA Comments on Project Number C-II00751 for Avenal Power Center LLC (08-AFC-Ol), September 13, 2010, the equipment emitting NOx from both the major and minor source project configurations would have the same permitted 1-hour emission rates, and therefore, the modeled short-term 1-hour NO2 impacts of the major source Project's emissions would be identical to that of the minor source project under consideration in the SJVAPCD's minor source permitting process.

[24] EPA's *Notice Regarding Modeling for New Hourly NO2 NAAQS, Updated - 02/25/2010*, states, in its discussion regarding procedures for calculating the NO2 design value for comparison to the 1-hour NAAQS: "The highest of the average 8th-highest (98th-percentile) concentrations across all receptors, based on the length of the meteorological data period, represents the modeled 1-hour NO2 design value based on the form of the standard." The District's analysis was based on five years of meteorological data (2004-2008). Therefore, the modeled 1-hour NO2 design value based on the form of the standard in this case would be the average 8th- highest (98th-percentile) based on the average of 5 years data.

potential air quality impacts of the Project.[25] With respect to air quality impacts, the Commission found that the combination of emissions controls and offsetting emission reductions would mitigate all project air quality impacts to a less than a significant level. Id. at 127. The CEC considered modeling that predicted maximum impacts of the facility on PM2.5 concentrations of 2.9 $\mu g/m^3$, which is approximately 8 percent of the 35 $\mu g/m^3$ National Air Quality Standard for PM2.5 concentrations averaged over a 24 hour period. This same modeling predicted maximum impacts on annual PM2.5 concentrations of 0.8 $\mu g/m^3$ which are approximately 6.5 percent of California's 12 $\mu g/m^3$ air quality standard.[26] Pre-existing background concentrations of PM2.5 in the non-attainment area are as high as 75 $\mu g/m^3$ over a 24-hour period and up to 18.4 $\mu g/m^3$ on an annual basis. Id. at 123.[27]

EPA is working with the California Air Resources Board (ARB) and the District to ensure that there is a comprehensive plan with adequate controls for attaining the annual and 65 $\mu g/m^3$ 24-hour PM2.5 ambient air quality standards by the Clean Air Act's deadline of 2015. See EPA's proposed action on the 2008 San Joaquin Valley PM2.5 plan at 75 FR 74518 (November 30, 2010) We will also be working closely with both agencies to develop a plan to meet the 35 $\mu g/m^3$ 24-hour standard, which is due to EPA in late 2012.

Since NOx is a precursor to ozone formation, the District required the Project to supply NOx offsets at a 1.5 to 1 ratio to mitigate NOx emissions from the facility. Because ozone formation is not localized, ozone and ozone precursors are considered area or basin-wide pollutants. While the NOx offsets provided by the applicant for this source were generated within the ozone non-attainment area, they were not required to be near the source. (The closest offsets to the facility were generated between 12 and 20 miles away.) The impacts of NO2, on the other hand, can be localized in nature. NOx offsets within the broader non-attainment area will have a mitigating effect on ozone formation within the non-attainment area, but they will not serve to mitigate any localized impacts of NO2 and therefore do not add meaningfully to EPA's analysis of potential NO2 impacts on the local communities. We should note that there may be some co-benefits for local areas from the NOx emissions reductions used for the project. However, we do not have data showing what these potential co-benefits might be.

[25] As previously mentioned, EPA has not yet commenced its investigation into the Title VI complaint's allegation that operation of the proposed Avenal power plant will result in adverse health impacts on the residents of color of Avenal and Kettleman City.

[26] The federal primary National Ambient Air Quality Standard for PM2.5 for the annual averaging period is 15.0 $\mu g/m^3$.

[27] The PM-2.5 values in the CEC report reflect data from the Bakersfield monitor, located approximately 80 miles southeast of the Avenal Energy Project. The Corcoran monitor, located within 28 miles east of the Project, reports 49 µg/m3 24-hour and 17.3 µg/m3 annual design value concentrations. See EPA's Air Quality System, http://www.epa.gov/ttn/airs/airsaqs/.

Conclusion

As explained above, with respect to all pollutants, including those not attaining the NAAQS in the affected area, the California Energy Commission found that the combination of emissions controls and offsetting emission reductions would mitigate all project air quality impacts to a less than a significant level. EPA's own analysis indicates that this project will not cause or contribute to air quality levels in excess of health standards for SO2, CO, PM10 and the annual NO2 standard and that there will not be disproportionately high and adverse human health or environmental effects with respect to these air pollutants on minority or low-income populations residing near the proposed project or the community as a whole. While EPA has no information indicating that short-term NO2 emissions from the project will negatively impact minority and low-income populations in the vicinity, it is difficult to speak definitively to this point due to the limitations of the available data.

Accordingly, EPA requests any additional information that might further inform the Agency's environmental justice analysis. EPA also requests public comment on this issue generally, but particularly in relation to the topics addressed below.

In light of the existing conditions in the local communities where this source proposes to construct, EPA intends to place an ambient NO2 monitor in an appropriate location in the vicinity of the proposed source to gather more information about the local NO2 concentrations. In EPA's recent NO2 monitoring rule that was part of the action to complete the 1-hour NO2 NAAQS, EPA specifically set aside up to 40 monitors to be sited in areas with minority and low income populations at the discretion of EPA Regional Administrators. Thus, the Agency has the discretion to place an air quality monitor in an appropriate location to develop air quality information for the Region and also to help assess air quality before and after operation of the Avenal plant. This monitor, along with other NO2 monitors that exist or may be sited in the San Joaquin Valley Air District, will be used by the ARB, the District and EPA to determine whether air quality in the region meets or exceeds the NAAQS for NO2, and will inform governmental plans to address any identified concerns. Any such plans would consider all contributing sources in the airshed, including the Avenal facility, in the effort to address any identified non-attainment challenges. EPA welcomes public comment on its intentions in this regard.

In the event that EPA were to gather air quality monitoring data that identify a concern in the local community from short-term NO2 emissions, EPA is considering options that EPA, ARB or the District might employ to mitigate such concerns. For example, EPA may have the option to direct federal funds to the local area to address sources of NO2 and provide for effective emissions reductions. In addition, the data from monitoring might be used to better inform measures that the ARB or the District could take (or might be required to take) to ensure attainment and maintenance of the 1-hour NO2 NAAQS. Indeed, if monitoring were to identify violations of the 1-hour NO2 NAAQS, the State would need to address those issues through the mandated attainment planning process to identify and implement measures to reduce NO2 sufficiently to assure air quality that meets the applicable standard. EPA requests public comment on the merits of such approaches.

EPA also requests comments on whether there are any conditions that should be included in the permit in response to these concerns. For example, because this area includes complex terrain and characterization of NO2 issues in that area can be challenging, EPA requests comment on considering establishing a condition in the permit that would require the applicant to monitor air quality conditions after construction of the facility. This monitoring, in coordination with the community-based NO2 monitor, could help provide better characterization of the NO2 concentrations in the area. Under section 52.21(m)(2) of EPA's regulations, EPA can require the permit applicant to conduct ambient monitoring "after construction of the stationary source … as the Administrator determines is necessary to determine the effect emissions from the stationary source … may have, or are having, on air quality in any area."

Regina McCarthy
Assistant Administrator for Air and Radiation

APPENDIX 1 – Demographic Maps for Avenal Energy Project EJ Analysis Project Impact Area

Figure 1 - Project Site and Population Density

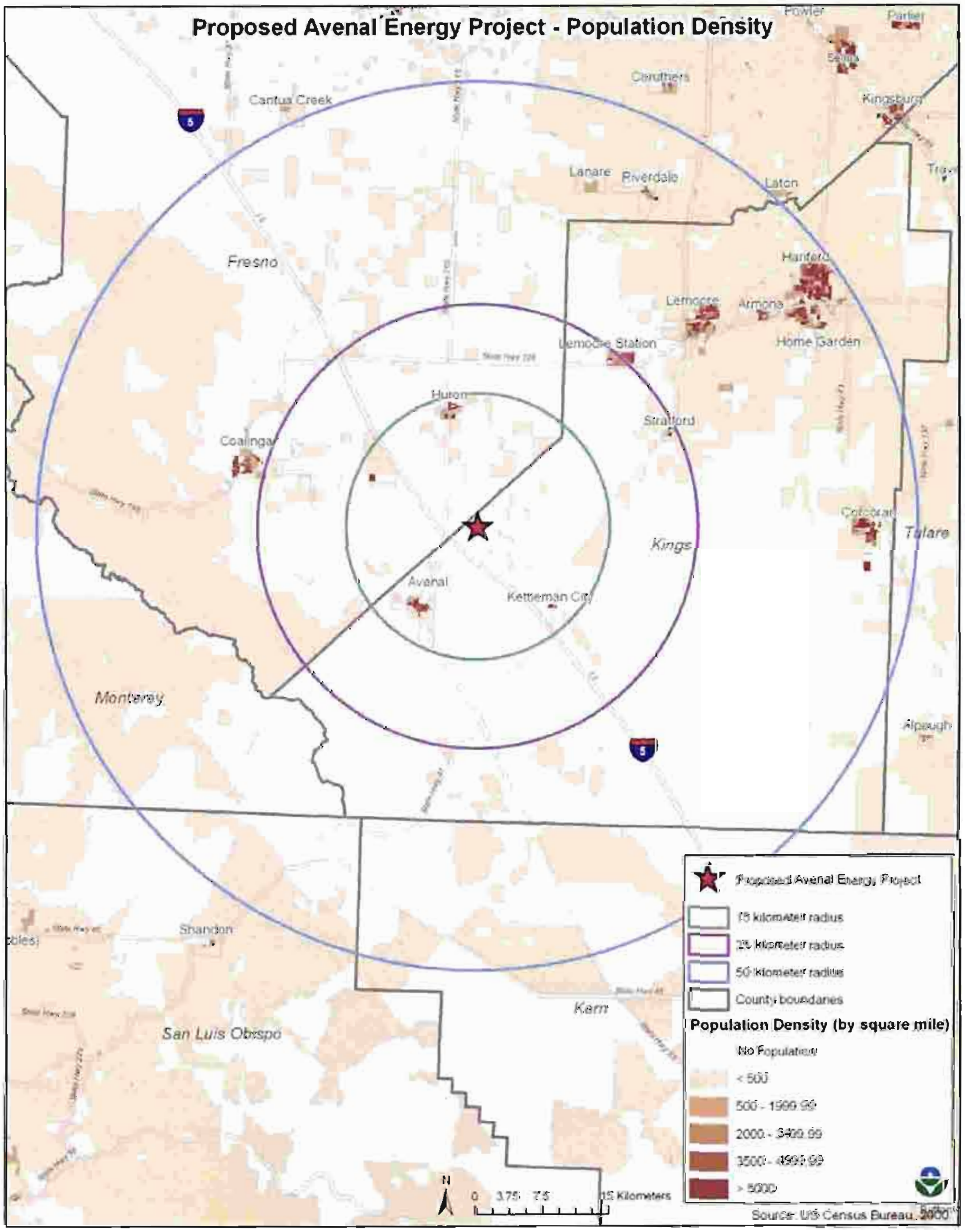
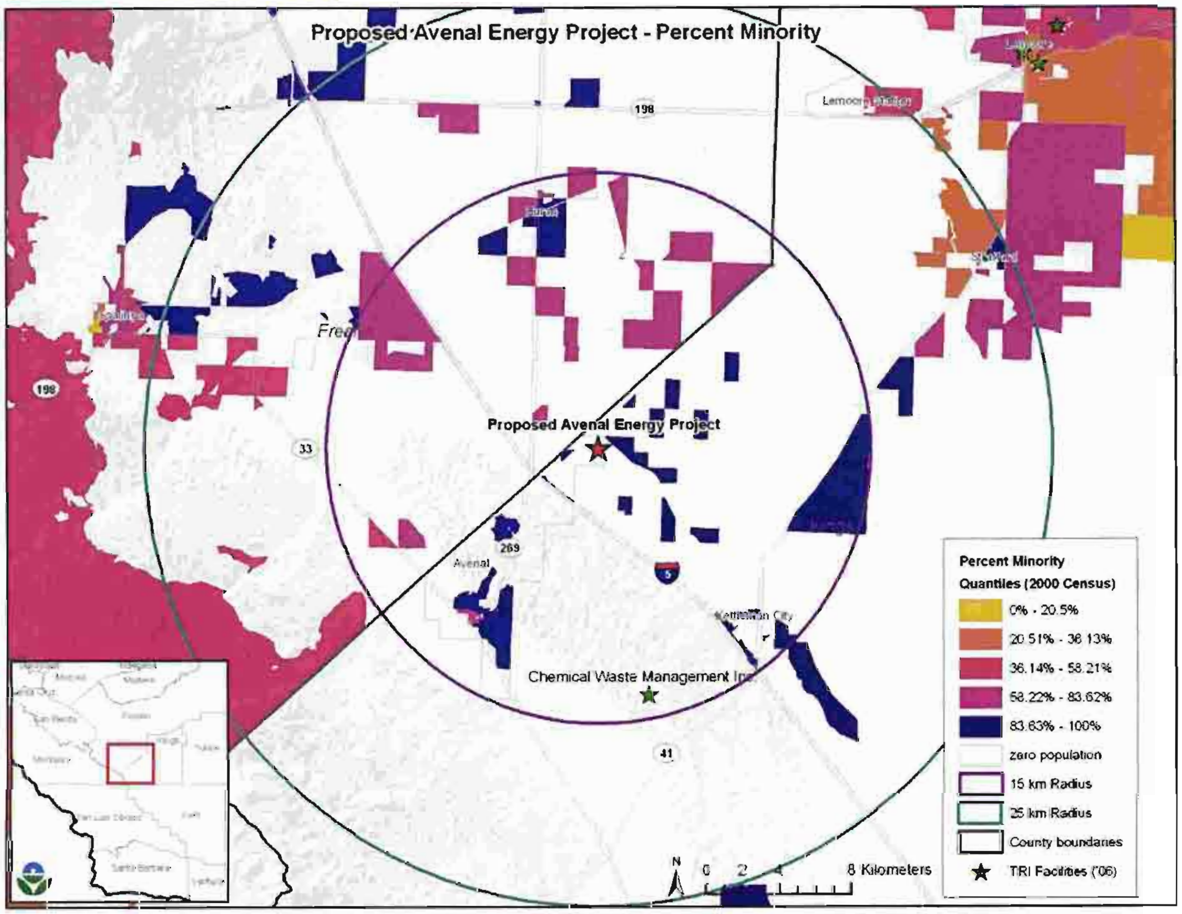


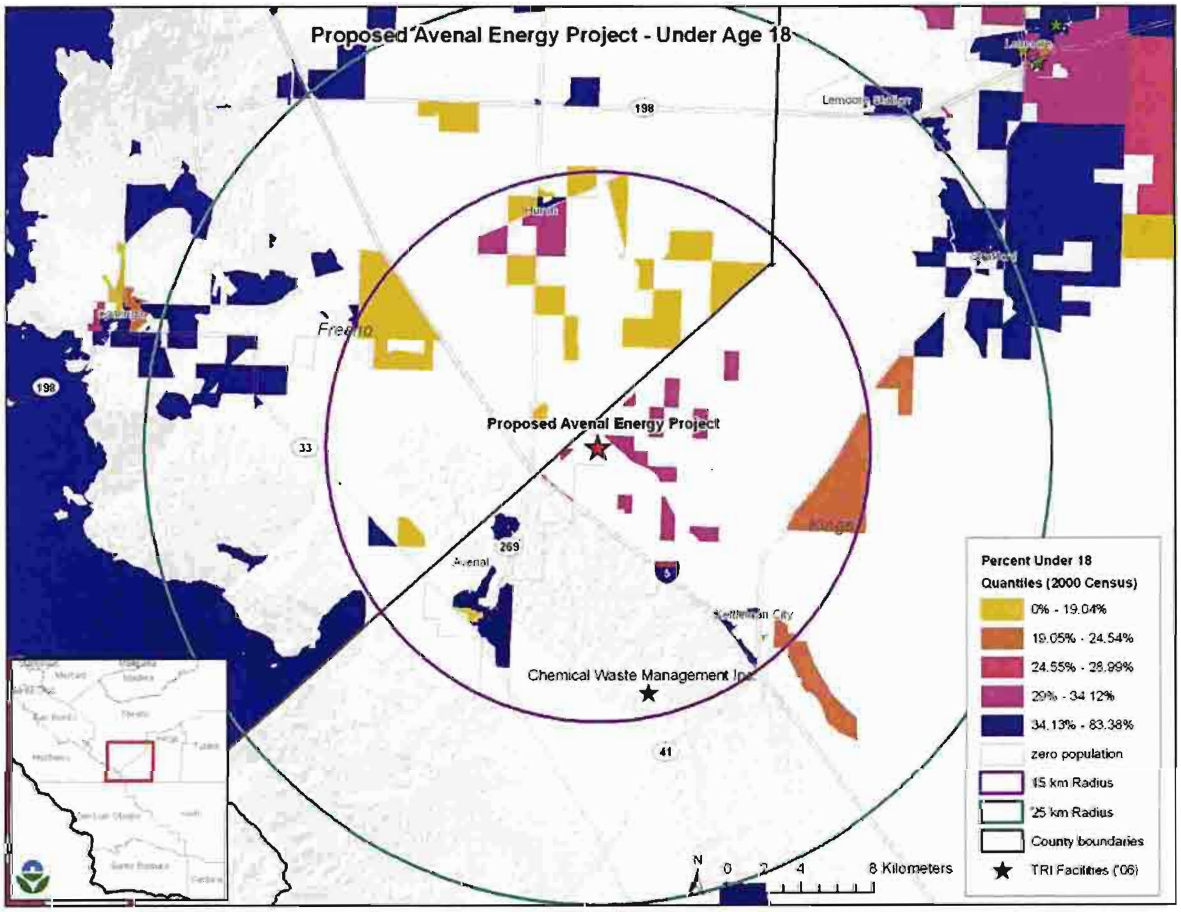
Figure 2 – Percent Minority



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
25	32,244	82	25	3	30	50	27,771
50	162,723	62	29	7	11	35	36,843
Kings County	129,461	59	29	7	9	31	35,749
Fresno County	799,407	60	32	10	10	32	34,725
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493

Source: US Census 2000, Summary Tape File 3

Figure 3 - Percent Under Age 18



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
25	32,244	82	25	3	30	50	27,771
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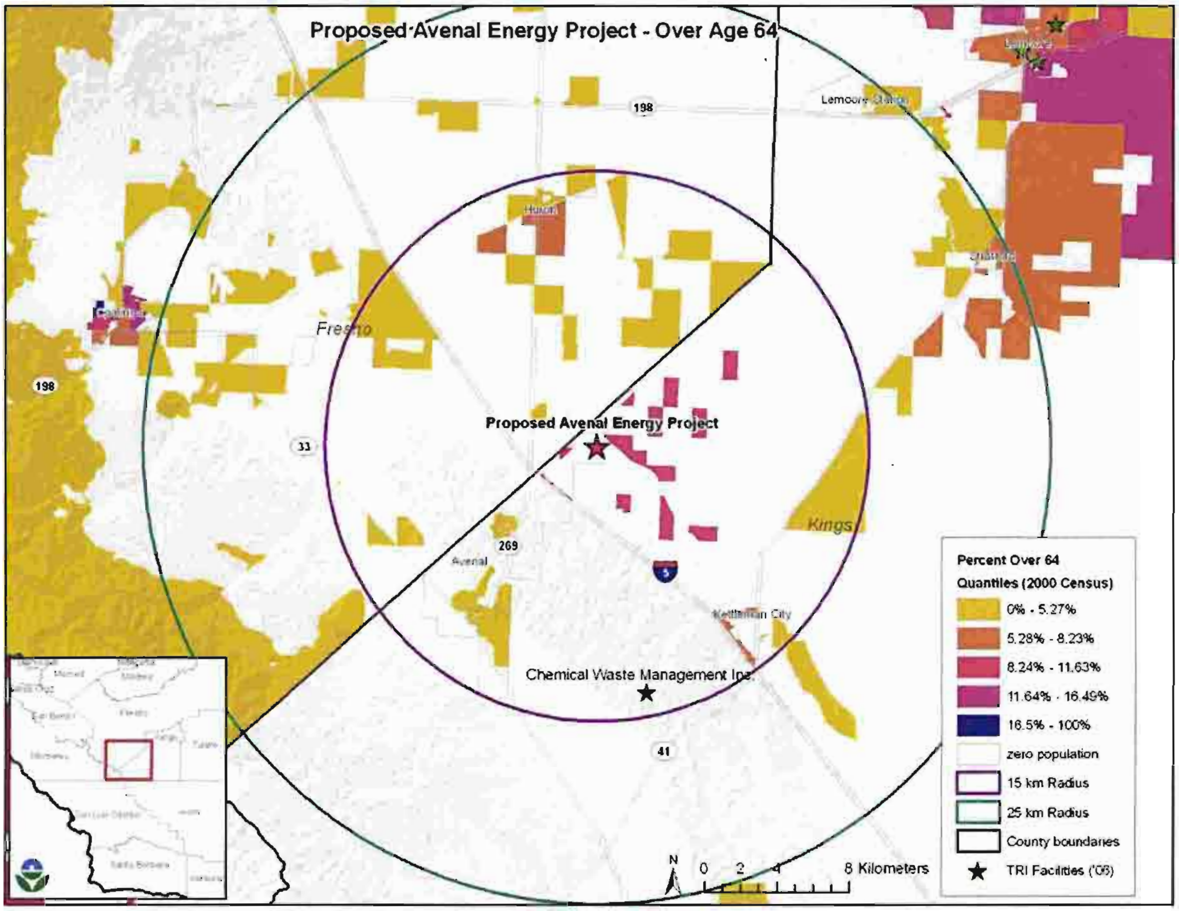
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493
							Source: US Census 2000, Summary Tape File 3

Figure 4 - Percent Over Age 64



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
25	32,244	82	25	3	30	50	27,771
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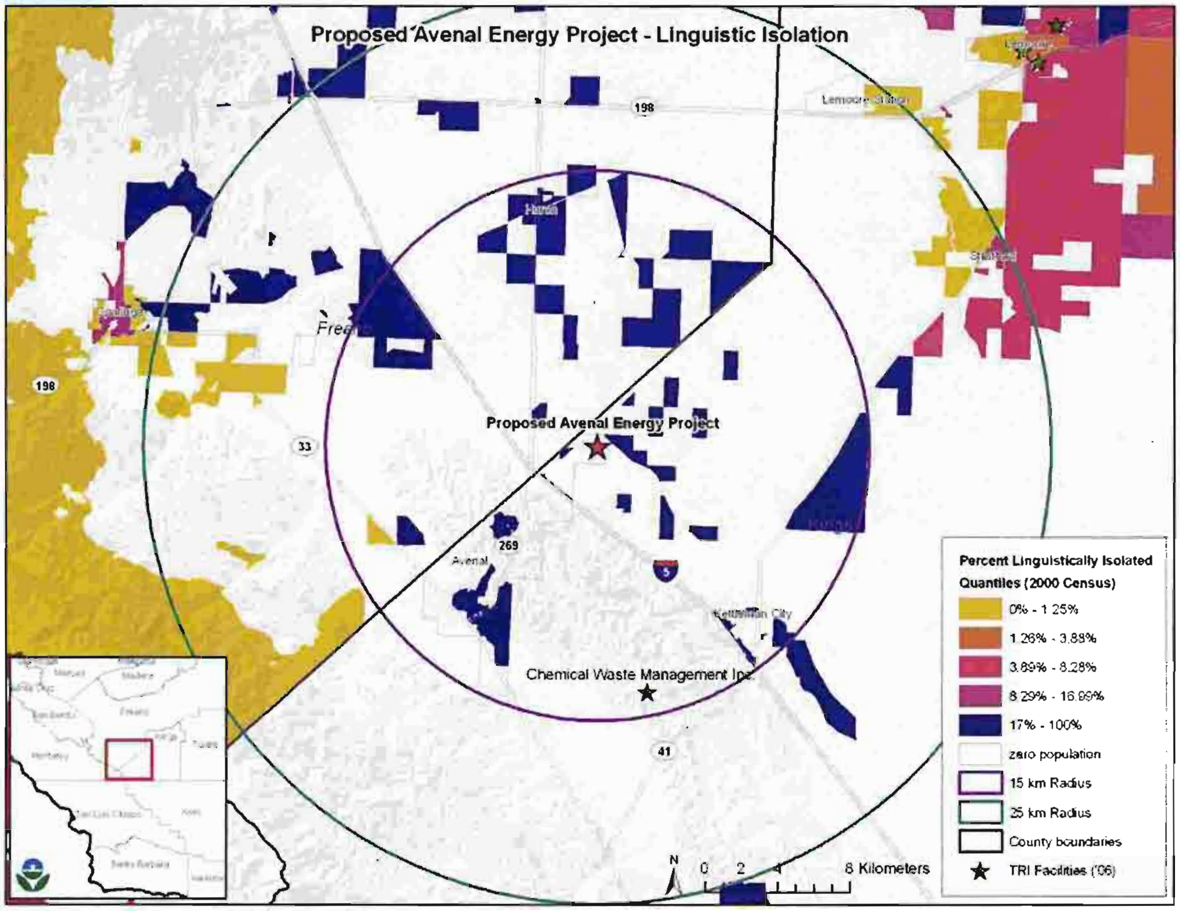
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493
Source: US Census 2000, Summary Tape File 3							

Figure 5 - Percent Linguistically Isolated



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
25	32,244	82	25	3	30	50	27,771
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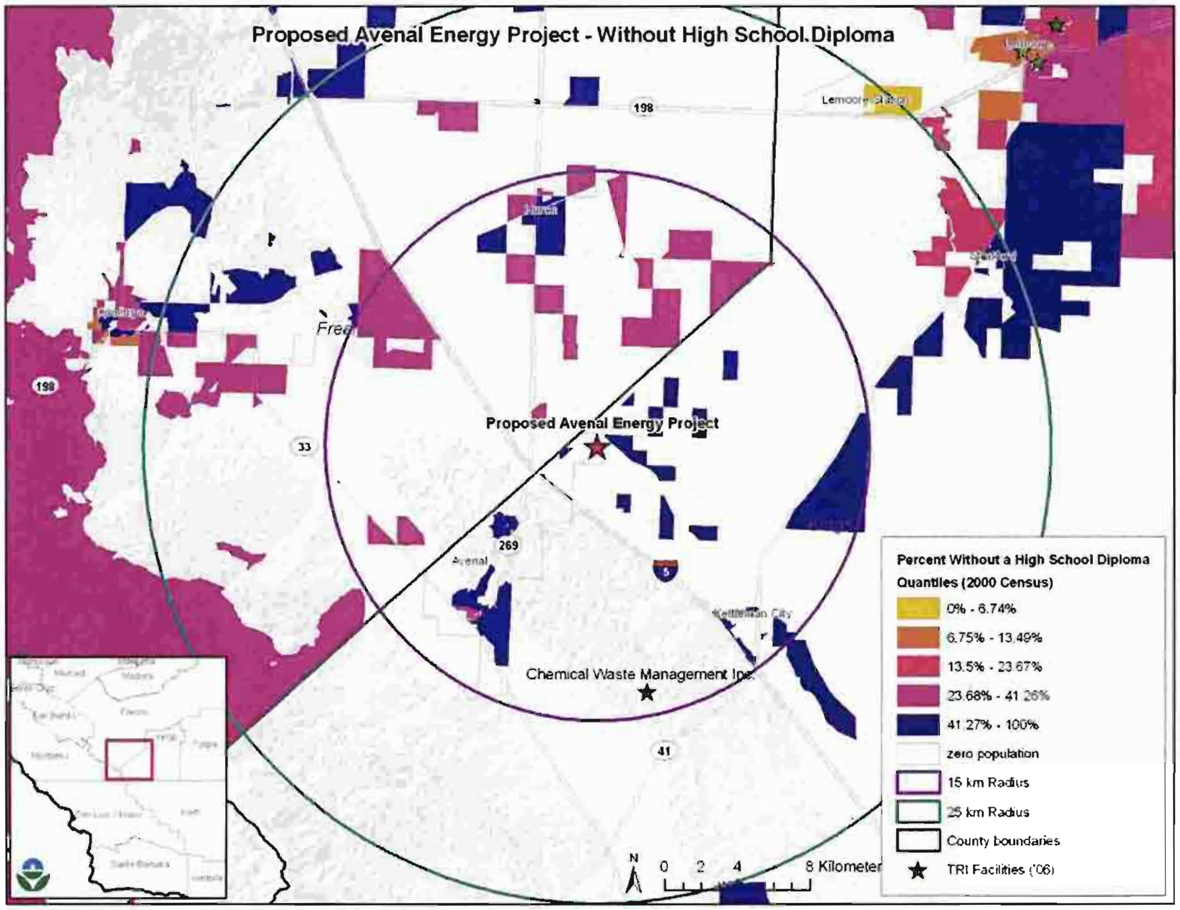
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493
Source: US Census 2000, Summary Tape File 3							

Figure 6 - Percent Age Over 25 without High School Diploma



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
15	25,660	85	24	3	34	51	27,221
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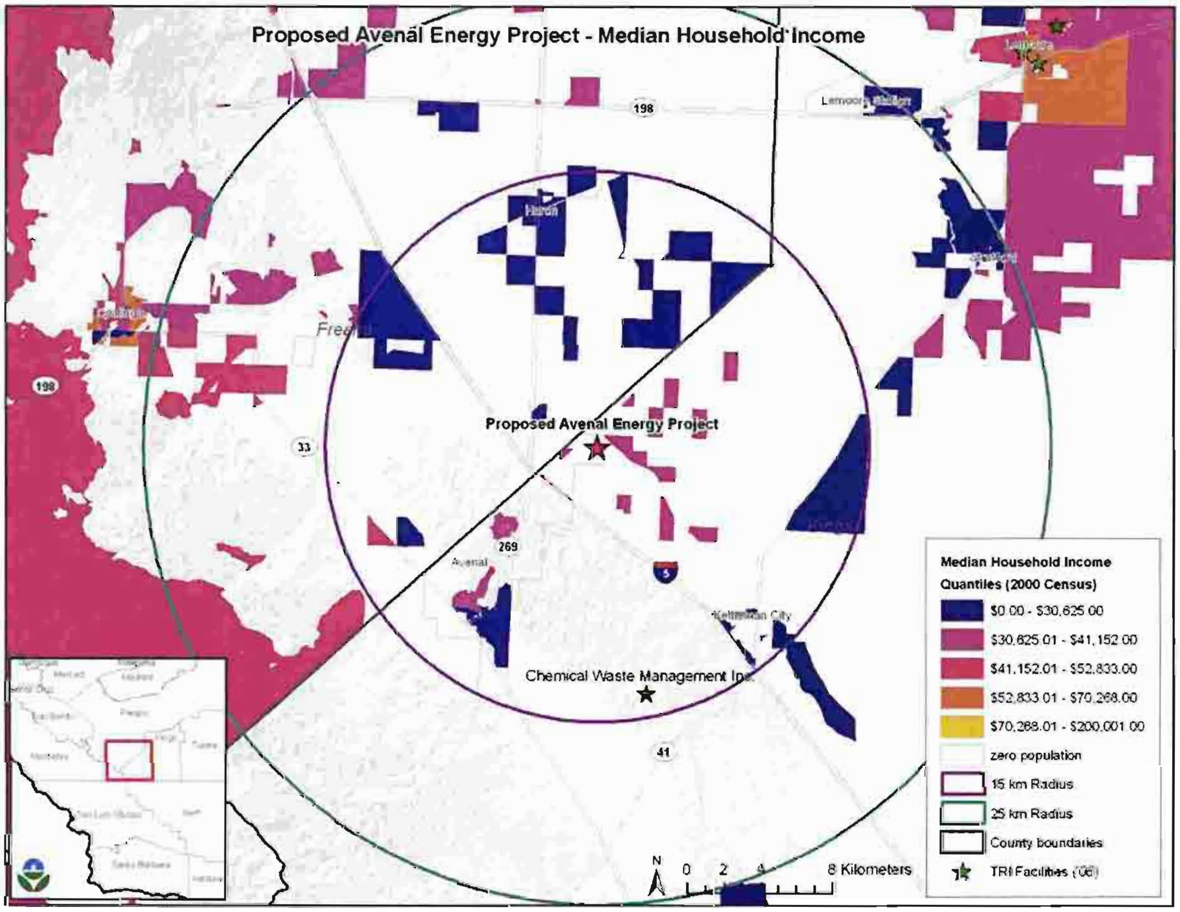
San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493
Source: US Census 2000, Summary Tape File 3							

Figure 7 - Median Household Income



Radius, km	Population	Percent Minority	Percent Under Age 18	Percent Over Age 64	Percent Linguistically Isolated	Percent w/o High School Diploma	Average Median Household Income, $
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San Joaquin Valley	3,182,529	55	33	10	9	33	38,162
State of CA	33,871,648	53	27	11	10	23	47,493
Source: US Census 2000, Summary Tape File 3							

Appendix 2

Monitored Hourly NO_2 Values in California (2006-2009)*

Monitor ID	Street Address	City Name	County Name	One Hour NO_2 Design Value (ppb)
06-001-0007-42602-1	793 RINCON AVE.	Livermore	Alameda	47.3
06-001-0009-42602-1	9925 International Blvd.	Oakland	Alameda	51.6
06-001-0011-42602-1	1100 21st Street	Oakland	Alameda	47.0
06-001-1001-42602-1	40733 CHAPEL WAY.	Fremont	Alameda	47.0
06-001-2004-42602-1	1340 Sixth Street	Berkeley	Alameda	45.0
06-007-0002-42602-1	468 MANZANITA AVE.	Chico	Butte	38.0
06-013-0002-42602-1	2956-A TREAT BOULEVARD	Concord	Contra Costa	36.6
06-013-1002-42602-1	5551 BETHEL ISLAND RD.	Bethel Island	Contra Costa	31.0
06-013-1004-42602-1	1865 D RUMRILL BLVD	San Pablo	Contra Costa	41.6
06-013-3001-42602-1	583 W. 10TH ST.	Pittsburg	Contra Costa	44.0
06-019-0007-42602-1	4706 E. DRUMMOND ST.	Fresno	Fresno	61.0
06-019-0008-42602-1	3425 N FIRST ST.	Fresno	Fresno	56.6
06-019-0242-42602-1	SIERRA SKYPARK#2-BLYTHE & CHNNLT	Fresno	Fresno	39.6
06-019-4001-42602-1	9240 S. RIVERBEND.	Parlier	Fresno	39.3
06-019-5001-42602-1	908 N VILLA AVE.	Clovis	Fresno	55.6
06-023-1004-42602-1	717 SOUTH AVENUE	Eureka	Humboldt	22.3
06-025-0005-42602-1	1029 ETHEL ST, CALEXICO HIGH SCHOOL	Calexico	Imperial	72.3
06-025-0006-42602-1	CALEXICO - EAST	Calexico	Imperial	70.6
06-025-1003-42602-1	150 9TH ST.	El Centro	Imperial	50.3
06-029-0007-42602-1	JOHNSON FARM.	Edison	Kern	40.0
06-029-0010-42602-1	1128 GOLDEN STATE HIGHWAY	Bakersfield	Kern	60.0
06-029-0014-42602-1	5558 CALIFORNIA AVE.	Bakersfield	Kern	61.0
06-029-5001-42602-1	20401 BEAR MTN BLVD, ARVIN, CA.	Arvin	Kern	31.6
06-029-6001-42602-1	548 WALKER ST.	Shafter	Kern	53.3
06-031-1004-42602-1	807 SOUTH IRWIN ST.	Hanford	Kings	50.0
06-037-0002-42602-2	803 N. LOREN AVE.	Azusa	Los Angeles	78.3
06-037-0016-42602-1	840 LAUREL	Glendora	Los Angeles	69.6
06-037-0113-42602-1	VA HOSPITAL	West Los Angeles	Los Angeles	63.3
06-037-1002-42602-2	228 W. PALM AVE.	Burbank	Los Angeles	75.3
06-037-1103-42602-1	1630 N MAIN ST.	Los Angeles	Los Angeles	81.3
06-037-1201-42602-2	18330 GAULT ST., RESEDA	Reseda	Los Angeles	59.6

Monitor ID	Street Address	City Name	County Name	One Hour NO_2 Design Value (ppb)
06-037-1301-42602-2	11220 LONG BEACH BLVD.	Lynwood	Los Angeles	76.5
06-037-1302-42602-1	700 North Bullis Road	Compton	Los Angeles	85.5
06-037-1602-42602-1	4144 SAN GABRIEL RIVER PKWY.	Pico Rivera	Los Angeles	83.0
06-037-1701-42602-2	924 N. GAREY AVE.	Pomona	Los Angeles	81.0
06-037-2005-42602-1	752 S. WILSON AVE.	Pasadena	Los Angeles	69.6
06-037-4002-42602-2	3648 N. LONG BEACH BLVD.	Long Beach	Los Angeles	78.3
06-037-5005-42602-1	7201 W. WESTCHESTER PARKWAY	Los Angeles	Los Angeles	71.3
06-037-6012-42602-1	22224 PLACERITA CANYON RD.	Santa Clarita	Los Angeles	57.3
06-037-9033-42602-1	43301 DIVISION ST.	Lancaster	Los Angeles	53.3
06-039-0004-42602-1	RD. 29 1/2 NO. OF AVE 8	Madera	Madera	40.3
06-041-0001-42602-1	534 4TH ST.	San Rafael	Marin	44.6
06-043-0003-42602-1	TURTLEBACK DOME	Yosemite National Park	Mariposa	5.1
06-045-0008-42602-1	306 E. GOBBI STREET	Ukiah	Mendocino	32.3
06-045-0009-42602-1	899 SO MAIN STREET	Willits	Mendocino	26.5
06-047-0003-42602-1	385 S. COFFEE AVENUE	Merced	Merced	43.3
06-053-1003-42602-1	867 E. LAUREL Dr	Salinas	Monterey	34.3
06-055-0003-42602-1	2552 JEFFERSON AVE.	Napa	Napa	39.3
06-057-0005-42602-1	200 LITTON DR.	Grass Valley	Nevada	26.0
06-059-0007-42602-5	1630 W. PAMPAS LANE	Anaheim	Orange	65.3
06-059-1003-42602-1	2850 MESA VERDE DR. EAST	Costa Mesa	Orange	60.3
06-059-5001-42602-2	621 W. LAMBERT	La Habra	Orange	69.0
06-061-0006-42602-1	151 NO SUNRISE BLVD.	Roseville	Placer	53.0
06-065-0004-42602-1	10551 Bellegrave	Mira Loma	Riverside	73.0
06-065-0012-42602-1	200 S. HATHAWAY ST.	Banning	Riverside	58.3
06-065-1003-42602-3	7002 MAGNOLIA AVE.	Riverside	Riverside	63.5
06-065-5001-42602-2	FS-590 RACQUET CLUB AVE.	Palm Springs	Riverside	45.0
06-065-8001-42602-2	5888 MISSION BLVD.	Rubidoux	Riverside	63.0
06-065-8005-42602-1	5130 POINSETTIA PLACE	Mira Loma	Riverside	59.0
06-065-9001-42602-1	506 W FLINT ST.	Lake Elsinore	Riverside	48.0
06-067-0002-42602-1	7823 BLACKFOOT WAY.	North Highlands	Sacramento	77.0
06-067-0006-42602-1	DEL PASO-2701 AVALON DR.	Sacramento	Sacramento	45.6

Monitor ID	Street Address	City Name	County Name	One Hour NO_2 Design Value (ppb)
06-067-0010-42602-1	1309 T ST.	Sacramento	Sacramento	55.6
06-067-0011-42602-1	12490 BRUCEVILLE RD.	Elk Grove	Sacramento	35.6
06-067-0012-42602-1	50 NATOMA STREET	Folsom	Sacramento	32.6
06-067-0013-42602-1	3801 AIRPORT ROAD	Sacramento	Sacramento	52.0
06-067-0014-42602-1	68 GOLDENLAND COURT	Sacramento	Sacramento	47.5
06-071-0001-42602-1	200 E. BUENA VISTA	Barstow	San Bernardino	63.0
06-071-0306-42602-1	14306 PARK AVE.	Victorville	San Bernardino	62.0
06-071-1004-42602-2	1350 SAN BERNARDINO RD.	Upland	San Bernardino	70.0
06-071-1234-42602-1	CORNER OF ATHOL AND TELESCOPE	Trona	San Bernardino	42.6
06-071-2002-42602-1	14360 ARROW BLVD.	Fontana	San Bernardino	74.0
06-071-9004-42602-1	24302 4TH ST.	San Bernardino	San Bernardino	63.6
06-073-0001-42602-1	80 E. 'J' ST.	Chula Vista	San Diego	58.6
06-073-0003-42602-1	1155 REDWOOD AVE.	El Cajon	San Diego	53.3
06-073-0006-42602-1	5555 OVERLAND AVE.	San Diego	San Diego	56.3
06-073-1002-42602-1	600 E. VALLEY PKWY.	Escondido	San Diego	62.6
06-073-1006-42602-1	2300 VICTORIA DR.	Alpine	San Diego	38.0
06-073-1008-42602-1	21441-W B STREET	Camp Pendleton (Marine Corps Base)	San Diego	58.6
06-073-1010-42602-1	1110 BEARDSLEY STREET	San Diego	San Diego	69.6
06-073-2007-42602-1	1100 PASEO INTERNATIONAL	Otay Mesa	San Diego	84.6
06-075-0005-42602-1	10 ARKANSAS ST.	San Francisco	San Francisco	54.3
06-077-1002-42602-2	HAZELTON-HD.	Stockton	San Joaquin	57.6
06-077-3005-42602-1	5749 S. TRACY BLVD.	Tracy	San Joaquin	38.6
06-079-3001-42602-1	MORRO BAY BLVD & KERN AVE.	Morro Bay	San Luis Obispo	34.6
06-079-4002-42602-1	NIPOMO REGIONAL PARK.	Nipomo	San Luis Obispo	29.3
06-079-8001-42602-1	6005 LEWIS AVENUE	Atascadero	San Luis Obispo	42.0
06-081-1001-42602-1	897 BARRON AVE.	Redwood City	San Mateo	45.6
06-083-0008-42602-1	EL CAPITAN ST PRK, HWY 10	Capitan	Santa Barbara	29.6
06-083-0011-42602-1	700 E. CANON PERDIDO	Santa Barbara	Santa Barbara	46.0
06-083-1008-42602-1	906 S BROADWAY	Santa Maria	Santa Barbara	42.3
06-083-1013-42602-1	HS & P FACILITY-500 M SW.	Lompoc	Santa Barbara	7.0
06-083-1014-42602-1	PARADISE RD.	Los Padres National Forest	Santa Barbara	6.3
06-083-1018-42602-1	GTC B-HWY 101 NEAR NOJOQUI PASS, GAVIOTA	Gaviota	Santa Barbara	23.3

Monitor ID	Street Address	City Name	County Name	One Hour NO_2 Design Value (ppb)
06-083-1021-42602-1	GOBERNADOR RD.	Carpinteria	Santa Barbara	18.3
06-083-1025-42602-1	LFC #1-LAS FLORES CANYON	Capitan	Santa Barbara	14.0
06-083-2004-42602-1	128 S 'H' ST.	Lompoc	Santa Barbara	28.3
06-083-2011-42602-1	380 N FAIRVIEW AVENUE	Goleta	Santa Barbara	35.3
06-083-4003-42602-1	STS POWER PLANT	Vandenberg Air Force Base	Santa Barbara	8.6
06-085-0005-42602-1	158B JACKSON ST.	San Jose	Santa Clara	53.3
06-087-0003-42602-1	Center St	Davenport	Santa Cruz	22.0
06-095-0004-42602-1	304 TUOLUMNE ST.	Vallejo	Solano	42.3
06-095-0006-42602-1	E SECOND ST.	Benicia	Solano	34.5
06-097-0003-42602-1	837 5TH ST.	Santa Rosa	Sonoma	38.0
06-099-0006-42602-1	900 S MINARET STREET	Turlock	Stanislaus	48.6
06-101-0003-42602-1	773 ALMOND ST.	Yuba City	Sutter	49.3
06-107-2002-42602-1	310 N CHURCH ST.	Visalia	Tulare	61.3
06-111-2002-42602-1	5400 COCHRAN STREET	Simi Valley	Ventura	44.6
06-111-3001-42602-1	RIO MESA SCHOOL	El Rio	Ventura	37.6
06-113-0004-42602-1	UC DAVIS-CAMPUS	Davis	Yolo	36.0
TT-586-0009-42602-1	Pechanga Tribal Government Building	Not in a city	Riverside	25.8

*Design values are calculated according to the Primary NO2 NAAQS Final Rule (40CFR Part 50 Appendix S, Section 3), based on data queried from EPA's Air Quality System (AQS, http://www.epa.gov/ttn/airs/airsaqs/).

Appendix 3

NOx Emissions Projections and Controls – Kings County, California

NOx Emissions Projections and Controls - Kings County, California annual average daily emissions in tons per day						
Source Category	Example sources	Year			Change 2010-2020	
		2010	2015	2020	Value	Percent
fuel combustion at stationary sources	boilers at utilities and factories, irrigation pumps,	2.2	1.5	2.3	0.1	3.7%
waste disposal	landfills, wastewater treatment plants	0.0	0.0	0.0	0.0	16.7%
residential fuel combustion	woodburning, water heaters, cooking	0.1	0.1	0.1	0.0	-4.0%
fires	structural and wild fires	0.0	0.0	0.0	0.0	14.3%
managed burning and disposal	agricultural waste burning, prescribed burning	0.3	0.3	0.3	0.0	-2.8%
passenger vehicles	cars, light duty trucks, motorcylces, motor homes	1.8	1.2	0.8	-1.0	-54.3%
medium and light heavy duty trucks		1.3	1.0	0.7	-0.7	-49.2%
heavy heavy duty diesel and gas trucks	local, intrastate, and interstate trucks	15.0	9.8	6.6	-8.4	-56.1%
buses	tour, transit, and school buses	0.4	0.4	0.4	0.0	-6.7%
aircraft	commerical and military	3.0	3.4	3.7	0.8	26.6%
trains		0.9	1.0	1.0	0.1	10.6%
recreational equipment	boats, off-road motorcycles	0.0	0.0	0.0	0.0	19.0%
off-road equipment	construction, oil/gas exploration, forklifts	0.6	0.5	0.4	-0.2	-34.4%
farm equipment	tractors, loaders	2.2	1.5	1.0	-1.2	-53.1%
Total annual average day NOx emissions, Kings County		27.837	20.711	17.320	-10.5	-37.8%

Source: ARB, CEPAM-2009 Almanac - 2/6/2011

APP. Q

California Communities Environmental Health Screening Tool, Version 1.1 (CalEnviroScreen 1.1)

Guidance and Screening Tool

September 2013 Update

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California Environmental Protection Agency

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Acknowledgements:

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Cal/EPA Boards and Departments who provided comments and data;
California Department of Public Health and the Public Health Institute

Residents and stakeholders who participated in our regional workshops; Tara Zagofsky, consultant and facilitator, University of California, Davis, Common Ground: Center for Cooperative Solutions

Dr. Rachel Morello-Frosch and academic colleagues at the University of California, Berkeley

Academic expert panel who provided comments at a workshop in September 2012

Graduate students assisting in the project, including Christopher Carosino, Laurel Plummer and Jocelyn Claude

PREFACE TO VERSION 1.1

CalEnviroscreen 1.1 is the latest iteration of the CalEnviroScreen tool. It uses the same methodology as Version 1.0 except that the indicator for race/ethnicity was removed from the calculation of a community's CalEnviroScreen score. This change was made to facilitate the use of the tool by government entities that may be restricted from considering race/ethnicity when making certain decisions. While race and ethnicity will not be used in compiling a score using CalEnviroScreen, a new section has been added that provides information on the racial and ethnic composition of communities throughout the state. This information will help us to better understand the correlation between race/ethnicity and the pollution burdens facing communities in California. Cal/EPA and OEHHA are committed to updating and expanding this section as new versions of the tool are released.

GUIDANCE FROM THE SECRETARY

During the past three years, one of our top priorities has been to integrate environmental justice principles throughout the California Environmental Protection Agency's (Cal/EPA's or Agency's) boards, departments and office. State law defines environmental justice to mean "the fair treatment of people of all races, cultures, and incomes with respect to the development, adoption, implementation and enforcement of environmental laws, regulations, and policies." This definition should not just be words or an illusory concept; rather, it must be a goal to strive for and achieve. Cal/EPA's mission is to restore, protect and enhance the environment, and to ensure public health, environmental quality and economic vitality. Environmental justice and investment in communities burdened by pollution are critical to accomplishing this mission.

Despite the best efforts of many segments of society, a large number of Californians live in the midst of multiple sources of pollution and some people and communities are more vulnerable to the effects of pollution than others. In order to respond to this situation, it is important to identify the areas of the state that face multiple pollution burdens so programs and funding can be targeted appropriately toward improving the environmental health and economic vitality of the most impacted communities. For this reason, the Agency and the Office of Environmental Health Hazard Assessment (OEHHA) have developed a science-based tool for evaluating multiple pollutants and stressors in communities, called the California Communities Environmental Health Screening Tool (CalEnviroScreen).

To ensure that CalEnviroScreen is properly understood and utilized, we are providing the following guidance to the Agency, its boards, departments, and office, as well as the public and stakeholders.

CalEnviroScreen should be used primarily to assist the Agency in carrying out its environmental justice mission: to conduct its activities in a manner that ensures the fair treatment of all Californians, including minority and low-income populations. The tool is the next step in the implementation of the Agency's 2004 Environmental Justice Action Plan, which called for the development of guidance to analyze the impacts of multiple pollution sources in California communities.

The tool shows which portions of the state have higher pollution burdens and vulnerabilities than other areas, and therefore are most in need of assistance. In a time of limited resources, it will provide meaningful insight into how decision makers can focus available time, resources, and programs to improve the environmental health of Californians, particularly those most burdened by pollution. The tool uses existing environmental, health, demographic and socioeconomic data to create a screening score for communities across the state. An area with a high score would be expected to experience much higher impacts than areas with low scores.

Cal/EPA and OEHHA are committed to revising the tool in the future, using an open and public process, as new information becomes available in order to make the tool as meaningful and as current as possible. Over the next several years, we plan to refine the tool by considering additional indicators, modifying the geographic scale, enhancing the current indicators, and reassessing the tool's methodology. In addition, we will look for new ways to ensure the tool is accessible and comprehensible to the public.

Background

Cal/EPA released the first draft of CalEnviroScreen for public review and comment in July 2012. This draft built upon a 2010 report[1] that described the underlying science and a general method for identifying communities that face multiple pollution burdens. It further developed and explained the methodology described in the 2010 report. After releasing the first draft, Cal/EPA and OEHHA conducted 12 public workshops in seven regions throughout the state. At these workshops, the methodology and our conclusions were discussed with the public and a wide range of stakeholders, including community, business, industry, academic and governmental groups. These regional workshops yielded over 1000 oral and written comments and questions. A subsequent draft was released in January 2013. Cal/EPA and OEHHA solicited additional comments and suggestions, and considered them in making additional changes to the tool.

Potential Uses

Potential uses of the tool by Cal/EPA and its boards, departments, and office include administering environmental justice grants, promoting greater compliance with environmental laws, prioritizing site-cleanup activities, and identifying opportunities for sustainable economic development in heavily impacted neighborhoods. Other entities and interested parties may identify additional uses for this tool and the information it provides.

Implementation of SB 535

CalEnviroScreen will inform Cal/EPA's identification of disadvantaged communities pursuant to Senate Bill 535 (De León, Chapter 830, Statutes of 2012). SB 535 requires Cal/EPA to identify disadvantaged communities based on geographic, socioeconomic, public health, and environmental hazard criteria. It also requires that the investment plan developed and submitted to the Legislature pursuant to Assembly Bill 1532 (John A. Pérez, Chapter 807, Statutes of 2012) allocate no less than 25 percent of available proceeds from the carbon auctions held under California's Global Warming Solutions Act of 2006 to projects that will benefit these disadvantaged communities. At least 10 percent of the available moneys from these auctions must be directly allocated in such communities. Since CalEnviroScreen has been developed to identify areas that are disproportionately affected by pollution and those areas whose populations are socioeconomically disadvantaged, it is well suited for the purposes described by SB 535.

Environmental Justice Activities

CalEnviroScreen will be useful in administering the Agency's Environmental Justice Small Grant Program, and may guide other grant programs as well as environmental education and community programs throughout the state. It will also help to inform Agency boards and departments when they are budgeting scarce resources for cleanup and abatement projects. Additionally, CalEnviroScreen will help to guide boards and departments when planning their community engagement and outreach efforts. Knowing which areas of the state have higher relative environmental burdens will not only help with efforts to increase compliance with environmental laws in disproportionately impacted areas, but also will provide Cal/EPA and its boards, departments, and office with additional insights on the potential implications of their activities and decisions.

Local and Regional Governments

Local and regional governments, including regional air districts, water districts, and planning and transit

[1] OEHHA and Cal/EPA (2012) *Cumulative Impacts: Building a Scientific Foundation*, Sacramento, CA. Available online at: http://www.oehha.ca.gov/ej/cipa123110.html

agencies, may also find uses for this tool. Cal/EPA will continue to work with local and regional governments to further explore the applicability of CalEnviroScreen for other uses. This includes the possibility of helping to identify and plan for opportunities for sustainable development in heavily impacted neighborhoods. These areas could also be targeted for cleaning up blight and promoting development in order to bring in jobs and increase economic stability. As an example, the tool could assist efforts to develop planning and financial incentives to retain jobs and create new, sustainable business enterprises in disproportionately impacted communities.

Of course, it will be important to work with organizations such as economic development corporations, workforce investment boards, local chambers of commerce, and others to develop strategies to help businesses thrive in the identified areas and to attract new businesses and services to those areas. CalEnviroScreen may also assist local districts and governments with meeting their obligations under certain state funding programs. Finally, it is important to remember that CalEnviroScreen provides a broad environmental snapshot of a given region. While the data gathered in developing the tool could be useful for decision makers when assessing existing pollution sources in an area, more precise data are often available to local governments and would be more relevant in conducting such an examination.

General Notes and Limitations

CalEnviroScreen was developed for Cal/EPA and its boards, departments, and office. Its publication does not create any new programs, regulatory requirements or legal obligations. There is no mandate express or implied that local governments or other entities must use the tool or its underlying data. Planning, zoning and development permits are matters of local control and local governments are free to decide whether the tool's output or the information contained in the tool provide an understanding of the environmental burdens and vulnerabilities in their localities.

While CalEnviroScreen will assist Cal/EPA and its boards, departments, and office in prioritizing resources and help promote greater compliance with environmental laws, it is important to note some of its limitations. The tool's output provides a relative ranking of communities based on a selected group of available datasets, through the use of a summary score. The CalEnviroScreen score is not an expression of health risk, and does not provide quantitative information on increases in cumulative impacts for specific sites or projects. Further, as a comparative screening tool, the results do not provide a basis for determining when differences between scores are significant in relation to public health or the environment. Accordingly, the tool is not intended to be used as a health or ecological risk assessment for a specific area or site.

Additionally, the CalEnviroScreen scoring results are not directly applicable to the cumulative impacts analysis required under the California Environmental Quality Act (CEQA). The statutory definition of "cumulative impacts" contained in CEQA is substantially different than the working definition of "cumulative impacts" used to guide the development of this tool. Therefore, the information provided by this tool cannot be used as a substitute for an analysis of the cumulative impacts of any specific project for which an environmental review is required by CEQA.

Moreover, CalEnviroScreen assesses environmental factors and effects on a regional or community-wide basis and cannot be used in lieu of performing an analysis of the potentially significant impacts of any specific project. Accordingly, a lead agency must determine independently whether a proposed project's impacts may be significant under CEQA based on the evidence before it, using its own discretion and judgment. The tool's results are not a substitute for this required analysis. Also, this tool considers some social, health, and economic factors that may not be relevant when doing an analysis under CEQA. Finally, as mentioned above, the tool's output should not be used as a focused risk assessment of a given community or site. It cannot predict or quantify specific health risks or effects associated with cumulative exposures identified for a given community or individual.

Conclusion

We are proud of the collaborative work of OEHHA and the input of the departments and boards in Cal/EPA as well as the level of public participation and level of input we received in the development of CalEnviroScreen. This project represents the largest public screening tool effort in the nation – both in geographic scope and level of detail. It is an achievement that could not have been realized had it not been for the tireless efforts of OEHHA and the invaluable input of all of our stakeholders. The development of CalEnviroScreen involved many residents, community-based organizations, nongovernmental organizations, local officials, state agencies and representatives from business, industry and academia. The release of the CalEnviroScreen was just the first step. If CalEnviroScreen is to succeed, that cooperative effort must continue. I welcome your active participation as we move forward with future versions of CalEnviroScreen and work to advance environmental justice and economic vitality.

Matthew Rodriquez
Secretary for Environmental Protection

April 2013
Updated September 2013

TABLE OF CONTENTS

INTRODUCTION

Californians are burdened by environmental problems and sources of pollution in ways that vary across the state. Some Californians are more vulnerable to the effects of pollution than others. This document describes a science-based method for evaluating multiple pollution sources in a community while accounting for a community's vulnerability to pollution's adverse effects. Factors that contribute to a community's pollution burden or vulnerability are often referred to as stressors. The CalEnviroScreen tool can be used to identify California's most burdened and vulnerable communities. This can help inform decisions at the California Environmental Protection Agency's (Cal/EPA) boards and departments by identifying places most in need of assistance.

Statewide Evaluation

Using CalEnviroScreen, a statewide analysis has been conducted that identifies communities in California most burdened by pollution from multiple sources and most vulnerable to its effects, taking into account their socioeconomic characteristics and underlying health status. In doing so, CalEnviroScreen

- Produces a *relative*, rather than absolute, measure of impact.
- Provides a baseline assessment and methodology that can be expanded upon and updated periodically as important additional information becomes available.
- Demonstrates a practical and scientific methodology for evaluating multiple pollution sources and stressors that takes into account a community's vulnerability to pollution.

Community impact assessment from multiple sources and stressors is complex and difficult to approach with traditional risk assessment practices. Chemical-by-chemical, source-by-source, route-by-route risk assessment approaches are not well suited to the assessment of community-scale impacts, especially for identifying the most impacted places across all of California. Although traditional risk assessment may account for the heightened sensitivities of some groups, such as children and the elderly, it has not considered other community characteristics that have been shown to affect vulnerability to pollution, such as socioeconomic factors or underlying health status.

Given the limits of traditional risk assessment, the Office of Environmental Health Hazard Assessment (OEHHA) and Cal/EPA developed a workable approach to conduct a statewide evaluation of community impacts. It built upon the general method and a description of the underlying science published in Cal/EPA's and OEHHA's 2010 report, *Cumulative Impacts: Building A Scientific Foundation*. The method emerges from basic risk assessment concepts and is sufficiently expansive to incorporate multiple factors that reflect community impacts that have not been included in traditional risk assessments. The tool presents a broad picture of the burdens and vulnerabilities different areas confront from environmental pollutants.

Stakeholder Involvement

Transparency and public input into government decision making and policy development are the cornerstones of environmental justice. In that spirit, the framework for the CalEnviroScreen was developed with the assistance of the Cumulative Impacts and Precautionary Approaches (CIPA) Work Group, consisting of representatives of business and non-governmental organizations, academia and government. The CIPA Work Group also reviewed draft versions of this report and provided critical feedback and input that guided the development of this tool. We appreciate the considerable time and effort that the Work Group has devoted to this project since 2008. We also appreciate the input from the general public we heard during the Work Group meetings.

Cal/EPA also received input on a previous draft of this document at a series of regional and stakeholder-specific public workshops and an academic workshop.[2] Input from California communities, businesses, local governments, California tribes, community-based organizations, and other stakeholders as well as academia was critical in the development of this project and is reflected in changes made to the final document.

Work in this field continues and presents opportunities to refine the tool. Thus, over the next several years we plan to release new versions of the tool that include improvements to the indicators used, the geographic scale, the methodology employed and the accessibility of the tool to the public. Cal/EPA remains committed to an open and public process in developing future versions of the tool.

This report describes CalEnviroScreen's methodological approach, which relies on the use of indicators to measure factors that affect pollution impacts in communities. The report describes the indicators and the criteria used to select them as well as the geographic scale used to define communities. Data representing the indicators for the different areas of the state were obtained and analyzed and are presented here as statewide maps.[3] All the indicators for a locale are combined to generate a score for the community. The report concludes by providing general results for the statewide evaluation, presented as maps showing the top 5 and10 percent of the most impacted communities in California.

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[2] Additional information on these workshops as well as the CIPA Work Group meetings and the development of the tool are available at www.oehha.ca.gov/ej/index.html.

[3] The community scores for individual indicators are available online at http://www.oehha.ca.gov/ej/index.html.

What is New in CalEnviroScreen 1.1?

Since CalEnviroScreen was originally released in April 2013, interest has emerged in using the screening tool for a number of applications outside of Cal/EPA, including for grant funding allocation decisions. In light of concerns over whether CalEnviroScreen's inclusion of a race/ethnicity indicator may place legal barriers to certain uses of the tool by government agencies, Cal/EPA has determined that removing it would best support these additional applications. Version 1.1 incorporates this change.

While the CalEnviroScreen 1.1 score no longer includes a race/ethnicity indicator, the report retains other key socioeconomic indicators, such as poverty, linguistic isolation, and educational attainment. Additionally, the CalEnviroScreen 1.1 report adds a new section that evaluates the relationship between CalEnviroScreen scores and race/ethnicity. These results reveal the disproportionate pollution burden and population vulnerability facing non-white communities.

METHOD

Definition of Cumulative Impacts

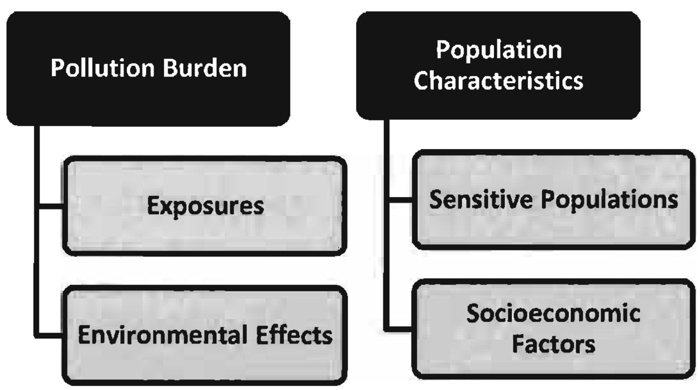
Cal/EPA adopted the following working definition of cumulative impacts[4] in 2005:

> *"Cumulative impacts means exposures, public health or environmental effects from the combined emissions and discharges, in a geographic area, including environmental pollution from all sources, whether single or multi-media, routinely, accidentally, or otherwise released. Impacts will take into account sensitive populations and socioeconomic factors, where applicable and to the extent data are available."*

CalEnviroScreen Model

The CalEnviroScreen model is based on the Cal/EPA working definition in that:

- The model is place-based and provides information for the entire State of California on a geographic basis. The geographic scale selected is intended to be useful for a wide range of decisions.
- The model is made up of multiple components cited in the above definition as contributors to cumulative impacts. The model includes two components representing pollution burden – exposures and environmental effects – and two components representing population characteristics – sensitive populations (e.g., in terms of health status and age) and socioeconomic factors.



[4] This definition differs from the statutory definition of "cumulative impacts" contained in the California Environmental Quality Act (CEQA). While the term is the same, they cannot be used interchangeably. For a detailed discussion of this issue, please see the Guidance from the Secretary.

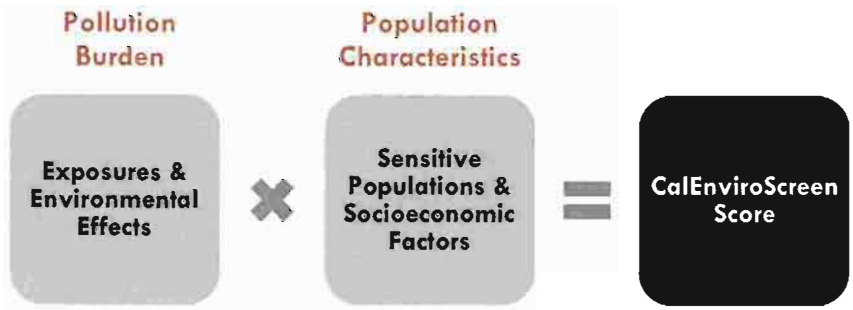
Model Characteristics

The model:

- Uses a suite of statewide indicators to characterize both pollution burden and population characteristics.
- Uses a limited set of indicators in order to keep the model simple.
- Assigns scores for each of the indicators in a given geographic area.
- Uses a scoring system to weight and sum each set of indicators within pollution burden and population characteristics components.
- Derives a CalEnviroScreen score for a given place relative to other places in the state, using the formula below.

Formula for Calculating CalEnviroScreen Score

After the components are scored, the scores are combined as follows to calculate the overall CalEnviroScreen Score:



Rationale for Formula

The mathematical formula for calculating scores uses multiplication. Scores for the pollution burden and population characteristics categories are multiplied together (rather than added, for example). Although this approach may be less intuitive than simple addition, there is scientific support for this approach to scoring.

Multiplication was selected for the following reasons:

1. *Scientific Literature*: Existing research on environmental pollutants and health risk has consistently identified socioeconomic and sensitivity factors as "effect modifiers." For example, numerous studies on the health effects of particulate air pollution have found that low socioeconomic status is associated with about a 3-fold increased risk of morbidity or mortality for a given level of particulate pollution (Samet and White, 2004). Similarly, a study of asthmatics found that their sensitivity to an air pollutant was up to 7-fold greater than non-asthmatics (Horstman *et al.*, 1986). Low-socioeconomic status African-American mothers exposed to traffic-related air pollution were twice as likely to deliver preterm babies (Ponce *et al.*, 2005). The young can be 10 times more sensitive to environmental carcinogen exposures than adults (OEHHA, 2009). Studies of increased

risk in vulnerable populations can often be described by effect modifiers that amplify the risk. This research suggests that the use of multiplication makes sense based on the existing scientific literature.

2. *Risk Assessment Principles*: Some members of the general population (such as children) may be 10 times more sensitive to some chemical exposures than others. Risk assessments, using principles first advanced by the National Academy of Sciences, apply numerical factors or multipliers to account for potential human sensitivity (as well as other factors such as data gaps) in deriving acceptable exposure levels (US EPA, 2012).
3. *Established Risk Scoring Systems*: Priority-rankings done by various emergency response organizations to score threats have used scoring systems with the formula: Risk = Threat × Vulnerability (Brody *et al.*, 2012). These formulas are widely used and accepted.

Maximum Scores for Combined Components

Component Group	Maximum Score*
Pollution Burden	
Exposures and Environmental Effects	10
Population Characteristics	
Sensitive Populations and Socioeconomic Factors	10
CalEnviroScreen Score	**Up to 100 (= 10 × 10)**

* The scores for each group were rounded to one decimal place before multiplying to calculate the CalEnviroScreen Score (for example, 6.5 out of a possible 10)

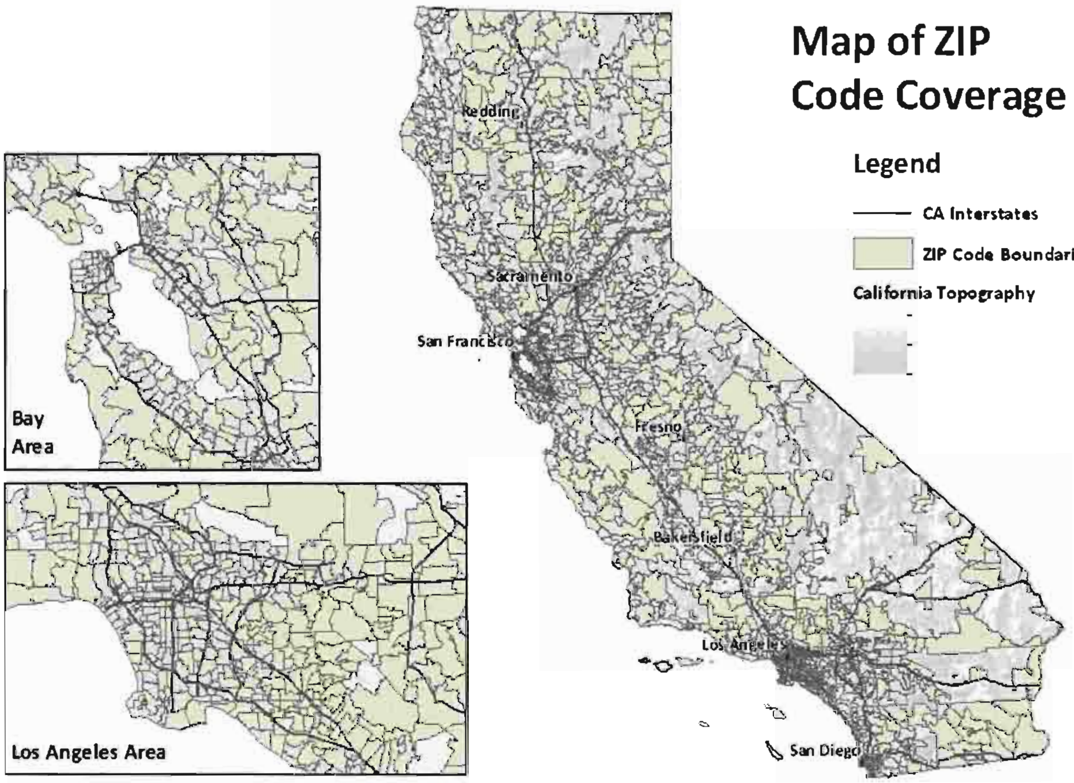
Notes on Scoring System

In the CalEnviroScreen scoring model, the Population Characteristics are considered to be a modifier of the Pollution Burden. In mathematical terms, the Pollution Burden is the multiplicand and Population Characteristics is the multiplier, with the CalEnviroScreen Score as the product. Because the final CalEnviroScreen score represents the product of two numbers, the final ordering of the communities is independent of the magnitude of the scale chosen for each (without rounding scores). That is, the communities would be ordered the same in their final score if the Population Characteristics were scaled to 3, 5, or 10, for example. Here, a scale up to 10 was chosen for convenience.

Selection of Geographic Scale

For this version of CalEnviroScreen, the ZIP code scale is the unit of analysis. A representation of ZIP codes, called ZCTAs (ZIP Code Tabulation Areas), is available from the Census Bureau. These were updated in 2010.[5] For simplicity, these areas are referred to as ZIP codes throughout this report.

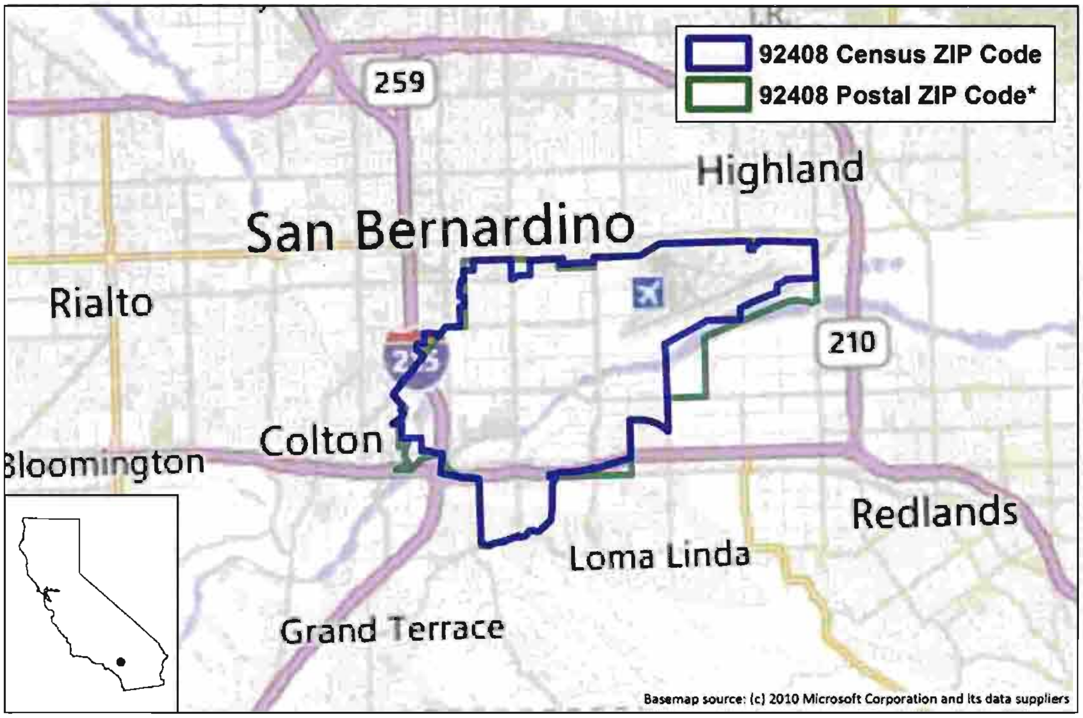
The census ZIP codes cover areas where people live, but do not include many sparsely populated places, like national parks. There are approximately 1,800 census ZIP codes in California, representing a relatively fine scale of analysis.[6]



[5] Additional information on the U.S. Census Bureau's ZIP Code Tabulation Areas may be found on their website: http://www.census.gov/geo/ZCTA/zcta.html.

[6] In a future version of the tool, results will also be available at the census tract scale.

The following map shows the relationship between census-derived ZIP codes (ZCTAs) and approximate postal service ZIP codes for an area in San Bernardino. For many ZIP codes they are similar.



* Postal service ZIP code approximations were obtained from Esri, Inc.

Analysis of CalEnviroScreen 1.1 Scores and Race/Ethnicity

The relationship between the calculated CalEnviroScreen score and race/ethnicity was examined. After sorting all the ZIP codes by CalEnviroScreen score, ZIP codes were placed in 10 groups (deciles), highest to lowest. The racial/ethnic composition of each decile was examined by using data from the U.S. Census Bureau.

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INDICATOR SELECTION AND SCORING

The overall CalEnviroScreen community scores are driven by indicators. Here are the steps in the process for selecting indicators and using them to produce scores.

Overview of the Process

1. Identify potential indicators for each component.
2. Find sources of data to support indicator development (see Criteria for Indicator Selection below).
3. Select and develop indicator, assigning a value for each geographic unit.
4. Assign a percentile for each indicator for each geographic unit, based on the rank-order of the value.
5. Generate maps to visualize data.
6. Derive scores for pollution burden and population characteristics components (see Indicator and Component Scoring below).
7. Derive the overall CalEnviroScreen score by combining the component scores (see below).
8. Generate maps to visualize overall results.

The selection of specific indicators requires consideration of both the type of information that will best represent statewide pollution burden and population characteristics, and the availability and quality of such information at the necessary geographic scale statewide.

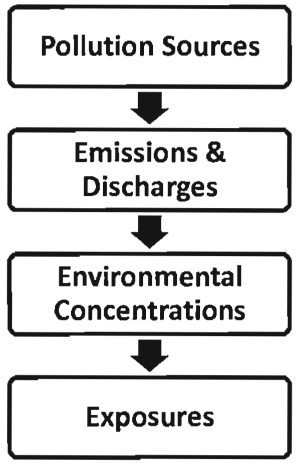
Criteria for Indicator Selection

- An indicator should provide a measure that is relevant to the component it represents, in the context of the 2005 Cal/EPA cumulative impacts definition.
- Indicators should represent widespread concerns related to pollution in California.
- The indicators taken together should provide a good representation of each component.
- Pollution burden indicators should relate to issues that may be potentially actionable by Cal/EPA boards and departments.
- Population characteristics indicators should represent demographic factors known to influence vulnerability to disease.
- Data for the indicator should be available for the entire state at the ZIP code level geographical unit or translatable to the ZIP code level.
- Data should be of sufficient quality, and be:
    - Complete
    - Accurate
    - Current

Exposure Indicators

People may be exposed to a pollutant if they come in direct contact with it, by breathing contaminated air, for example.

No data are available statewide that provide direct information on exposures. Exposures generally involve movement of chemicals from a source through the environment (air, water, food, soil) to an individual or population. For purposes of the CalEnviroScreen, data relating to pollution sources, releases, and environmental concentrations are used as indicators of potential human exposures to pollutants. Six indicators were identified and found consistent with criteria for exposure indicator development. They are:



- Ozone concentrations in air
- PM2.5 concentrations in air
- Diesel particulate matter emissions
- Use of certain high-hazard, high-volatility pesticides
- Toxic releases from facilities
- Traffic density

Environmental Effect Indicators

Environmental effects are adverse environmental conditions caused by pollutants.

Environmental effects include various aspects of environmental degradation, ecological effects and threats to the environment and communities. The introduction of physical, biological and chemical pollutants into the environment can have harmful effects on different components of the ecosystem. Effects can be immediate or delayed. In addition to direct effects on ecosystem health, the environmental effects of pollution can also affect people by limiting the ability of communities to make use of ecosystem resources (e.g., eating fish or swimming in local rivers or bays). Also, living in an environmentally degraded community can lead to stress, which may affect human health. In addition, the mere presence of a contaminated site or high-profile facility can have tangible impacts on a community, even if actual environmental degradation cannot be documented. Such sites or facilities can contribute to perceptions of a community being undesirable or even unsafe.

Statewide data on the following topics were identified and found consistent with criteria for indicator development:

- Toxic cleanup sites
- Groundwater threats from leaking underground storage sites and

cleanups
- Hazardous waste facilities and generators
- Impaired water bodies
- Solid waste sites and facilities

Sensitive Population Indicators

Sensitive populations are populations with biological traits that result in increased vulnerability to pollutants.

Sensitive individuals may include those undergoing rapid physiological change, such as children, pregnant women and their fetuses, and individuals with impaired physiological conditions, such as the elderly or people with existing diseases such as heart disease or asthma. Other sensitive individuals include those with lower protective biological mechanisms due to genetic factors.

Pollutant exposure is a likely contributor to many observed adverse outcomes at the population level, and has been demonstrated for some outcomes such as asthma, low birth weight, and heart disease. People with these health conditions are also more susceptible to health impacts from pollution. With few exceptions, adverse health conditions are difficult to attribute solely to exposure to pollutants. High quality statewide data related to these and other health conditions that can be influenced by toxic chemical exposures were identified and found consistent with criteria for development of these indicators:

- Prevalence of children and elderly
- Asthma
- Low birth-weight infants

Socioeconomic Factor Indicators

Socioeconomic factors are community characteristics that result in increased vulnerability to pollutants.

A growing body of literature provides evidence of the heightened vulnerability of people of color and lower socioeconomic status to environmental pollutants. For example, a study found that individuals with less than a high school education who were exposed to particulate pollution had a greater risk of mortality. Here, socioeconomic factors that have been associated with increased population vulnerability were selected.

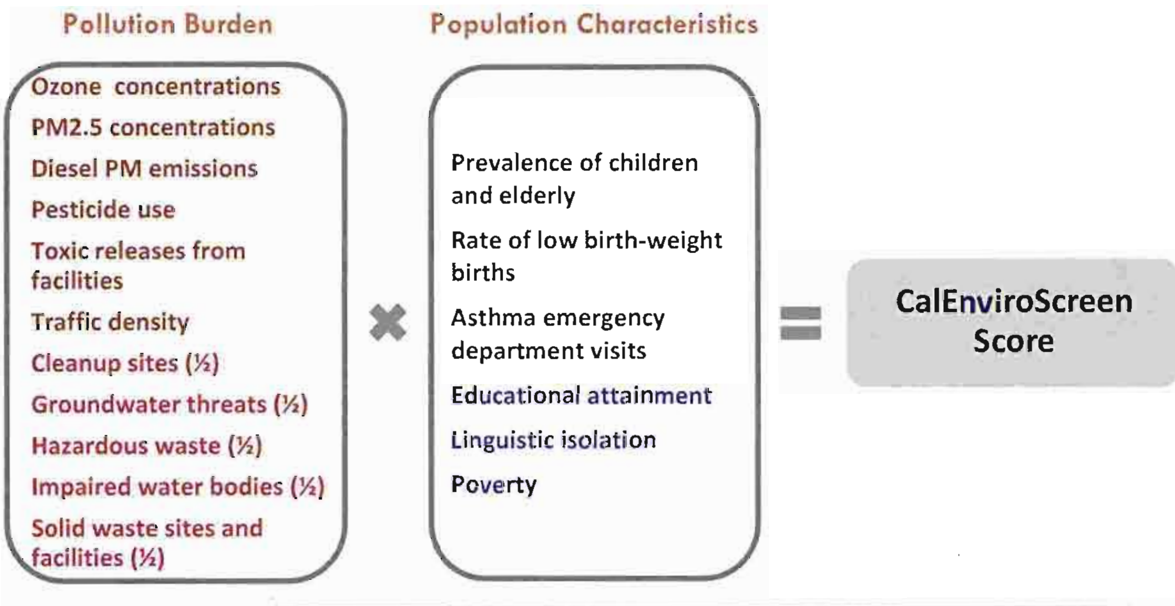
Data on the following socioeconomic factors were identified and found consistent with criteria for indicator development:

- Educational attainment
- Linguistic isolation
- Poverty

Indicator and Component Scoring

- The indicator values for the entire state are ordered from highest to lowest. A percentile is calculated from the ordered values for all areas that have a score.* Thus each area's percentile rank for a specific indicator is relative to the ranks for that indicator in the rest of the places in the state.
  - The indicators used in this analysis have varying underlying distributions, and percentile rank calculations provide a useful way to describe data without making any potentially unwarranted assumptions about those distributions.
  - A geographic area's percentile for a given indicator simply tells the percentage of areas with lower values of that indicator.
  - A percentile cannot describe the magnitude of the difference between two or more areas. For example, an area ranked in the 30th percentile is not necessarily three times more impacted than an area ranked in the 10th percentile.
- Indicators from Exposures and Environmental Effects components were grouped together to represent Pollution Burden. Indicators from Sensitive Populations and Socioeconomic Factors were grouped together to represent Population Characteristics (see figure below).
- Scores for the Pollution Burden and Population Characteristics groups of indicators are calculated as follows:
  - First, the percentiles for all the individual indicators in a group are averaged. Each indicator from the Environmental Effects component was weighted half as much as those indicators from the Exposures component. This was done because the contribution to possible pollutant burden from the Environmental Effects indicators was considered to be less than those from sources in the Exposures indicators. Thus the score for the Pollution Burden category is a weighted average, with Exposure indicators receiving twice the weight as Environmental Effects indicators.
  - Second, Pollution Burden and Population Characteristics group percentile averages are assigned scores from their defined ranges (up to 10) by dividing by 10 and rounding to one decimal place (*e.g.*, 5.4).

* When a geographic area has no indicator value (for example, the area has no facilities with toxic releases present), it is excluded from the percentile calculation and assigned a score of zero for that indicator. When data are unavailable or missing for a geographic area (for example, the area is greater than 50 kilometers from an air monitor), it is excluded from the percentile calculation and is not assigned any score for that indicator. Thus the percentile score can be thought of as a comparison of one geographic area to other localities in the state where the hazard effect or population characteristic is present.



CalEnviroScreen Score and Maps

- The overall CalEnviroScreen score is calculated from the Pollution Burden and Population Characteristics groups of indicators by multiplying the two scores. Since each group has a maximum score of 10, the maximum CalEnviroScreen Score is 100.
- The geographic areas are ordered from highest to lowest, based on their overall score. A percentile for the overall score is then calculated from the ordered values. As with the percentiles for individual indicators, a geographic area's overall CalEnviroScreen percentile equals the percentage of all ordered CalEnviroScreen scores that fall below the score for that area.
- Maps are developed showing the percentiles for all the ZIP codes of the state. Maps are also developed highlighting the ZIP codes scoring the highest.

Uncertainty and Error

There are different types of uncertainty that are likely to be introduced in the development of any screening method for evaluating pollution burden and population vulnerability in different geographic areas. Several important ones are:

- The degree to which the data that are included in the model are correct.
- The degree to which the data and the indicator metric selected reflect meaningful contributions in the context of identifying areas that are impacted by multiple sources of pollution and may be especially vulnerable to their effects.
- The degree to which data gaps or omissions influence the results.

Efforts were made to select datasets for inclusion that are complete, accurate and current. Nonetheless, there are uncertainties that may arise because environmental conditions change over time, large databases may contain errors, or there are possible biases in how complete the data sets are across the state, among others. Some of these uncertainties were addressed in the development of indicators. For example:

- Clearly erroneous place-based information for facilities or sites has been removed.
- Low incidences or small counts (e.g., health outcomes) have been excluded from the analysis.
- Highly uncertain measurements (for example, >50 kilometers from an air monitor) have been excluded from the analysis.

Other types of uncertainty, such as those related to how well indicators measure what they are intended to represent in the model, are more difficult to measure quantitatively. For example:

- How well data on chemical uses or emission data reflect potential contact with pollution.
- How well vulnerability of a community is characterized by demographic data.

Generally speaking, indicators are surrogates for the characteristic being modeled, so a certain amount of uncertainty is inevitable. That said, this model comprised of a suite of indicators is considered useful in identifying places burdened by multiple sources of pollution with populations that may be especially vulnerable. Places that score highly for many of the indicators are likely to be identified as impacted. Since there are tradeoffs in combining different sources of information, the results are considered most useful for identifying communities that score highly using the model. Using a limited data set, an analysis of the sensitivity of the model to changes in weighting showed it is relatively robust in identifying more impacted areas (Meehan August *et al.*, 2012). Use of broad groups of areas, such as those scoring in the highest 5 and 10 percent, is expected to be the most suitable application of the CalEnviroScreen results.

Reference

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INDIVIDUAL INDICATORS: DESCRIPTION AND ANALYSIS

AIR QUALITY: OZONE

Exposure Indicator

Ozone pollution causes numerous adverse health effects, including respiratory irritation and lung disease. The health impacts of ozone and other criteria air pollutants (particulate matter (PM), nitrogen dioxide, carbon monoxide, sulfur dioxide, and lead) have been considered in the development of health-based standards. Of the six criteria air pollutants, ozone and particle pollution pose the most widespread and significant health threats. The California Air Resources Board maintains a wide network of air monitoring stations that provides information that may be used to better understand exposures to ozone and other pollutants across the state.

Indicator

Portion of the daily maximum 8-hour ozone concentration over the federal 8-hour standard (0.075 ppm), averaged over three years (2007 to 2009).

Data Source

Air Monitoring Network,
California Air Resources Board (CARB)

CARB, local air pollution control districts, tribes and federal land managers maintain a wide network of air monitoring stations in California. These stations record a variety of different measurements including concentrations of the six criteria air pollutants and meteorological data. In certain parts of the state, the density of the stations can provide high-resolution data for cities or localized areas around the monitors. However, not all cities have stations.

The information gathered from each air monitoring station audited by the CARB includes maps, geographic coordinates, photos, pollutant concentrations, and surveys.

http://www.arb.ca.gov/aqmis2/aqmis2.php
http://www.epa.gov/airquality/ozonepollution/
http://www.niehs.nih.gov/health/topics/agents/ozone/

Rationale

Ozone is an extremely reactive form of oxygen. In the upper atmosphere ozone provides protection against the sun's ultraviolet rays. Ozone at ground level is the primary component of smog. Ground-level ozone is formed from the reaction of oxygen-containing compounds with other air pollutants in the presence of sunlight. Ozone levels are typically at their highest in the afternoon and on hot days (NRC, 2008).

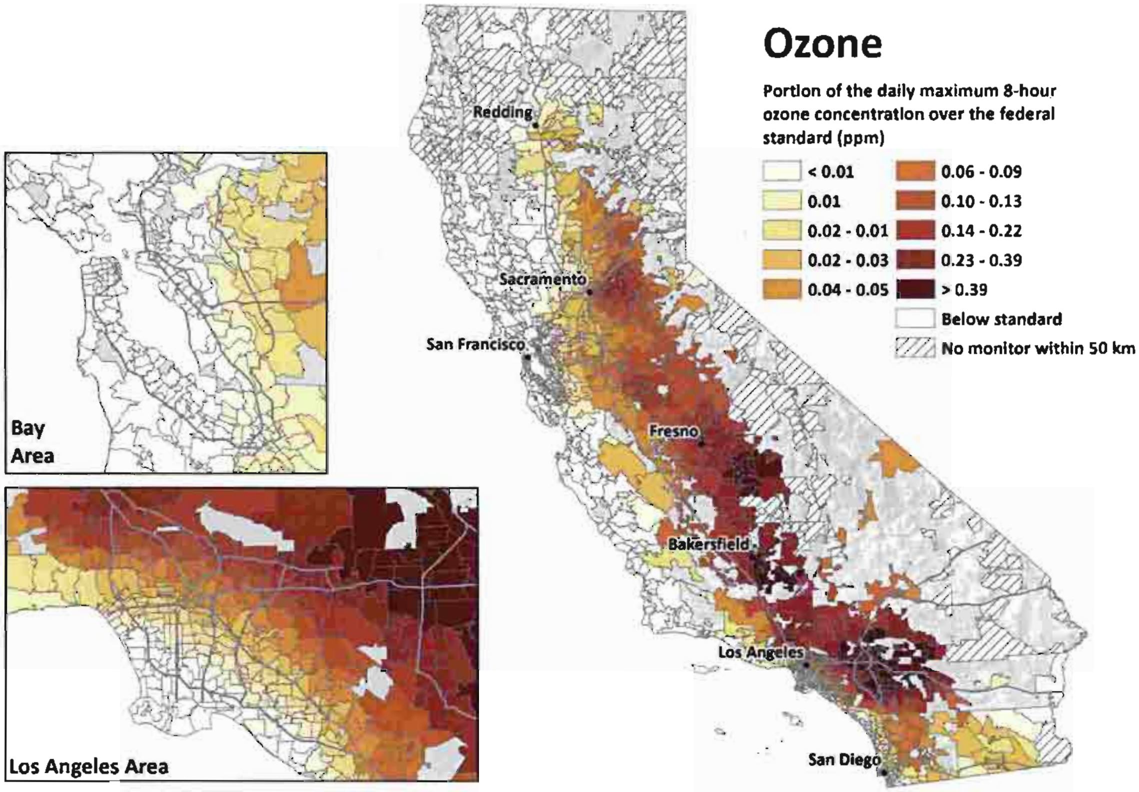
Adverse effects of ozone, including lung irritation, inflammation and exacerbation of existing chronic conditions, can be seen at even low exposures (Alexis *et al.* 2010, Fann *et al.* 2012, Zanobetti and Schwartz 2011). A long-term study in southern California found that rates of asthma hospitalization for children increased during warm season episodes of high ozone concentration (Moore *et al.* 2008). Additional studies have shown that the increased risk is higher among children under 2 years of age, young males, and African American children (Lin *et al.*, 2008, Burnett *et al.*, 2001). Increases in ambient ozone have also been associated with higher mortality, particularly in the elderly, women and African Americans (Medina-Ramon, 2008). Some of the relationships between CalEnviroScreen scores and race are explored in the final section of the report. Together with PM2.5, ozone is a major contributor to air pollution-related morbidity and mortality (Fann *et al.* 2012).

Method

- Daily maximum 8-hour average concentrations for all monitoring sites in California were extracted from CARB's air monitoring network database for the years 2007-2009.
- The federal 8-hour standard (0.075 ppm) is subtracted from the monitoring data to arrive at the portion of the 8-hour concentration above the federal standard. Only concentrations over the federal standard from 2007-2009 were used.
- For each day in the 2007-2009 time period, the 8-hour ozone concentrations over the standard were estimated at the geographic center of the ZIP code using a geostatistical method that incorporates the monitoring data from nearby monitors (ordinary kriging).
- The estimated daily concentrations over the standard were averaged to obtain a single value for each ZIP code.
- ZIP codes were ordered by ozone concentration values and assigned a percentile based on the statewide distribution of values.

Indicator Map

Note: Values at ZIP codes with centers more than 50km from the nearest monitor were not estimated (signified by cross-hatching in the map below).



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AIR QUALITY: PM2.5

Exposure Indicator

Particulate matter pollution, and fine particle (PM2.5) pollution in particular, has been shown to cause numerous adverse health effects, including heart and lung disease. PM2.5 contributes to substantial mortality across California. The health impacts of PM2.5 and other criteria air pollutants (ozone, nitrogen dioxide, carbon monoxide, sulfur dioxide, and lead) have been considered in the development of health-based standards. Of the six criteria air pollutants, particle pollution and ozone pose the most widespread and significant health threats. The California Air Resources Board maintains a wide network of air monitoring stations that provides information that may be used to better understand exposures to PM2.5 and other pollutants across the state.

Indicator

Annual mean concentration of PM2.5 (average of quarterly means), over three years (2007-2009).

Data Source

Air Monitoring Network,
California Air Resources Board (CARB)

CARB, local air pollution control districts, tribes and federal land managers maintain a wide network of air monitoring stations in California. These stations record a variety of different measurements including concentrations of the six criteria air pollutants and meteorological data. The density of the stations is such that specific cities or localized areas around monitors may have high resolution. However, not all cities have stations.

The site information gathered from each air monitoring station audited by CARB includes maps, locations coordinates, photos, pollutant concentrations, and surveys.

http://www.arb.ca.gov/aqmis2/aqmis2.php
http://www.epa.gov/airquality/particlepollution/

Rationale

Particulate matter (PM) is a complex mixture of aerosolized solid and liquid particles including such substances as organic chemicals, dust, allergens and metals. These particles can come from many sources, including cars and trucks, industrial processes, wood burning, or other activities involving combustion. The composition of PM depends on the local and regional sources, time of year, location and weather. The behavior of particles and the potential for PM to cause adverse health effects is directly related to particle size. The smaller the particle size, the more deeply the particles can penetrate into the lungs. Some fine particles have also been shown to enter the bloodstream. Those most susceptible to the effects of PM exposure include children, the elderly, and persons suffering from cardiopulmonary disease, asthma, and chronic illness (US EPA, 2012a).

PM2.5 refers to particles that have a diameter of 2.5 micrometers or less. Particles in this size range can have adverse effects on the heart and lungs, including lung irritation, exacerbation of existing respiratory disease, and cardiovascular effects. The US EPA has set a new standard for ambient PM2.5 concentration of 12 $\mu g/m^3$, down from 15 $\mu g/m^3$. According to EPA's projections, by the year 2020 only 7 counties nationwide will have PM2.5 concentrations that exceed this standard. All are in California (US EPA, 2012b).

In children, researchers associated high ambient levels of PM2.5 in Southern California with adverse effects on lung development (Gauderman *et al.*, 2004). Another study in California found an association between components of PM2.5 and increased hospitalizations for several childhood respiratory diseases (Ostro *et al.*, 2009). In adults, studies have demonstrated relationships between daily mortality and PM2.5 (Ostro *et al.* 2006), increased hospital admissions for respiratory and cardiovascular diseases (Dominici *et al.* 2006), premature death after long-term exposure, and decreased lung function and pulmonary inflammation due to short term exposures (Pope, 2009). Exposure to PM during pregnancy has also been associated with low birth weight and premature birth (Bell *et al.* 2007; Morello-Frosch *et al.*, 2010).

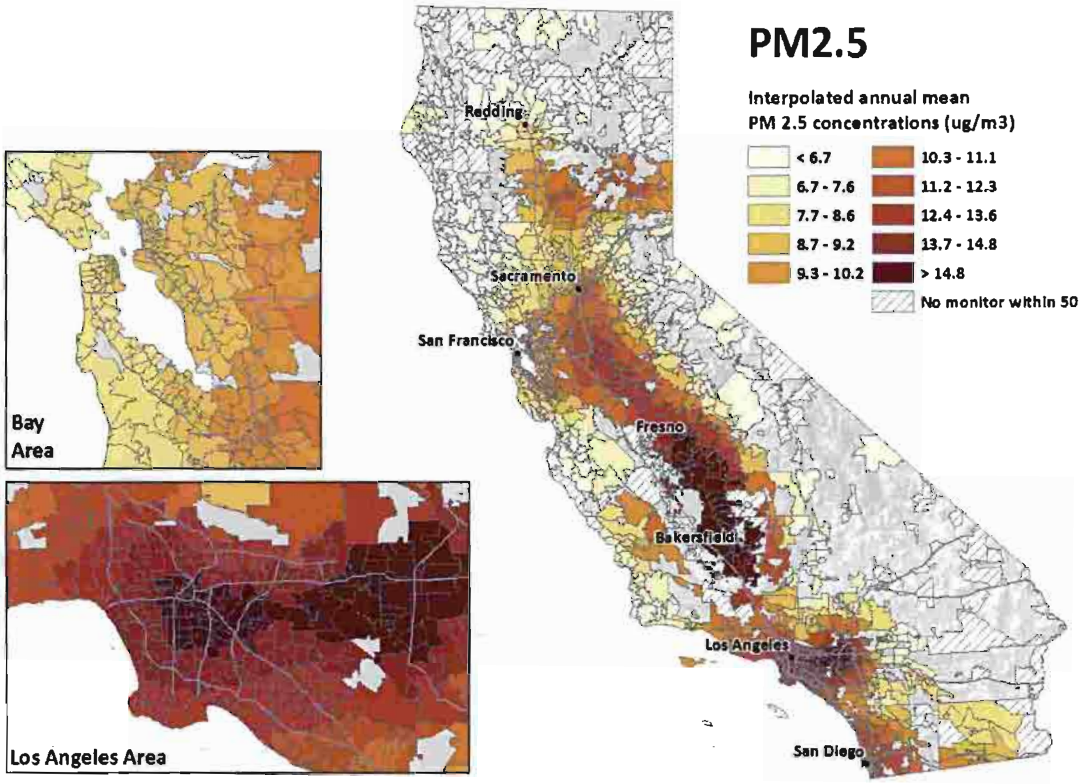
An additional source of PM2.5 in California is wildfires. Fires are not uncommon during dry seasons, particularly in Southern California and the Central Valley. Smoke particles fall almost entirely within the size range of PM2.5. Although the long term risks from exposure to smoke during a wildfire are relatively low, sensitive populations are more likely to experience severe symptoms, both acute and chronic (Lipsett *et al.* 2008). During the wildfires that spread throughout the state in June 2008, PM2.5 concentrations at a site in the northeast San Joaquin Valley were far above air quality standards and approximately ten times more toxic than normal ambient PM (Wegesser *et al.* 2009).

Method

- PM2.5 annual mean monitoring data for was extracted all monitoring sites in California from CARB's air monitoring network database for the years 2007-2009.
- Monitors that reported fewer than 75% of the expected number of observations, based on scheduled sampling frequency, were dropped from the analysis.
- For all measurements in the time period, the quarterly mean concentrations were estimated at the geographic center of the ZIP code using a geostatistical method that incorporates the monitoring data from nearby monitors (ordinary kriging).
- Annual means were then computed for each year by averaging the quarterly estimates and then averaging those over the three year period.
- ZIP codes were ordered by the PM2.5 concentration values and assigned a percentile based on the statewide distribution of values.

Indicator Map

Note: Values at ZIP codes with centers more than 50km from the nearest monitor were not estimated (signified by cross-hatching in the map below).



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DIESEL PARTICULATE MATTER

Exposure Indicator

Diesel particulate matter (diesel PM) occurs throughout the environment from both on-road and off-road sources. Major sources of diesel PM include trucks, buses, cars, ships and locomotive engines. Diesel PM is concentrated near ports, rail yards and freeways where many such sources exist. Exposure to diesel PM has been shown to have numerous adverse health effects including irritation to the eyes, throat and nose, cardiovascular and pulmonary disease, and lung cancer.

Indicator

Spatial distribution of gridded diesel PM emissions from on-road and non-road sources for a 2010 summer day in July (kg/day).

Data Source

California Air Resources Board (CARB)

The CARB produces grid-based emission estimates for a variety of pollutants by emissions category on a 4km by 4km statewide Cartesian grid system to support specific regulatory and research programs. Diesel PM emissions from on- and off-road sources were extracted for a July 2010 weekday from the latest grid-based emissions. This data source does not account for meteorological dispersion of emissions at the neighborhood scale, which can have local-scale and year-to-year variability, or significant local-scale spatial gradients known to exist within a few hundred meters of a high-volume roadway or other large source of diesel PM. Nevertheless it is a reasonable *regional* metric of exposure to diesel PM emissions.

http://www.arb.ca.gov/diesel

Rationale

Diesel PM is the particle phase of diesel exhaust emitted from diesel engines such as trucks, buses, cars, trains, and heavy duty equipment. This phase is composed of a mixture of compounds, including sulfates, nitrates, metals and carbon particles. The diesel particulate matter indicator is distinct from other air pollution indicators in CalEnviroScreen, PM2.5 in particular. Diesel PM includes known carcinogens, such as benzene and formaldehyde (Krivoshto *et al.*, 2008) and 50% or more of the particles are in the ultrafine range (USEPA, 2002). As particle size decreases, the particles may have increasing potential to deposit in the lung (Löndahl *et al.* 2012). The ultrafine fraction of diesel PM (aerodynamic diameter less than 0.1 µm) is of concern because researchers believe these particles penetrate deeper into the lung, can carry toxic compounds on particle surfaces, and are more biologically reactive than larger particles (Betha and Balasubramanian, 2013; Nemmar *et al.*, 2007). In urban areas, diesel PM is a major component of the particulate air pollution from traffic (McCreanor *et al.*, 2007).

Children and those with existing respiratory disease, particularly asthma, appear to be especially susceptible to the harmful effects of exposure to airborne PM from diesel exhaust, resulting in increased asthma symptoms and attacks along with decreases in lung function (McCreanor *et al.*, 2007; Wargo, 2002).

People that live or work near heavily-traveled roadways, ports, railyards, bus yards, or trucking distribution centers may experience a high level of exposure (USEPA, 2002; Krivoshto *et al.*, 2008). People that spend a significant amount of time near heavily-traveled roadways may also experience a high level of exposure. A study of U.S. workers in the trucking industry found an increasing risk for lung cancer with increasing years on the job (Garshick *et al.*, 2008). The same trend was seen among railroad workers, who showed a 40% increased risk of lung cancer (Garshik *et al.*, 2004). Studies have found strong associations between diesel particulate exposure and exacerbation of asthma symptoms in asthmatic children who attend school in areas of heavy truck traffic (Patel *et al.* 2010, Spira-Cohen *et al.* 2011). Studies of both men and women demonstrate cardiovascular effects of diesel PM exposure, including coronary vasoconstriction and premature death from cardiovascular disease (Krivoshto *et al.*, 2008).

Exposure to diesel PM, especially following periods of severe air pollution, can lead to increased hospital visits and admissions due to worsening asthma and emphysema-related symptoms (Krivoshto *et al.*, 2008). Diesel exposure may also lead to reduced lung function in children living in close proximity to roadways (Brunekreef *et al.*, 1997).

Method

Gridded diesel PM emissions from on-road sources were calculated as follows:

- CARB's on-road emissions model, EMFAC2013, was used to calculate 2010 county-wide estimates of diesel PM emissions for a July weekday.
  http://www.arb.ca.gov/msei/modeling.htm
- EMFAC2013 county-wide emission estimates are spatially distributed to 4km-by-4km grid cells based on the distribution of regional vehicle activity represented in local agency transportation networks and Caltrans' statewide transportation network (where local agency data are not available) using the Direct Travel Impact model (DTIM4). Transportation networks are produced from travel demand modeling conducted by local agencies and Caltrans.

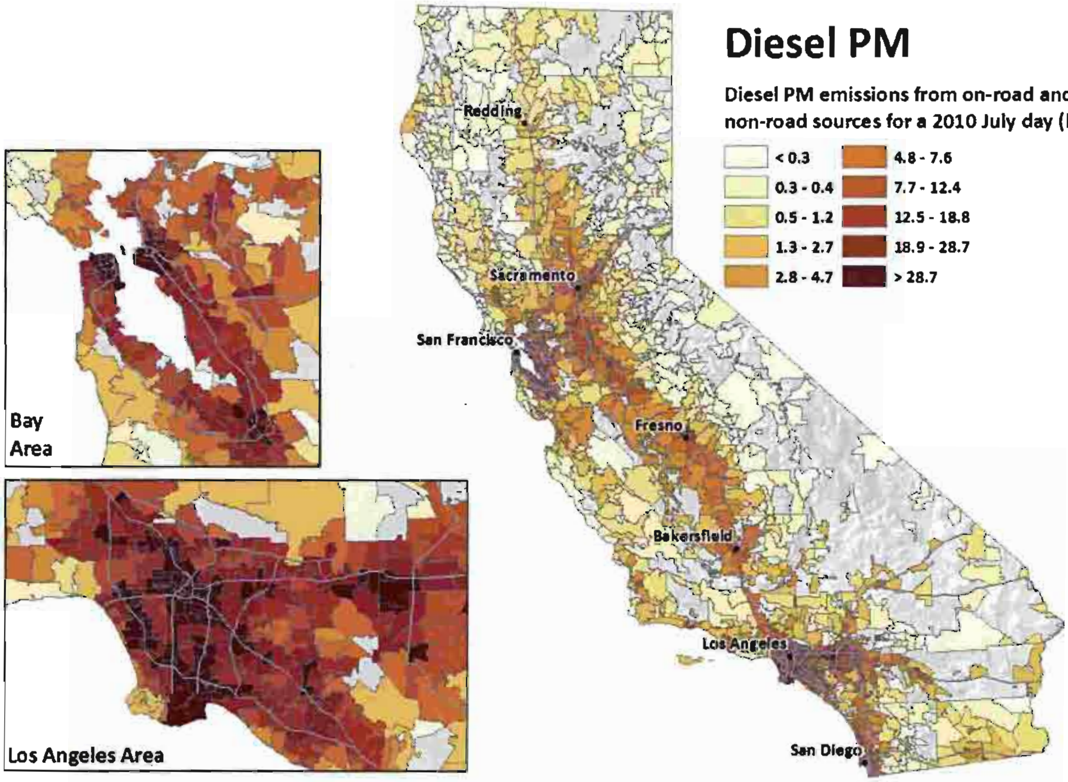
Gridded diesel PM from non-road sources were calculated as follows:

- County-wide estimates of diesel PM from non-road sources for a July weekday were extracted from CARB's emissions inventory forecasting system, CEPAM.
  http://www.arb.ca.gov/app/emsinv/fcemssumcat2009.php
- County-wide emission estimates are spatially distributed to 4km-by-4km grid cells based on a variety of gridded spatial surrogate datasets. Each category of emissions is mapped to a spatial surrogate that generally represents the expected sub-county

locations of source-specific activities. The surrogates include, for example: Lakes and Coastline; Population; Housing and Employment; Industrial Employment; Irrigated Cropland; Unpaved Roads; Single-Housing Units; Forrest Land; Military Bases; Non-irrigated Pasture Land; Rail Lines; Non-Urban Land; Commercial Airports; and Ports.

Resulting gridded emission estimates from the on-road and non-road categories were summed into a single gridded dataset. Gridded diesel PM emission estimates are then allocated to ZCTA zones in ArcMap using a weighted average where the proportion of a grid-cell intersecting a ZIP code is used as the weight. The resulting ZCTA totals are assigned a percentile based on the statewide distribution of values.

Indicator Map



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APP. R

An Estimate of the Burden of Valley Fever in Kings County

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12 April 2011

Coccidioidomycosis is the disease more commonly known as Valley Fever (VF). The disease most commonly occurs when "spores" of a soil growing fungus are inhaled. Rarely infection occurs when the "spores" enter the body through a break in the skin. Valley Fever is not transmitted from person to person. The range of the soil fungus is limited to a few areas of the United States, Mexico and South America. In the United States VF is recognized as a major public health issue only in Arizona and parts of California. In California most of the cases are reported from the southern San Joaquin Valley, the "valley" in Valley Fever. The restricted distribution of this disease in the United States has consequences for the people of Kings County.

Valley Fever is an orphan disease, that is, one of marginal importance. From a national perspective few people are at risk for Valley Fever. The numbers are too small to make it an attractive disease for private sector pharmaceutical research and development. In the public sector Valley Fever must compete with many other causes of disease, disability and death. There is very little funded research on Valley Fever. There are many things we don't know about Valley Fever. The treatments we have available are suboptimal and some people do poorly despite receiving the best treatment available. There are no practical preventive interventions that are known to be effective for the people who live in VF areas.

Kings County

Kings is a small county located in the southern San Joaquin Valley. The 2010 Census data puts the population at 152,982. The population is more than 50% ethnically Hispanic/Latino. Multiple years of drought depressed the agricultural-based economy before the onset of the current Great Recession. Before the drought the county had a high poverty rate.

The population of the county is concentrated in the eastern half of the county. The western half has a very low population density and has only two communities, Avenal and Kettleman City, both of which are located close to the western edge of the county. Avenal is roughly ten times larger than Kettleman City. The inmates of Avenal State Prison constitute about 45% of the population of Avenal. The two communities are more than three quarters Hispanic/ Latino. Avenal State Prison inmates are disproportionately African-American compared with Kings County. An unknown, but presumably large, number of people transit through western Kings County every day. Interstate Highway 5, one of three major north/south highways in California, passes through the far western part of Kings County.

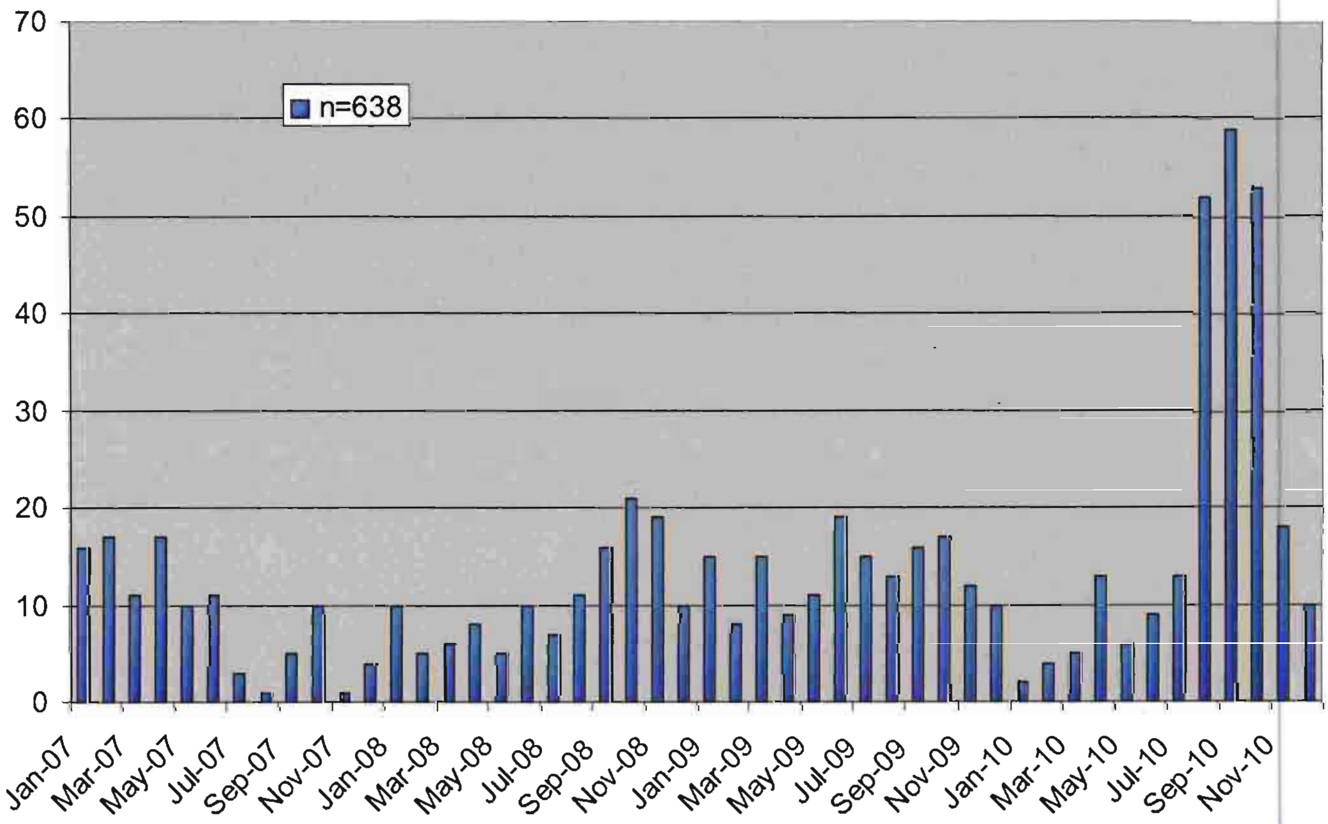
Counting, Describing Cases in the County

Valley Fever is known to occur in Kings County. Beginning in 2007 the Kings County Department of Public Health (KCDPH) devoted additional resources to defining the effect of Valley Fever on the people of our county. We did this without grants or other outside resources. This wouldn't have happened without the dedication and commitment of the department staff. The departmental people who've made this report possible are listed in the appendix. Through their efforts, the department has made some progress in identifying the people most affected and when they became infected.

Having no practical prevention recommendations for the general population, the Department decided to look closely at when people in Kings County contract Valley Fever, knowing that might suggest a preventive intervention. If weather patterns affect the growth of the fungus in the soil, as seems plausible, experience in Arizona, for example, likely wouldn't apply to Kings County. The VF literature gives two to four weeks as the time period between when someone becomes infected and when they begin to feel symptoms. We needed to determine the date they knew they were ill, which is often called the date of onset.

This date was usually missing or inaccurate on the illness reports we received before 2007. Beginning January 1, 2007, our department mandated additional requirements for VF disease reports submitted by doctors or other health care providers. . (The state requires that certain diseases be reported to the local health department.) Although in general the physicians and other providers were very cooperative, the workload of the department's staff increased as a result of this local mandate. They at times had to obtain clinic notes. Sometimes the nurses had to call the patients when the needed information wasn't in the clinical record. Despite these efforts, 25% of the time we have been unable to determine the date of onset of the illness.

Figure 1: Valley Fever in Kings County by Date of Onset 2007-2010



We know that there often is a lag time between the onset of the illness and when it is diagnosed and reported. Our internal process also adds time. The data for 2010 is likely incomplete. As of February 25, 2011 we recorded 854 cases of VF in Kings County for the period 2007-2010. We identified a date of onset for 638 of the cases. The distribution of the 638 cases is shown in Figure 1.

Looking at four years of onset data, we couldn't find any patterns over time. We found no consistent differences by month or season. To date we have no explanation for the differences. We have found that rain fall and wind data in Kings County is somewhat limited.

For the period 2007-2010, our data show that the risk of VF in Kings County isn't evenly distributed by groups of people or by location in the county. Inmates of the state prisons represent approximately 14% of the county's population but accounted for 58% of the reported cases in the four-year period. The excess rate in state prisoners was previously noted and reported in 2005 to the California Department of Public Health. Within the inmate group, those in Avenal State Prison accounted for all the increased rate of illness. The inmates at Avenal State Prison represent approximately 5% of the county population but represent 50% of the reported cases. The two prisons in Corcoran account for 9% of the county population and 9% of the reported cases. In 2007 the state reported on the increased VF rate in state inmates in Pleasant Valley State Prison in Fresno County. The cause for the excess rate in state prisoners is unknown. Because previous exposure to VF provides partial immunity , state prisoners from areas without VF would be at higher risk for developing VF than would be people who've previously lived where VF is common. It is also possible that there is a diagnostic bias in the prisons. That is, because of increased awareness in the prisons; milder cases are more likely to be tested and diagnosed. Nothing has been published to date to support this explanation.

In Kings County diagnostic bias would not explain the observed excess rate at the Avenal prison compared with the two Corcoran prisons. The prison in Avenal may be located in an area where the fungus is particularly abundant.

The department has previously reported on the increased rate of Valley Fever in the west side of the county. This trend was again noted for the period 2007-2010. Although Kettleman City and Avenal, including Avenal State Prison, represent only 12% of the county population, for the four-year period they accounted for 67% of the reported cases. The two communities, excluding the inmates, represent 7% of the county population and 17% of the reported cases. Even with the exclusion of the state inmates, the observed rate of disease in the western county remains elevated. An increased risk has also been reported in the non-prisoner population in the western part of neighboring Fresno County.

Males were disproportionately affected in Kings County. Eighty-three percent of the 2007-2010 cases occurred in males. Researchers have previously noted that males are disproportionately affected. For example, the California Department of Public Health reported that 65% of the 2000-2006 cases in California were male. The population of Kings County is disproportionately male. While California is close to 50% male, Kings County is 57.7% male. This predominance of males in Kings County likely is due primarily to the 14% of the population that are male state prisoners. The Naval Air Station in Lemoore may also contribute. Assuming that males experience an excess rate of VF in Kings and elsewhere, there is no agreement about the cause.

The age distribution of the cases is shown in Figure 2. The relatively low rate in children is not surprising. Other researchers have noted that children are less likely to develop disease than are adults. Old research has demonstrated a high rate of infection in children. The available evidence suggests that children tolerate infection better than adults. If true, this observation remains unexplained. The observed age distribution, as was noted with gender distribution, likely is highly influenced by the age distribution of the inmates at Avenal State Prison.

Figure 2: Age Distribution of Valley Fever Cases 2007-2011

Age Range	% (number) Cases	% Kings Population 2005-2009
<5 years	1 % (n=8)	8.4%
5-19 years	9 % (n=70)	22.4%
20-34 years	27 % (n=224)	27.3%
35-54 years	47 % (n=394)	27.3%
>55 years	19 % (n=158)	14.6%

Cases: n= 854 02/25/2011

The race and ethnicity of the cases is shown in Figure 3. The relatively high rate of unknown race/ethnicity makes interpretation problematic. We have found that race/ethnicity data often are not noted in clinic records. The apparent increase in cases in African-Americans is unexplained. African-Americans are known to be at much higher risk for complicated VF. Reports out of Kern County have suggested that African-Americans are at higher risk for any VF disease.

Figure 3: Valley Fever Cases Race / Ethnicity, Kings County 2007-2010

Race / Ethnicity	% (number) Cases	Kings County*	Avenal*
Hispanic	42% (n=362)	50.9%	71.9%
African-Amer/ Black	18% (n=151)	6.7%	9.9%
White / Non-Hispanic	21% (n=182)	35.2%	15.2%
Native American	<1% (n=3)	0.8%	0.5%
Asian	—	3.5%	0.7%
Unknown	18% (n=156)		

Cases: n=854 02/25/2011
**From 2010 Census*

The disproportionate occurrence of VF in the west county and especially in the inmate population of Avenal State Prison affects the race, age and gender distribution of cases in Kings County. It is also apparent that a broad range of Kings County residents throughout the county were affected by Valley Fever in the four-year reporting period.

In addition to better counting of cases, the mandated increased reporting requirement has also allowed us to better characterize the nature of the illness at the time the disease is reported. This data is not included in this report.

Adventist Health Study

Knowing the number of cases provides only one measure of estimating the burden of VF on our communities. Diabetes, cancer and even motor vehicle accidents may cause more burden than VF in Kings County. The data we obtain from disease reporting generally doesn't provide an adequate measure of the seriousness of the disease. In the case of VF some initially mild cases can later become complicated. If you will, how important is VF for our community?

The range of illness associated with VF is very broad. The national estimate is that as many as 60% of persons infected with the fungus have no symptoms. Some of these may have a localized rash and may not seek medical attention. The rash is termed erythma nodosum. It is more common in younger people and in females. This rash is sometimes the only manifestation of the disease. Most people with symptoms have either a nonspecific influenza-like illness or a non-specific pneumonia. Rarely, the pneumonia improves but never resolves completely. Approximately 2% of people develop very serious, often prolonged disease. In these cases the fungus spreads from the lungs to involve bones, joints, lymph nodes, the linings of the brain or other organs. VF is uncommonly fatal, but can be, even with optimal available therapy. Some people are recognized as being at increased risk for complicated disease. For reasons unexplained African-Americans and Asians, especially Filipino-Americans, have been reported to be at increased risk for complicated VF. People with a compromised immune system, pregnant women and people with diabetes are known to be at increased risk. To further estimate the burden of Valley Fever in our community, we partnered with Adventist Health to look at cases that required inpatient care.

During the 2007 - 2009 study period, Adventist Health was the largest health care provider in Kings County and a significant provider in two adjacent counties. They operated two hospitals in Kings County and one in Fresno County. In addition to clinics in Fresno and Tulare Counties, Adventist Health has outpatient clinics throughout Kings County.

The Adventist Health Study has some acknowledged limitations. Not all these admissions involved Kings County residents. One of Adventist Health's three facilities is located outside the county. On the other hand, admission to Adventist Health facilities provides only a partial picture of inpatient care for Kings County residents. Patients admitted to Corcoran District Hospital or Lemoore Naval Station hospital weren't included. Patients admitted to facilities outside the county weren't included. Often Kings County residents are hospitalized outside the county, e.g., patients with Kaiser insurance coverage, patients admitted to Coalinga Regional Medical Center and Children's Hospital of Central California.

The Health Insurance Portability and Accountability Act (HIPAA) allows the Health Officer to have access to the records of all VF-related hospital admissions. Records were reviewed for the years 2007 to 2009. The reviewed cases had VF as either the primary or a secondary diagnosis. Adventist Health also provided data on the length of hospital stay and the charges. Because the Health Officer was able to access the medical records electronically, he was able to complete the record reviews as time permitted. It is unlikely that he would have been able to perform an on-site record review. In addition to the current report, the data will be used to produce a second, clinical report for community health providers. This report will follow in July 2011.

During this three-year period there were 147 admissions, and some persons had more than one admission. To avoid exaggerating the burden, only those admissions found to be primarily VF related were included in the analysis. Valley Fever may and likely did contribute to the remaining admissions, e.g., by prolonging the hospital stay. Lacking a means to estimate this contribution, these cases were excluded. Ninety five of the 147 admissions (65%) were included in the study. Seventy two persons were involved in the 95 admissions. Sixty four percent of these were residents of Kings County; 30.5% were Fresno County residents and 5.5% were Tulare County residents. None of the admissions involved a state correctional inmate. With the exception of one adolescent, no children were admitted during the study period. Pediatric admissions during this period likely would have been admitted elsewhere.

The average age of the 72 patients was 45.7 years with a range of 15-78 years. Sixty-nine percent of the 72 patients were male. The race/ethnicity of the study group is noted in Figure 4. No race/ethnicity population distribution for the Adventist Health catchment area is available for comparison.

Figure 4: Adventist Health Valley Fever Admissions 2007-2009: Gender and Race/Ethnicity

Gender:	Male n=50 (69%)	Female n=22 (30.5%)
Race / Ethnicity		
White/Hispanic	68%	n=49
African-American	7%	n=5
Filipino	3%	n=2
White / Non-Hispanic	22%	n=16

Forty-six patients (64%) were admitted with community-acquired pneumonia (CAP). The other 26 (36%) admitted with other clinical manifestations of VF. The non-CAP cases were on the average more severely affected. They accounted for a disproportionate number of hospital days and charges. See Figure 5.

Figure 5: Adventist Health VF Admissions 2007-2009, LOS and Charges

	Length of Stay	Total Charges
CAP	338 days	$2,035,911
Non-CAP	578 days	$3,869,197
Totals	916 days	$5,905,108

Selma Community Hospital in Fresno County accounted for only 6% of the hospital days and 5% of the hospital charges
Charges are not the actual amount paid by patients or insurers

The non-community-acquired pneumonia group (n=26) represented only 36% of the inpatients but accounted for 63% of the hospital days and 65.5% of the hospitalization charges.

Fourteen of the 95 hospital admissions were transfers from other hospitals. Eight of the hospital discharges were transfers to other hospitals. With one exception these were to tertiary care hospitals (higher level care). One patient had several discharges and readmissions to and from higher level care hospitals. This patient had a combined, continuous hospital stay of 103 days. Of the 72 patients, one died during the hospital stay. Our study was limited to Adventist Health admissions. We did not capture the additional length of stay and hospital charges incurred by hospitalizations outside the Adventist Health system.

Eight of 26 (31%) of the non-CAP group had a diagnosis of VF prior to their 2007-2009 admission. Four of this group had a diagnosis of complicated VF at the time of their first 2007-2009 admission. Eight of 26 (31%) had a diagnosis of VF meningitis, a condition that will require lifelong treatment. Twelve of 26 (46%) had other serious medical conditions, and one was pregnant.

In the CAP group, 19 of 46 (41%) had another serious medical condition. Diabetes was the most common associated medical condition for both groups. Nineteen of 72 (26%) had a diagnosis of diabetes at the time of admission. None of the patients tested positive for HIV, but 65% of the patients had no record of HIV testing. Again, while other medical conditions were common 57% of the 72 patients were previously healthy before their hospitalization for VF.

As noted, the Adventist data, with one exception, didn't capture pediatric admissions. We know that there were five pediatric admissions to Children's Hospital of Central California in association with the observed outbreak in 2010. As of mid-March 2011, four had been discharged. The child still hospitalized had been hospitalized for 109 days by Mid-March. Of the four who had been discharged, the average length of stay in the hospital was 71 days.

The AH inpatient data demonstrates a considerable VF burden on our community with almost one thousand inpatient days and almost six million dollars in hospital charges. The inpatient data is limited by the absence of a reference population. We don't know the demographics of the population of people who use Adventist Health as their inpatient health care provider. Around one third of the cases are not residents of Kings County. The observed burden on our community may still be an underestimate. Although state inmates account for over half the VF cases observed in Kings county, there were no inmate admissions to the AH system in 2007-2009. There likely were many inmate admissions and the associated hospital days and charges weren't captured in the AH study. The selection process used may have excluded additional hospital admissions. We know that some of the patients in this study were discharged from or transferred to outside hospitals. It is likely that other non-inmate, Kings County residents were admitted to non-Adventist hospitals during the period 2007-2009. A more comprehensive study of inpatient burden would entail resources beyond those of the Kings County Department of Public Health. Without the full cooperation of the Adventist Health System, we couldn't have collected the data we have.

Valley Fever can be fatal. Including the VF-caused death noted previously, there have been five Kings County VF deaths since 2007.

Westside Study

Hospitalization analysis can provide only a partial picture of the burden of this disease in our community. We know that many people who eventually fully recover can have a prolonged disability associated with VF. Recognizing that the west side of the county has a higher risk for VF, beginning in 2010 the KCDPH implemented a survey in Avenal and Kettleman City. State prisoners were not included in this study. Every reported case was contacted and asked to participate in the survey. The survey was designed to assess the VF burden on these affected individuals. They are asked about the number of days missed from work or school, clinical care and duration of illness. Our methodology involves following them until they have fully recovered. We recognize that this is an additional imposition on these families and appreciate their cooperation with our study. The number of cases available is still limited and some of them remain open. Our preliminary results do add to the assessment of the burden of VF on the county.

Of 72 cases in 2010, ten either declined to participate or couldn't be located. Forty-nine of the 62 study cases (79%) reported missed school or work days. (This may be low because we didn't correct for people who were unemployed prior to their illness.) The average number of missed days was 43. Fifty-one of 62 (83%) reported days when they were unable to perform their normal activities. They didn't feel well enough to do what they normally do. The average number of days of decreased activities was 64 days. The study participants reported 372 outpatient visits (either Emergency Department or clinic) for an average of six visits per person. Seventeen of 62 (28%) were hospitalized for VF. These 17 people had 21 hospitalizations for a total of 459 days or an average of 27 days per person. Few of these hospitalizations (12%) occurred in Kings County. Our methodology doesn't allow us to collect the hospital charges for these hospitalizations.

Statistically the 62 people in our Westside Study should eventually have a full recovery. Clearly the medical care and the temporary disability involved in VF are significant even when a full recovery is expected.

KCDPH

In addition to studying VF in Kings County, the KCDPH has taken action to lessen the burden of VF on our residents. Our public health nurses reported that some patients experienced problems getting Valley Fever medications. Some of these patients were found to be covered by the state's Medi-Cal program. We found that the needed medications required a treatment authorization. This resulted in delays and sometimes in denials. With the help of our California Department of Public Health colleagues, the Medi-Cal authorization requirement for Valley Fever treatment was removed. We've confirmed that there are no medication barriers for patients covered by the County Medical Services Program. We have posted on our website guidance for medical providers to use in getting free or very low cost medications for their indigent but uninsured patients.

In partnership with the Valley Fever Center for Excellence in Arizona we have identified VF educational resources for community health care providers. Physicians new to the area and to VF can now take a high-quality online training program on VF.

The KCDPH will continue to receive disease reports and will continue to track this disease in our community. We will continue to try to explain the observed variation in disease occurrence.

KCDPH will continue to raise VF awareness. For example, Valley Fever may cause more disease in California than is generally recognized. Travelers on Interstate 5 in Kings County probably are at risk for contracting VF. Infection and illness have been documented elsewhere after brief, transient exposure. Few of those affected would likely be properly diagnosed if they reside in an area free of VF. Physicians unfamiliar with Valley Fever are very unlikely to diagnose it and most patients would eventually recover without specific treatment.

COUNTY RESIDENTS

We have no preventive strategy for the general population of residents. The KCDPH Environmental Health Division is available to consult and provide information to employers and the public on risk reduction and prevention of occupational Valley Fever. The Division can provide assistance in identifying, evaluating and controlling the occupational routes of exposure. The Environmental Health Division can be reached by phone by calling (559) 584-1411.

Individuals with medical conditions and those taking medications that alter immune functions should consult with their health care provider about VF risk reduction. County residents may want to ask their clinical providers to test for VF when they have a compatible illness. Fever and cough are the most common symptoms with or without a rather profound fatigue. Most people don't have a rash. However, rash may accompany or precede the fever. A rash may be generalized and nonspecific. The rash, previously mentioned, erythema nodosum, is suggestive of VF. Usually on the legs, the rash is circular/oval, red, firm, under the skin surface and slightly tender to the touch. With the exception of the rash just mentioned, there is nothing specific about the symptoms and signs of VF. We don't know that treatment with the medications we have available reliably shortens the duration or intensity of the illness. Having the diagnosis may still be helpful in explaining your symptoms and in avoiding unnecessary diagnostic studies and treatment with antibiotics.

COMMUNITY

Valley Fever disproportionately affects some county residents. The following is an example of someone heavily burdened by Valley Fever.

A Kings County resident— who, at the time he became ill with Valley Fever was a 21 years old, African-American college student.. In addition to being a full-time student, he worked part-time. A successful high school athlete, he also kept himself fit and trim. He had disseminated disease as his first sign of illness. His disease had spread beyond the lungs when he first became ill. He was hospitalized four times in Kings County and had several admissions to referral hospitals. He was hospitalized for over 90 days in Kings County and his hospital charges for the Kings County admissions were over a half a million dollars. His weight dropped from a lean 165 to a skeletal 115 lbs. For quite a while he was unable to even get out of bed without assistance. Thankfully, he is now recovering. After missing one and a half years of school because of his illness, he's resumed his college education. He has daily pain that requires treatment. He must continue on daily VF treatment. He is now learning to live with the fact that his disease could return despite daily treatment. This young man is an excellent example of why we need to prevent Valley Fever or, failing that, have more effective treatment.

RECOMMENDATIONS

The orphan status of this disease means that we need to generate community support for the necessary research and development. In the past both the state and the federal governments have provided some support for VF research. We should encourage our state and federal representatives to continue to support VF research. Community civic organizations should consider adopting this orphan disease for their support. The Valley Fever Vaccine Project, housed at California State University, Bakersfield, is making progress on the development of a vaccine. The Valley Fever Center for Excellence at the University of Arizona is working on a promising new drug for the treatment of Valley Fever.

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APPENDIX

I would like to acknowledge the following Health Department staff for their dedication and commitment to all that went into making this report possible:

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I would also like to acknowledge the staff from Adventist Health—Central Valley Network for their assistance on the Adventist Health Study portion of this report:

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APP. S

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

Department of Toxic Substances Control

News Release

T – 12 – 13
Deborah O. Raphael, Director

FOR IMMEDIATE RELEASE
July 2, 2013

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DTSC Issues Draft Decision on Kettleman Facility and Announces Initiative to Reduce Landfill Waste by 50 percent

SACRAMENTO, Calif. – The Department of Toxic Substances Control (DTSC) made two significant announcements today that affect California's hazardous waste management system.

DTSC released a draft decision on a permit modification that would allow Chemical Waste Management (CWM) to increase the capacity of the hazardous waste landfill in Kettleman Hills. The Department also announced an effort to reduce the amount of hazardous waste disposed in California by 50 percent by the year 2025. The reduction would affect the amount of wastes going to landfills in Kettleman Hills, Buttonwillow near Bakersfield and Westmoreland in Imperial County.

If approved, the permit modification would allow CWM to increase the size of its landfill, which is operating near capacity, by five million cubic yards. The draft decision is subject to a 60-day comment period.

Brian Johnson, Deputy Director of DTSC's Hazardous Waste Management Program, said the draft decision to allow expansion of CWM's Kettleman Hills landfill was made following the most comprehensive review of a permit application in California history.

"We understand the importance of this decision as well as the depth of community interest that this facility is operated safely," Johnson said. "We looked at all facets of its operation as part of our nearly five-year review."

The draft permit modification includes extensive and stringent conditions that ensure the community is protected from any potential hazards.

For example, the draft modification requires CWM to significantly reduce the amount of diesel emissions from trucks delivering waste, improving the quality of air. Trucks using the facility must meet model year 2007 emissions standards or be manufactured after 2007, when more restrictive air emission standards went into effect in California. Starting in 2018, trucks will have to meet 2010 emission standards, which are even higher.

DTSC's review took into account the findings of multiple health studies including the "Cal EPA Kettleman City Community Exposure Assessment," the "California Department of Public Health Birth Defect Study" and results of a US EPA examination of the risks of exposure to polychlorinated biphenyls (PCBs). DTSC also reviewed air and groundwater monitoring data from the facility.

The review also took into account the facility's enforcement record, dating back to 1983. None of the violations, including a $311,000 fine in March 2013 for failing to report 72 small spills, caused offsite impacts.

"The facility's response to enforcement actions indicates it is able and willing to take all necessary steps to ensure the community is safe," Johnson said.

Aside from the use of low-emission trucks, additional protections to the community provided by the proposed permit modification include:

- Increased air sampling that allows for the detection of very low concentrations of PCBs;
- Enhanced air monitoring;
- Increased sampling and analysis of water that leaches through and collects in a system below the landfill;
- Enhanced public outreach;
- Improved containment systems to control spills; and
- Annual aerial and land surveys of the landfill to verify CWM estimates of remaining capacity.

DTSC will also enhance its surveillance effort at the facility by increasing inspections and collaborating with US EPA's inspection efforts.

At the same time, DTSC announced an ambitious effort to cut in half the amount of hazardous waste disposed of in California by the year 2025.

California generated an average of 1.7 million tons of hazardous waste each year for the past 10 years. About 600,000 tons ended up annually in the Kettleman or Buttonwillow landfills (the Westmorland facility does not currently accept hazardous waste). Each year, approximately 333,000 tons of waste was shipped to and landfilled in states where environmental regulations are not as strict as California. About 50 percent of the material landfilled at the Kettleman and Buttonwillow facilities comes from contaminated soil removed as part of a cleanup project.

"There is an equity issue for communities that surround the three hazardous waste landfills in California," said DTSC Director Debbie Raphael. "Despite studies that show the landfills are safe, they are bearing the burden of California's hazardous waste disposal, often in combination with many other environmental impacts.

"We must start the discussion on how we can end or significantly reduce our dependence on landfills and develop sustainable solutions that protect this generation and generations to come. Setting a goal for reducing hazardous waste disposal will create incentives that can lead to innovations in science and technology and develop sustainable solutions that protect this generation and generations to come."

DTSC will conduct a dialogue among industry, public interest groups, local governments, elected officials and the public. Meetings across the state will focus on identifying innovative, safe and effective ways for reducing hazardous wastes going to landfills, including developing incentives for reducing the generation of waste.

Raphael said the goal is closely tied to the proposed decision on Kettleman.

“Right now we still generate a significant amount of waste that must be transported, treated or disposed of safely. We want to begin the larger discussion as to how we can greatly reduce hazardous waste going to facilities like Kettleman Hills.”

The 60-day public-comment period for the proposed decision will close September 4, 2013. DTSC will host a community open house on Wednesday July 31 at the Kettleman City Elementary School, a community “drop-in” session on August 1 at the Kettleman City Community Center; and a public hearing on August 27 at the Kettleman City Elementary School.

DTSC will conduct six workshops throughout the state to collect public input on the goal to reduce hazardous waste generation by 50 percent by 2025. The first workshop will take place in the fall of 2013. Locations and times of the workshops will be posted on DTSC’s web site in the near future.

###

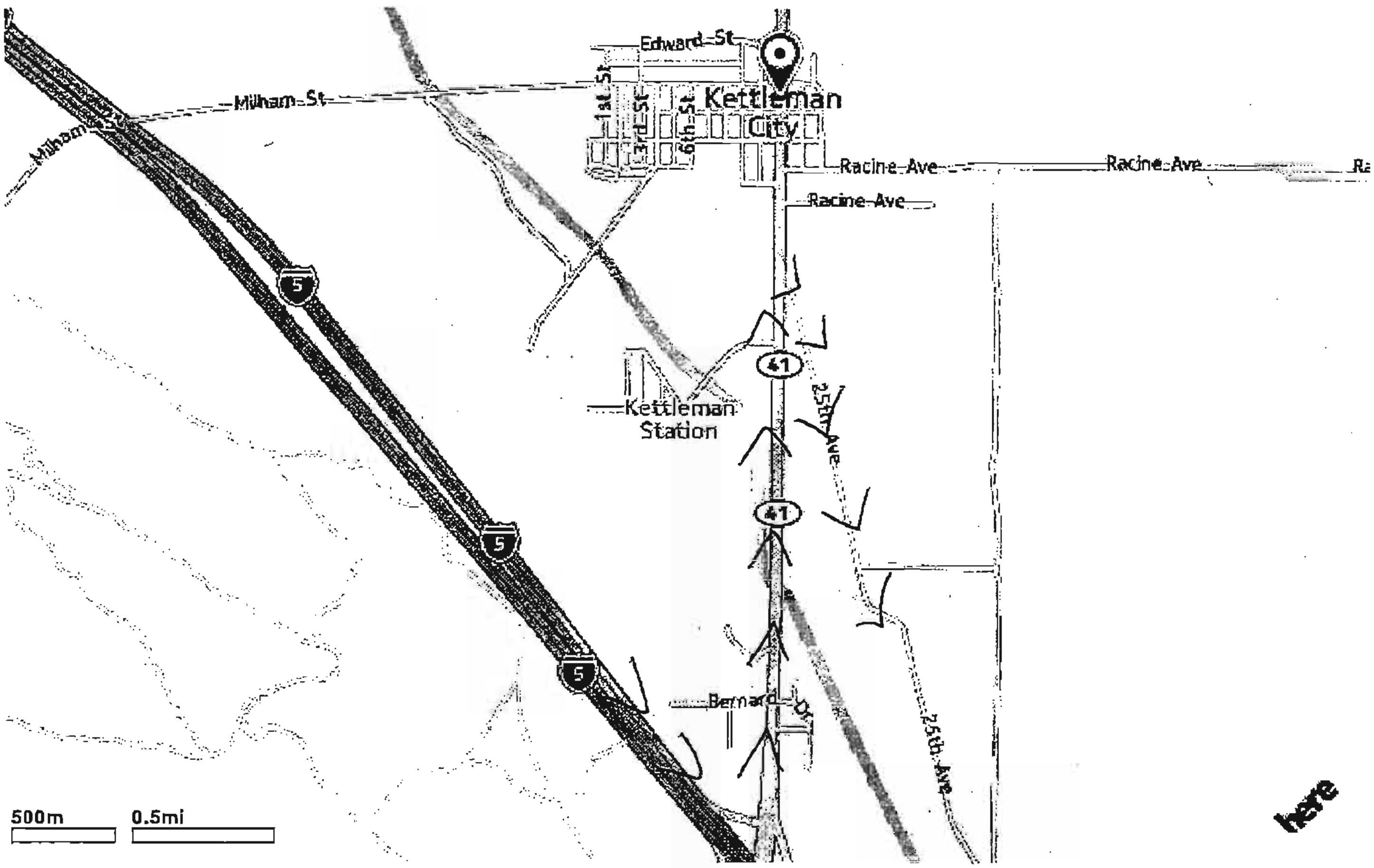
FOR GENERAL INQUIRIES: Contact the Department of Toxic Substances Control by phone at (800) 728-6942 or visit www.dtsc.ca.gov. To report illegal handling, discharge, or disposal of hazardous waste, call the Waste Alert Hotline at (800) 698-6942.

The Mission of DTSC is to protect California’s people and environment from harmful effects of toxic substances by restoring contaminated properties, identifying and promoting safer ingredients in consumer products, and ensuring stewardship through enforcement, regulation and pollution prevention.

APP. T

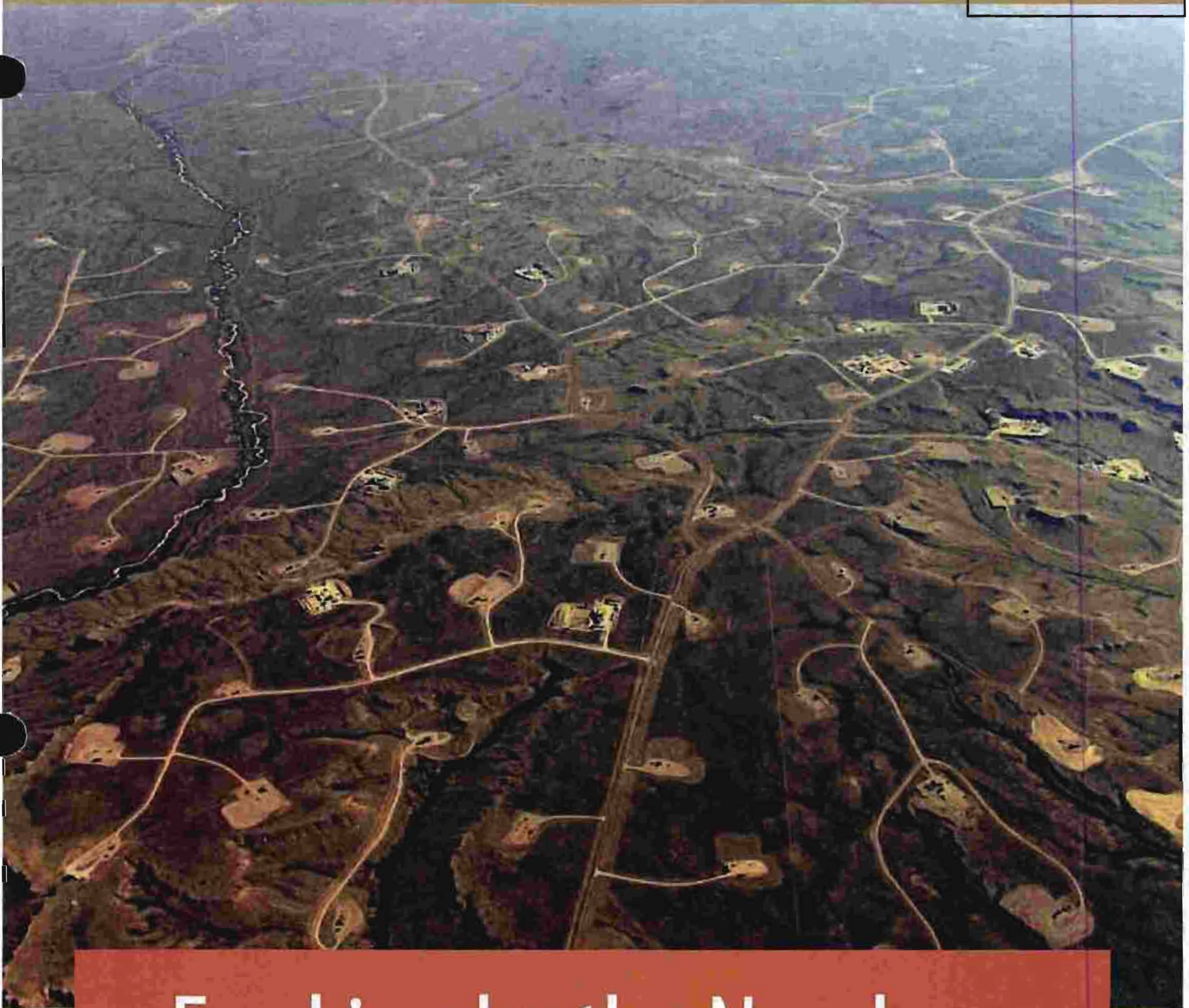
YAHOO! MAPS

Kettleman City, CA



When using any driving directions or map, It is a good idea to double check and make sure the road still exists, watch out for construction, and follow all traffic safety precautions. This is only to be used as an aid in planning

APP. U



Fracking by the Numbers

Key Impacts of Dirty Drilling at the State and National Level

ENVIRONMENT CALIFORNIA
RESEARCH & POLICY CENTER

Fracking by the Numbers

Key Impacts of Dirty Drilling at the State and National Level

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RESEARCH & POLICY CENTER

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October 2013

Acknowledgments

Environment California Research & Policy Center sincerely thanks John Amos of SkyTruth, Anthony Ingraffea, Ph.D., P.E., and Kari Matsko, Director of People's Oil & Gas Collaborative-Ohio for their review of drafts of this document, as well as their insights and suggestions. Tareq Alani, Spencer Alt, Elise Sullivan and Anna Vanderspek provided valuable research assistance. Thanks also to Travis Madsen of Frontier Group for technical assistance, and Tony Dutzik and Benjamin Davis of Frontier Group for editorial help.

We also are grateful to the many state agency staff who answered our numerous questions and requests for data. Many of them are listed by name in the methodology.

Environment California Research & Policy Center thanks the V. Kann Rasmussen Foundation and the Park Foundation for making this report possible.

The authors bear responsibility for any factual errors. The recommendations are those of Environment California Research & Policy Center. The views expressed in this report are those of the authors and do not necessarily reflect the views of our funders or those who provided review.

The Environment California Research & Policy Center is a 501(c)(3) organization. We are dedicated to protecting California's air, water and open spaces. We investigate problems, craft solutions, educate the public and decision-makers, and help Californians make their voices heard in local, state and national debates over the quality of our environment and our lives. For more information about Environment California Research & Policy Center or for additional copies of this report, please visit www.environmentcaliforniacenter.org.

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Layout: To the Point Publications, www.tothepointpublications.com

Cover photo: Peter Aengst via SkyTruth/EcoFlight

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Executive Summary

Over the past decade, the oil and gas industry has fused two technologies—hydraulic fracturing and horizontal drilling—in a highly polluting effort to unlock oil and gas in underground rock formations across the United States.

As fracking expands rapidly across the country, there are a growing number of documented cases of drinking water contamination and illness among nearby residents. Yet it has often been difficult for the public to grasp the scale and scope of these and other fracking threats. Fracking is already underway in 17 states, with more than 80,000 wells drilled or permitted since 2005. Moreover, the oil and gas industry is aggressively seeking to expand fracking to new states—from New York to California to North Carolina—and to areas that provide drinking water to millions of Americans.

This report seeks to quantify some of the key impacts of fracking to date—including the production of toxic wastewater, water use, chemicals use, air pollution, land damage and global warming emissions.

To protect our states and our children, states should halt fracking.

Toxic wastewater: Fracking produces enormous volumes of toxic wastewater—often containing cancer-causing and even radioactive material. Once brought to the surface, this toxic waste poses hazards for drinking water, air quality and public safety:

- Fracking wells nationwide produced an estimated 280 billion gallons of wastewater in 2012.
- This toxic wastewater often contains cancer-causing and even radioactive materials, and has contaminated drinking water sources from Pennsylvania to New Mexico.
- Scientists have linked underground injection of wastewater to earthquakes.
- In New Mexico alone, waste pits from all oil and gas drilling have contaminated groundwater on more than 400 occasions.

Table ES-1. National Environmental and Public Health Impacts of Fracking

Fracking Wells since 2005	82,000
Toxic Wastewater Produced in 2012 (billion gallons)	280
Water Used since 2005 (billion gallons)	250
Chemicals Used since 2005 (billion gallons)	2
Air Pollution in One Year (tons)	450,000
Global Warming Pollution since 2005 (million metric tons CO_2-equivalent)	100
Land Directly Damaged since 2005 (acres)	360,000

Water use: Fracking requires huge volumes of water for each well.

- Fracking operations have used at least 250 billion gallons of water since 2005. (See Table ES-2.)
- While most industrial uses of water return it to the water cycle for further use, fracking converts clean water into toxic wastewater, much of which must then be permanently disposed of, taking billions of gallons out of the water supply annually.
- Farmers are particularly impacted by fracking water use as they compete with the deep-pocketed oil and gas industry for water, especially in drought-stricken regions of the country.

Chemical use: Fracking uses a wide range of chemicals, many of them toxic.

- Operators have hauled more than 2 billion gallons of chemicals to thousands of fracking sites around the country.
- In addition to other health threats, many of these chemicals have the potential to cause cancer.
- These toxics can enter drinking water supplies from leaks and spills, through well blowouts, and through the failure of disposal wells receiving fracking wastewater.

Table ES-2. Water Used for Fracking, Selected States

State	Total Water Used since 2005 (billion gallons)
Arkansas	26
Colorado	26
New Mexico	1.3
North Dakota	12
Ohio	1.4
Pennsylvania	30
Texas	110
West Virginia	17

Air pollution: Fracking-related activities release thousands of tons of health-threatening air pollution.

- Nationally, fracking released 450,000 tons of pollutants into the air that can have immediate health impacts.
- Air pollution from fracking contributes to the formation of ozone "smog," which reduces lung function among healthy people, triggers asthma attacks, and has been linked to increases in school absences, hospital visits and premature death. Other air pollutants from fracking and the fossil-fuel-fired machinery used in fracking have been linked to cancer and other serious health effects.

Global warming pollution: Fracking produces significant volumes of global warming pollution.

- Methane, which is a global warming pollutant 25 times more powerful than carbon dioxide, is released at multiple steps during fracking, including during hydraulic fracturing and well completion, and in the processing and transport of gas to end users.
- Global warming emissions from completion of fracking wells since 2005 total an estimated 100 million metric tons of carbon dioxide equivalent.

Damage to our natural heritage: Well pads, new access roads, pipelines and other infrastructure turn forests and rural landscapes into industrial zones.

- Infrastructure to support fracking has damaged 360,000 acres of land for drilling sites, roads and pipelines since 2005.
- Forests and farmland have been replaced by well pads, roads, pipelines and other gas infrastructure, resulting in the loss of wildlife habitat and fragmentation of remaining wild areas.

- In Colorado, fracking has already damaged 57,000 acres of land, equal to one-third of the acreage in the state's park system.
- The oil and gas industry is seeking to bring fracking into our national forests, around several of our national parks, and in watersheds that supply drinking water to millions of Americans.

Fracking has additional impacts not quantified here—including contamination of residential water wells by fracking fluids and methane leaks; vehicle and workplace accidents, earthquakes and other public safety risks; and economic and social damage including ruined roads and damage to nearby farms.

Defining "Fracking"

In this report, when we refer to the impacts of "fracking," we include impacts resulting from all of the activities needed to bring a shale gas or oil well into production using high-volume hydraulic fracturing (fracturing operations that use at least 100,000 gallons of water), to operate that well, and to deliver the gas or oil produced from that well to market. The oil and gas industry often uses a more restrictive definition of "fracking" that includes only the actual moment in the extraction process when rock is fractured—a definition that obscures the broad changes to environmental, health and community conditions that result from the use of fracking in oil and gas extraction.

To address the environmental and public health threats from fracking across the nation:

- States should prohibit fracking. Given the scale and severity of fracking's myriad impacts, constructing a regulatory regime sufficient to protect the environment and public health from dirty drilling—much less enforcing such safeguards at more than 80,000 wells, plus processing and waste disposal sites across the country—seems implausible. In states where fracking is already underway, an immediate moratorium is in order. In all other states, banning fracking is the prudent and necessary course to protect the environment and public health.
- Given the drilling damage that state officials have allowed fracking to incur thus far, at a minimum, federal policymakers must step in and close the loopholes exempting fracking from key provisions of our nation's environmental laws.
- Federal officials should also protect America's natural heritage by keeping fracking away from our national parks, national forests, and sources of drinking water for millions of Americans.
- To ensure that the oil and gas industry—rather than taxpayers, communities or families—pays the costs of fracking damage, policymakers should require robust financial assurance from fracking operators at every well site.
- More complete data on fracking should be collected and made available to the public, enabling us to understand the full extent of the harm that fracking causes to our environment and health.

Introduction

Many Americans have an image of the damage caused by fracking. Documentaries and YouTube videos have shown us tap water catching on fire and families experiencing headaches, dizziness, nausea and other illnesses while living near fracking operations. Plane trips over Texas or Colorado reveal the grids of wells across the landscape.

These snapshots illustrate the damage that fracking does to the environment and our health. But, until now, it has been difficult to comprehend the cumulative extent of that damage. Individual fracking wells, we know, can pollute the air and water of a neighborhood or town. But what does it mean now that the nation has not dozens or hundreds but tens of thousands of fracking wells in at least 17 states? What, for example, is the magnitude of the risk those wells present to drinking water? How many iconic landscapes are being damaged?

In this report, we have quantified several of the key impacts of fracking on water, air and land, at the state and national level, using the best available sources of information on the extent of fracking and the impacts of fracking on our environment and health.

Our analysis shows that damage from fracking is widespread and occurs on a scale unimagined just a few years ago. Moreover, three factors suggest that the total damage from fracking is far worse than we have tabulated here. Severe limitations in available data constrain our ability to see the full extent of the damage. Second, there are broad categories of fracking damage—such as the number of water wells contaminated—that would be difficult to ascertain under any circumstances. Finally, there remain major gaps in the scientific community's understanding of issues such as the long-term consequences of pumping toxic fluids into the ground.

Even the limited data that are currently available, however, paint an increasingly clear picture of the damage that fracking has done to our environment and health. It will take decisive action to protect the American people and our environment from the damage caused by dirty drilling.

Our analysis shows that damage from fracking is widespread and occurs on a scale unimagined just a few years ago.

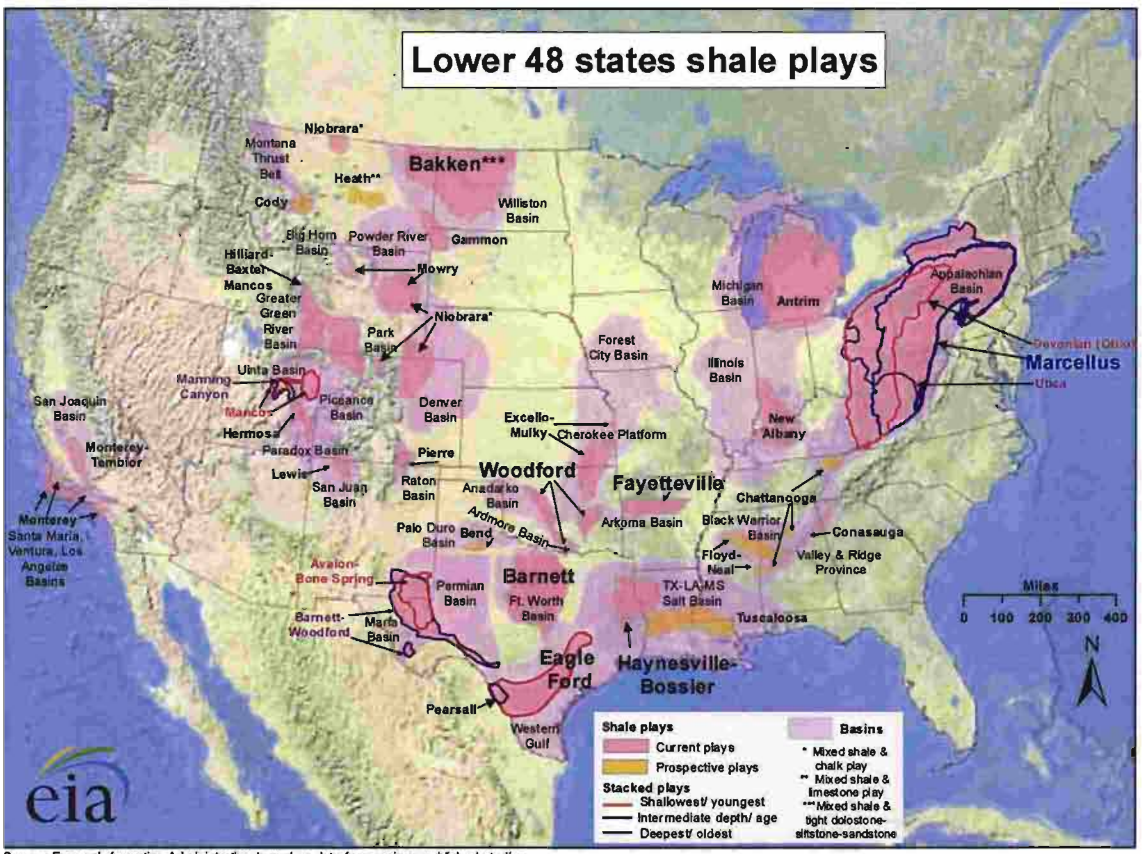
Fracking Poses Grave Threats to the Environment and Public Health

Over the past decade, the oil and gas industry has used hydraulic fracturing to extract oil and gas from previously inaccessible rock formations deep underground. The use of high-volume hydraulic fracturing—colloquially known as "fracking"—has expanded dramatically from its origins in the Barnett Shale region of Texas a decade ago to tens of thousands of wells nationwide today.

Roughly half of U.S. states, stretching from New York to California, sit atop shale or other rock formations with the potential to produce oil or gas using fracking. (See Figure 1.)

Fracking has unleashed a frenzy of oil and gas drilling in several of these shale formations—posing severe threats to the environment and public health.

Figure 1. Shale Gas and Oil Plays[1]



Source: Energy Information Administration based on data from various published studies.
Updated: May 9, 2011

Contaminating Drinking Water

Fracking has polluted both groundwater and surface waterways such as rivers, lakes and streams. Fracking pollution can enter our waters at several points in the process—including leaks and spills of fracking fluid, well blowouts, the escape of methane and other contaminants from the well bore into groundwater, and the long-term migration of contaminants underground. Handling of toxic fracking waste that returns to the surface once a well has been fracked presents more opportunities for contamination of drinking water. State data confirm more than 1,000 cases of water contaminated by dirty drilling operations. For example:

- In Colorado, approximately 340 of the leaks or spills reported by drilling operators engaged in all types of oil and gas drilling over a five-year period polluted groundwater;[2]
- In Pennsylvania, state regulators identified 161 instances in which drinking water wells were impacted by drilling operations between 2008 and the fall of 2012;[3] and
- In New Mexico, state records show 743 instances of all types of oil and gas operations polluting groundwater—the source of drinking water for 90 percent of the state's residents.[4]

Spills and Leaks of Fracking Fluids

Toxic substances in fracking chemicals and wastewater have been linked to a variety of negative health effects on humans and fish. Chemical components of fracking fluids, for example, have been linked to cancer, endocrine disruption and neurological and immune system problems.[5] Wastewater brought to the surface by drilling can contain substances such as volatile organic compounds with potential impacts on human health.[6]

There are many pathways by which fracking fluids can contaminate drinking water supplies. Spills from trucks, leaks from other surface equipment, and well blowouts can release polluted water to groundwater and surface water. For example, in September 2009 Cabot Oil and Gas caused three spills in Dimock Township, Pennsylvania, in less than a week, dumping 8,000 gallons of fracturing fluid components into Stevens Creek and a nearby wetland.[7]

Leaks of Methane and Other Contaminants from the Well Bore

A study by researchers at Duke University found that the proximity of drinking water wells to fracking wells increases the risk of contamination of residential wells with methane in Pennsylvania. The researchers pointed to faulty well casing as a likely source.[8] Data from fracking wells in Pennsylvania from 2010 to 2012 show a 6 to 7 percent well failure rate due to compromised structural integrity.[9]

Migration of Contaminants

A recent study of contamination in drinking water wells in the Barnett Shale area of North Texas found arsenic, selenium and strontium at elevated levels in drinking water wells close to fracking sites.[10] The researchers surmise that fracking has increased pollution in drinking water supplies by freeing naturally available chemicals to move into groundwater at higher concentrations or through leaks from faulty well construction.

Toxic Fracking Waste

The wastewater produced from fracking wells contains pollutants both from fracking fluids and from natural sources underground. It returns to the surface in huge volumes—both as "flowback" immediately after fracking and "produced water" over a longer period while a well is producing oil or gas. Yet fracking operators have no safe, sustainable way of dealing with this toxic waste. The approaches that drilling companies have devised for dealing with wastewater can pollute waterways through several avenues.

- Waste pits can fail. In New Mexico, substances from oil and gas pits have contaminated groundwater at least 421 times.[11] Moreover, waste pits also present hazards for nearby wildlife and livestock. For example, in May 2010, when a Pennsylvania fracturing wastewater pit owned by East Resources leaked into a farm field, the state Department of Agriculture was forced to quarantine 28 cattle exposed to the fluid to prevent any contaminated meat from reaching the market.[12]

- Discharge of fracking wastewater into rivers can pollute drinking water supplies. For example, after water treatment plants discharged fracking wastewater into the Monongahela River, local authorities issued a drinking water advisory to 350,000 people in the area.[13] In addition, fracking wastewater discharged at treatment plants can cause a different problem for drinking water: when bromide in the wastewater mixes with chlorine (often used at drinking water treatment plants), it produces trihalomethanes, chemicals that cause cancer and increase the risk of reproductive or developmental health problems.[14]

- Drilling companies deliberately spread wastewater on roads and fields. Pollutants from the water can then contaminate local waterways. Drilling operators sometimes spray wastewater on dirt and gravel roads to control dust, or on paved roads to melt ice. In some Western states, fracking waste is spread on farmland or used to water cattle.[15]

- Deep disposal wells are a common destination for fracking waste, but these wells can fail over time, allowing the wastewater and its pollutants to mix with groundwater or surface water.[16] For example,

Photo: The Downstream Project via SkyTruth/LightHawk.

Fracking wastewater is often stored in open waste pits such as these, near Summit, Pennsylvania. Leaks from pits can contaminate drinking water supplies.

wastewater injected into a disposal well contaminated the Cenozoic Pecos Alluvium Aquifer with 6.2 billion gallons of water near Midland, Texas.[17] In Pennsylvania, a disposal well in Bell Township, Clearfield County, lost mechanical integrity in April 2011, but the operator, EXCO Resources, continued to inject fracking wastewater into the well for another five months.[18] The U.S. Environmental Protection Agency (EPA) fined the company nearly $160,000 for failing to protect drinking water supplies. Nationally, routine testing of injection wells in 2010 revealed that 2,300 failed to meet mechanical integrity requirements established by the EPA.[19]

- Pressure from injection wells may cause underground rock layers to crack, accelerating the migration of wastewater into drinking water aquifers. For example, at two injection wells in Ohio, toxic chemicals pumped underground in the 1980s, supposedly secure for at least 10,000 years, migrated into a well within 80 feet of the surface over the course of two decades.[20] Investigators believe that excessive pressure within the injection well caused the rock to fracture, allowing chemicals to escape.

Despite the risk presented to drinking water supplies by fracking, the oil and gas industry is seeking to drill near sources of drinking water for millions of people, including George Washington National Forest in Virginia, White River National Forest in Colorado, Otero Mesa in New Mexico, Wayne National Forest in Ohio, and the Delaware River Basin.

Consuming Scarce Water Resources

Each well that is fracked requires hundreds of thousands of gallons of water depending on the shale formation and the depth and length of the horizontal portion of the well. Unlike most industrial uses of water which return water to the water cycle for further use, fracking converts clean water into toxic wastewater, much of which must then be permanently disposed of, taking billions of gallons out of the water supply annually. Moreover, farmers are particularly impacted by fracking water use, as they must now compete with the deep-pocketed oil and gas industry for water, especially in the drought-stricken regions of the country.

In some areas, fracking makes up a significant share of overall water demand. In 2010, for example, fracking in the Barnett Shale region of Texas consumed an amount of water equivalent to 9 percent of the city of Dallas' annual water use.[21] An official at the Texas Water Development Board estimated that one county in the Eagle Ford Shale region will see the share of water consumption devoted to fracking and similar activities increase from zero a few years ago to *40 percent* by 2020.[22] Unlike other uses, water used in fracking is permanently lost to the water cycle, as it either remains in the well, is "recycled" (used in the fracking of new wells), or is disposed of in deep injection wells, where it is unavailable to recharge aquifers.

Already, demand for water by oil and gas companies has harmed farmers and local communities:

- In Texas, water withdrawals by drilling companies caused drinking water wells in the town of Barnhart to dry up. Companies drilling in the Permian Basin have drilled wells and purchased well water drawn from the Edwards-Trinity-Plateau Aquifer, drying up water supplies for residential and agricultural use.[23]
- Wells that provided water to farms near Carlsbad, New Mexico, have gone dry due to demand for water for drilling and years of low rainfall.[24]

Competition for limited water resources from fracking can increase water prices for farmers and communities—especially in arid western states. A 2012 auction of unallocated water conducted by the

Northern Water Conservation District in Colorado saw gas industry firms submit high bids, with the average price of water sold in the auction increasing from $22 per acre-foot in 2010 to $28 per acre-foot in the first part of 2012.[25] For the 25,000 acre-feet of water auctioned, this would amount to an added cost of $700,000.

Moreover, water pumped from rivers for fracking reduces the quality of the water remaining in the river because pollution becomes more concentrated. A 2011 U.S. Army Corps of Engineers study of the Monongahela River basin of Pennsylvania and West Virginia, where oil and gas companies withdraw water from the river for fracking, concluded that, "The quantity of water withdrawn from streams is largely unregulated and is beginning to show negative consequences."[26] The Corps report noted that water is increasingly being diverted from the relatively clean streams that flow into Corps-maintained reservoirs, limiting the ability of the Corps to release clean water to help dilute pollution during low-flow periods.[27] It described the water supply in the Monongahela basin as "fully tapped."[28]

Excessive water withdrawals undermine the ability of rivers and streams to support wildlife. In Pennsylvania, water has been illegally withdrawn for fracking numerous times, to the extent of streams being sucked dry. Two streams in southwestern Pennsylvania—Sugarcamp Run and Cross Creek—were reportedly drained for water withdrawals for fracking, triggering fish kills.[29]

Nationally, nearly half of all fracking wells are located in regions with very limited water supplies. A study by Ceres, a coalition of business and environmental interests, found that nearly 47 percent of wells fracked from January 2011 through September 2012 were located in areas with "high or extremely high water stress."[30]

Endangering Public Health with Air Pollution

Air pollution from fracking threatens the health of people living and working close to the wellhead, as well as those far away. Children, the elderly and those with respiratory diseases are especially at risk.

Fracking produces air pollution from the well bore as the well is drilled and gas is vented or flared. Emissions from trucks carrying water and materials to well sites, as well as from compressor stations and other fossil fuel-fired machinery, also contribute to air pollution. Well operations, storage of gas liquids, and other activities related to fracking add to the pollution toll.

Making Local Residents Sick

People who live close to fracking sites are exposed to a variety of air pollutants including volatile organic compounds (VOCs) such as benzene, xylene and toluene. These chemicals can cause a wide range of health problems—from eye irritation and headaches to asthma and cancer.[31]

Existing data demonstrate that fracking operations are releasing these pollutants into the air at levels that threaten our health. In Texas, monitoring by the Texas Department of Environmental Quality detected levels of benzene—a known cancer-causing chemical—in the air that were high enough to cause immediate human health concern at two sites in the Barnett Shale region, and at levels that pose long-term health concern at an additional 19 sites. Several chemicals were also found at levels that can cause foul odors.[32] Air monitoring in Arkansas has also found elevated levels of volatile organic compounds (VOCs)—some of which are also hazardous air pollutants—at the perimeter of hydraulic fracturing sites.[33] Local air pollution problems have also cropped up in Pennsylvania. Testing conducted by the Pennsylvania Department of Environmental Protection detected components of gas in the air near Marcellus Shale drilling operations.[34]

Residents living near fracking sites have long suffered from a range of acute and chronic health problems, including headaches, eye irritation, respiratory problems and nausea.[35] An investigation by the journalism website ProPublica uncovered numerous reports of illness in western states from air pollution from fracking.[36] In Pennsylvania, a homeowner in the town of Carmichaels described how she and her children began to suffer from a variety of symptoms after a compressor station was built 780 feet from her house.[37] Pam Judy explained to the nearby Murrysville Council that "Shortly after operations began, we started to experience extreme headaches, runny noses, sore/scratchy throats, muscle aches and a constant feeling of fatigue. Both of our children are experiencing nose bleeds and I've had dizziness, vomiting and vertigo to the point that I couldn't stand and was taken to an emergency room." Eventually, she convinced state officials to test air quality near her home. That testing revealed benzene, styrene, toluene, xylene, hexane, heptane, acetone, acrolein, carbon tetrachloride and chloromethane in the air.[38]

All indications are that these known stories just scratch the surface of health damage from fracking. In cases where families made sick from fracking have sought to hold drilling companies accountable in court, the companies have regularly insisted on gag orders as conditions of legal settlements—in a recent case even the children were barred from talking about fracking, for life.[39]

Workers at drilling sites also suffer from health impacts. A recent investigation by the National Institute for Occupational Safety and Health (NIOSH) found that workers at some fracking sites may be at risk of lung disease as a result of inhaling silica dust from sand injected into wells. The NIOSH investigation reviewed 116 air samples at 11 fracking sites in Arkansas, Colorado, North Dakota, Pennsylvania and Texas. Nearly half (47 percent) of the samples had levels of silica that exceeded the Occupational Safety and Health Administration's (OSHA) legal limit for workplace exposure, while 78 percent exceeded OSHA's recommended limits. Nearly one out of 10 (9%) of the samples exceeded the legal limit for silica by a factor of 10, exceeding the threshold at which half-face respirators can effectively protect workers.[40]

Over the past few years, health clinics in fracking areas of Pennsylvania have reported seeing a number of patients experiencing illnesses associated with exposure to toxic substances from fracking, all of whom have used false names and paid in cash. David Brown, a toxicologist with the Southwest Pennsylvania Environmental Health Project believes that these are mostly fracking workers, who are afraid that any record of their work making them sick will cost them their jobs.[41]

Regional Air Pollution Threats

Fracking also produces a variety of pollutants that contribute to regional air pollution problems. VOCs and nitrogen oxides (NO_x) in gas formations contribute to the formation of ozone "smog," which reduces lung function among healthy people, triggers asthma attacks, and has been linked to increases in school absences, hospital visits and premature death.[42]

Fracking is a significant source of air pollution in areas experiencing large amounts of drilling. A 2009 study in five Dallas-Fort Worth-area counties experiencing heavy Barnett Shale drilling activity found that oil and gas production was a larger source of smog-forming emissions than cars and trucks.[43] In Arkansas, gas production in the Fayetteville Shale region was estimated to be responsible for 5,000 tons of NO_x.[44] In Wyoming, pollution from fracking contributed to such poor air quality that, for the first time, the state failed to meet federal air quality standards.[45] An analysis conducted for New York State's revised draft environmental impact statement on Marcellus Shale drilling posited that, in a worst case scenario of widespread drilling and lax emission controls, shale gas production could add 3.7 percent to state NO_x emissions and 1.3 percent to statewide VOC emissions compared with 2002 emissions levels.[46]

Exacerbating Global Warming

Global warming is a profound threat to virtually every aspect of nature and human civilization—disrupting the functioning of ecosystems, increasing the frequency and violence of extreme weather, and ultimately jeopardizing health, food production, and water resources for Americans and people across the planet. Gas extraction produces enormous volumes of global warming pollution.

Fracking's primary impact on the climate is through the release of methane, which is a far more potent contributor to global warming than carbon dioxide. Over a 100-year timeframe, a pound of methane has 25 times the heat-trapping effect of a pound of carbon dioxide.[47] Methane is even more potent relative to carbon dioxide at shorter timescales, at least 72 times more over a 20-year period.

Intentional venting and leaks during the extraction, transmission and distribution of gas release substantial amounts of methane to the atmosphere. The U.S. Environmental Protection Agency revised downward its estimate of fugitive methane emissions from fracking in April 2013, citing improved practices by the industry.[48] A study conducted with industry cooperation and released in September 2013 found very low fugitive emissions of methane at the wells included in the study, though the findings may not be representative of standard industry practice.[49]

However, recent air monitoring by researchers at the National Oceanic and Atmospheric Administration and the University of Colorado, Boulder, near a gas and oil field in Colorado revealed fugitive methane emissions equal to 2.3 to 7.7 percent of the gas extracted in the basin, not counting the further losses that occur in transportation.[50] Recent aerial sampling of emissions over an oil and gas field in Uintah County, Utah, revealed methane emissions equal to 6.2 to 11.7 percent of gas production.[51]

The global warming impact of fracked natural gas is so great that electricity produced from natural gas may have a greater global warming impact than electricity from coal, especially when evaluated on a short timeline. An analysis by Professor Robert Howarth at Cornell and others found that, on a 20-year timescale, electricity from natural gas is more polluting than electricity from coal.[52]

Regardless of the fugitive emissions level from fracked gas, increased production of and reliance on gas is not a sound approach to reducing our global warming emissions. Investments in gas production and distribution infrastructure divert financing and efforts away from truly clean energy sources such as energy efficiency and wind and solar power. Gas is not a "bridge fuel" that prepares us for a clean energy future; rather, increasing our use of gas shifts our reliance from one polluting fuel to another.

Additionally, to the extent that fracking produces oil instead of gas, fracking does nothing to reduce global warming pollution: in fact, refining oil into useable products like gasoline and diesel, and then burning those products, is a huge source of global warming pollution.

Damaging America's Natural Heritage

Fracking transforms rural and natural areas into industrial zones. This development threatens national parks and national forests, damages the integrity of landscapes and habitats, and contributes to water pollution problems that threaten aquatic ecosystems.

Before drilling can begin, land must be cleared of vegetation and leveled to accommodate drilling equipment, gas collection and processing equipment, and vehicles. Additional land must be cleared for roads to the well site, as well as for any pipelines and compressor stations needed to deliver gas to market. A study by the Nature Conservancy of fracking infrastructure in Pennsylvania found that well pads average 3.1 acres and related infrastructure damages an additional 5.7 acres.[53] Often, this development occurs on remote and previously undisturbed wild lands.

As oil and gas companies expand fracking activities, national parks, national forests and other iconic landscapes are increasingly at risk. Places the industry is seeking to open for fracking include:

- **White River National Forest** – Located in Colorado, this forest draws 9.2 million visitors per year for hiking, camping and other recreation, making it the most visited national forest in the country.[54] The forest also hosts 4,000 miles of streams that provide water to several local communities and feed into the Colorado River.
- **Delaware River Basin** – This basin, which spans New Jersey, New York, Pennsylvania and Delaware, is home to three national parks and provides drinking water to 15 million people.[55]
- **Wayne National Forest** – Part of Ohio's beautiful Hocking Hills region, most of the acres in the forest are to be leased for drilling near the sole drinking water source for 70,000 people.[56]

Photo: Peter Aengst via SkyTruth/EcoFlight.

Wells and roads built to support fracking in Wyoming's Jonah gas field have caused extensive habitat fragmentation.

- **George Washington National Forest** – This area hosts streams in Virginia and West Virginia that feed the James and Potomac Rivers, which provide the drinking water for millions of people in the Washington, D.C., metro area.
- **Otero Mesa** – A vital part of New Mexico's natural heritage, Otero Mesa is home to pronghorn antelope and a freshwater aquifer that could be a major source of drinking water in this parched southwestern state.[57]

The disruption and fragmentation of natural habitat can put wildlife at risk. In Wyoming, for example, extensive gas development in the Pinedale Mesa region has coincided with a significant reduction in the region's population of mule deer. A 2006 study found that the construction of well pads drove away female mule deer.[58] The mule deer population in the area dropped by 50 percent between 2001 and 2011, as fracking in the area continued and accelerated.[59]

Concerns have also been raised about the impact of gas development on pronghorn antelope. A study by the Wildlife Conservation Society documented an 82 percent reduction in high-quality pronghorn habitat in Wyoming's gas fields, which have historically been key wintering grounds.[60]

Birds may also be vulnerable, especially those that depend on grassland habitat. Species such as the northern harrier, short-eared owl, bobolink, upland sandpiper, loggerhead shrike, snowy owl, rough-legged hawk and American kestrel rely on grassland habitat for breeding or wintering habitat.[61] These birds typically require 30 to 100 acres of undisturbed grassland for habitat.[62] Roads, pipelines and well pads for fracking may fragment grassland into segments too small to provide adequate habitat.

The clearing of land for well pads, roads and pipelines may threaten aquatic ecosystems by increasing sedimentation of nearby waterways and decreasing shade. A study by the Academy of Natural Sciences of Drexel University found an association between increased density of gas drilling activity and degradation of ecologically important headwater streams.[63]

Water contamination related to fracking has caused several fish kills in Pennsylvania. In 2009, a pipe containing freshwater and flowback water ruptured in Washington County, Pennsylvania, triggering a fish kill in a tributary of Brush Run, which is part of a high-quality watershed.[64] That same year, in the same county, another pipe ruptured at a well drilled in a public park, killing fish and other aquatic life along a three-quarter-mile length of a local stream.[65]

Imposing Costs on Communities

As with prior extractive booms, the fracking oil and gas rush disrupts local communities and imposes a wide range of immediate and long term costs on them.

Ruining Roads, Straining Services

As a result of its heavy use of publicly available infrastructure and services, fracking imposes both immediate and long-term costs on taxpayers.

The trucks required to deliver water to a single fracking well cause as much damage to roads as 3.5 million car journeys, putting massive stress on roadways and bridges not constructed to handle such volumes of heavy traffic. Pennsylvania estimates that repairing roads affected by Marcellus Shale drilling would cost $265 million.[66]

Fracking also strains public services. Increased heavy vehicle traffic has contributed to an increase in traffic accidents in drilling regions. At the same time, the influx of temporary workers that typically accompanies fracking puts pressure on housing supplies, thereby causing social dislocation. Governments respond by increasing their spending on social services and subsidized housing, squeezing tax-funded budgets.

Governments may even be forced to spend tax money to clean up orphaned wells—wells that were never properly closed and whose owners, in many cases, no longer exist as functioning business entities. Though oil and gas companies face a legal responsibility to plug wells and reclaim drilling sites, they have a track record of leaving the public holding the bag.[67]

Risks to Local Businesses, Homeowners and Taxpayers

Fracking imposes damage on the environment, public health and public infrastructure, with significant economic costs, especially in the long run after the initial rush of drilling activity has ended. A 2008 study by the firm Headwaters Economics found that Western counties that have relied on fossil-fuel extraction for growth are doing worse economically than their peers, with less-diversified economies, a less-educated workforce, and greater disparities in income.[68]

Other negative impacts on local economies include downward pressure on home values and harm to farms. Pollution, stigma and uncertainty about the future implications of fracking can depress the prices of nearby properties. One Texas study found that homes valued at more than $250,000 and located within 1,000 feet of a well site lost 3 to 14 percent of their value.[69] Fracking also has the potential to affect agriculture, both directly through damage to livestock from exposure to fracking fluids, and indirectly through economic changes that undermine local agricultural economies.

Fracking can increase the need for public investment in infrastructure and environmental cleanup. Fracking-related water demand may also lead to calls for increased public spending on water infrastructure. Texas, for example, adopted a State Water Plan in 2012 that calls for $53 billion in investments in the state water system, including $400 million to address unmet needs in the mining sector (which includes hydraulic fracturing) by 2060.[70] Fracking is projected to account for 42 percent of water use in the Texas mining sector by 2020.[71]

The cost of cleaning up environmental damage from the current oil and gas boom may fall to taxpayers, as has happened with past booms. For example, as of 2006, more than 59,000 orphan oil and gas wells were on state waiting lists for plugging and remediation across the United States, with at least an additional 90,000 wells whose status was unknown or undocumented.[72] Texas alone has more than 7,800 orphaned oil and gas wells.[73] These wells pose a continual threat of groundwater pollution and have cost the state of Texas more than $247 million to plug.[74] The current fracking boom ultimately may add to this catalog of orphaned wells.

Threatening Public Safety

Fracking harms public safety by increasing traffic in rural areas where roads are not designed for such high volumes, by creating an explosion risk from methane, and by increasing earthquake activity.

Increasing traffic—especially heavy truck traffic—has contributed to an increase in traffic accidents and fatalities in some areas in which fracking has unleashed a drilling boom, as well as an increase in demands for emergency response. In the Bakken Shale oil region of North Dakota for example, the number of highway crashes increased by 68 percent between 2006 and 2010, with the share of crashes involving heavy trucks also increasing over that period.[75] A 2011 survey by StateImpact Pennsylvania in eight counties found that 911 calls had increased in seven of them, with the number of calls increasing in one county by 49 percent over three years, largely due to an increase in incidents involving heavy trucks.[76]

Methane contamination of well water poses a risk of explosion if the gas builds up inside homes. In both Ohio and Pennsylvania, homes have exploded after high concentrations of methane inside the buildings were ignited by a spark.[77]

Another public safety hazard stems from earthquakes triggered by injection wells. For example, on New Year's Eve in 2011—shortly after Ohio began accepting increasing amounts of wastewater from Pennsylvania—a 4.0 earthquake shook Youngstown, Ohio. Seismic experts at Columbia University determined that pumping fracking wastewater into a nearby injection well caused the earthquake.[78] Earthquakes triggered by injection well wastewater disposal have happened in Oklahoma, Arkansas, Texas, Ohio and Colorado. The largest quake—a magnitude 5.7 temblor in Oklahoma that happened in 2011—injured two people, destroyed 14 homes and buckled highways. People felt the quake as far as 800 miles away.[79]

As fracking wastewater volumes have increased dramatically since 2007, the number of earthquakes in the central United States, where injection well disposal is common, has increased by more than 1,100 percent compared to earlier decades.[80] Scientists at the U.S. Geological Survey have concluded that humans are likely the cause.[81] After reviewing data on the Oklahoma quake, Dr. Geoffrey Abers, a seismologist at the Lamont-Doherty Earth Observatory, concluded that, "the risk of humans inducing large earthquakes from even small injection activities is probably higher" than previously thought.[82]

Quantifying the State and National Impacts of Fracking

Fracking imposes numerous costly impacts on our environment and public health. This report seeks to estimate several key impacts of fracking for oil and gas, with a primary focus on high-volume fracking.

There have been few, if any, efforts to quantify the cumulative impacts of fracking at a state or national scale. The task is made difficult, in part, by differing definitions and data collection practices for unconventional drilling used in the states. These variations in data make it difficult to isolate high-volume fracking from other practices. To address this challenge, we collected data on unconventional drilling targets (shale gas, shale oil, and tight-gas sands) and practices (horizontal and directional drilling) to ensure the comprehensiveness of the data. Where possible, we then narrowed the data to include only those wells using high-volume hydraulic fracturing involving more than 100,000 gallons of water.

Photo: The Downstream Project via SkyTruth/LightHawk.

More than 6,000 shale gas/liquids wells, such as this well site in Tioga County, have been drilled in Pennsylvania since 2005.

The data presented in the following sections come from multiple sources, including state databases, estimates from knowledgeable state employees, and information provided by oil and gas companies to a national website. As a result, the quality of the data varies and figures may not be directly comparable from state to state. Nonetheless, the numbers paint an initial picture of the extensive environmental and public health damage from fracking.

Table 1. Estimate of Fracking Wells[83]

State	Fracking Wells since 2005	Fracking Wells Drilled in 2012
Arkansas	4,910	719
Colorado	18,168	1,896
Kansas	407	236
Louisiana	2,327	139
Mississippi	9	Unavailable
Montana	264	174
New Mexico	1,353	482
North Dakota	5,166	1,713
Ohio	334	234
Oklahoma	2,694	Unavailable
Pennsylvania	6,651	1,349
Tennessee	30	Unavailable
Texas	33,753	13,540
Utah	1,336	765
Virginia	95	1
West Virginia*	3,275	610
Wyoming	1,126	468
TOTAL	**81,898**	**22,326**

"Unavailable" means information was not available to determine when wells were drilled. See methodology for complete details.

** Data for West Virginia is for permitted fracking wells, not wells that have been drilled. Data were not available on drilled wells.*

Wells Fracked by State

The most basic measure of fracking's scope is a tally of how many fracking wells have been drilled. In addition, having an accurate count of wells by state offers a basis for estimating specific impacts to water, air and land.

Fracking has occurred in at least 17 states (see Table 1), affecting approximately 82,000 wells. In the eastern U.S., Pennsylvania reports the most fracking wells since 2005, with 6,651 wells tapping into the Marcellus and Utica shales. More than 5,000 fracking wells have been drilled in North Dakota to produce oil from the Bakken formation. Western states with the most fracking include Colorado, New Mexico and Utah.

Absent policies to rein in fracking, fracking is likely to expand in these and other states. Tennessee currently has a handful of wells but more will soon be fracked in the Cumberland Forest.[84] One test well was fracked in Georgia in the past year.[85] Illinois recently adopted new regulations governing fracking, paving the way for the practice there.[86] Oil and gas companies are seeking to expand to states such as California, New York, Maryland and North Carolina where there has been no such activity to date. In New York, as many as 60,000 wells could be drilled.[87]

Wastewater Produced

One of the more serious threats fracking poses to drinking water is the millions of gallons of toxic wastewater it generates.

While there are many ways in which fracking can contaminate drinking water—including but not limited to spills of fracking fluid, well blowouts, leaks of methane and other contaminants from the well bore into groundwater, and the possible eventual migration of fluids from shale to the water table—one of the most serious threats comes from the millions of gallons of toxic wastewater fracking generates.

Table 2 shows how much wastewater has been produced from fracking wells in selected states. In some states, such as New Mexico, North Dakota, Ohio, Pennsylvania and Utah, well operators submit regular reports on the volume of wastewater, oil and gas produced from their wells. In some states where operators do not report wastewater volumes, we estimated wastewater volumes using state-specific data as described in the methodology. These estimates are for wastewater only, and do not include other toxic wastes from fracking, such as drilling muds and drill cuttings.

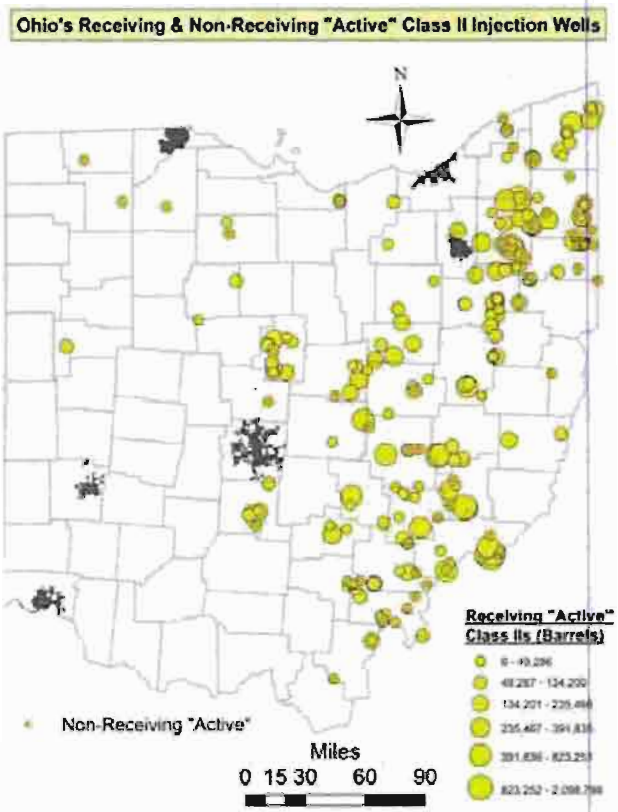
The rapid growth of fracking has caused wastewater volumes to increase rapidly. In the Marcellus Shale underlying Pennsylvania, West Virginia and Ohio, for example, wastewater production increased six-fold from 2004 to 2011.[89]

Table 2. Wastewater from Fracking in 2012[88]

State	Wastewater Produced (million gallons)
Arkansas	800
Colorado	2,200
Kansas	No estimate
Louisiana	No estimate
Mississippi*	10
Montana	360
New Mexico	3,000
North Dakota**	12,000
Ohio	30
Oklahoma	No estimate
Pennsylvania	1,200
Tennessee	No estimate
Texas	260,000
Utah	800
Virginia	No estimate
West Virginia	No estimate
Wyoming	No estimate
TOTAL	**280,000**

** Data for Mississippi are for 2012-2013.*

*** Data for North Dakota are cumulative to early 2013.*



Fracking wastewater is disposed into Class II injection wells in Ohio. "Receiving" wells currently accept fracking wastewater. "Non-receiving" wells are those wells that could receive fracking wastewater but haven't to date. Data mapped by the FracTracker Alliance on FracTracker.org. Original data source: *Bulk Transporter Magazine*, accessed at www.fractracker.org/2013/06/oh-waste-network, 23 July 2013.

In 2012 alone, fracking in Pennsylvania produced 1.2 billion gallons of wastewater, almost as much as was produced in a three-year period from 2009 to 2011.[90]

This huge volume of polluted wastewater creates many opportunities for contaminating drinking water. More wells and more wastewater increase the odds that the failure of a well casing or gasket, a wastewater pit or a disposal well will occur and that drinking water supplies will be contaminated. Moreover, as the sheer volume of wastewater generated exceeds local disposal capacity, drilling operators are increasingly looking to neighboring states as convenient dumping grounds. For example, in 2011, more than 100 million gallons of Pennsylvania's fracking waste were trucked to Ohio for disposal into underground injection wells.[91] (See map of Ohio disposal wells.)

As the volume of this toxic waste grows, so too will the likelihood of illegal dumping. For example, in 2013 Ohio authorities discovered that one drilling waste operator had dumped thousands of gallons of fracking wastewater into the Mahoning River.[92] And in Pennsylvania, prosecutors recently charged a different company with dumping fracking waste.[93]

For other industries, the threats posed by toxic waste have been at least reduced due to the adoption of the federal Resource Conservation Recovery Act (RCRA), which provides a national framework for regulating hazardous waste. Illegal dumping is reduced by cradle-to-grave tracking and criminal penalties. Health-threatening practices such as open waste pits, disposal in ordinary landfills, and road spreading are prohibited. However, waste from oil and gas fracking is exempt from the hazardous waste provisions of RCRA—exacerbating the toxic threats posed by fracking wastewater.

Chemicals Used

Fracking fluid consists of water mixed with chemicals that is pumped underground to frack wells. Though in percentage terms, chemicals are a small component of fracking fluid, the total volume of chemicals used is immense.

The oil and gas industry estimates that 99.2 percent of fracking fluid is water (by volume) and the other 0.8 percent is a mix of chemicals.[94] Assuming that this percentage is correct and has held true since 2005, that means oil and gas companies have used 2 billion gallons of chemicals.

These chemicals routinely include toxic substances. According to a 2011 congressional report, the toxic chemicals used in fracking include methanol, glutaraldehyde, ethylene glycol, diesel, naphthalene, xylene, hydrochloric acid, toluene and ethylbenzene.[95] More recently, an independent analysis of data submitted by fracking operators to FracFocus revealed that *one-third* of all frack jobs reported there use at least one cancer-causing chemical.[96] These toxic substances can enter drinking water supplies from the well, well pad or in the wastewater disposal process.

Water Used

Since 2005, fracking has used at least 250 billion gallons of water across the nation. Extrapolating from industry-reported figures on water use at more than 36,000 wells since 2011, we estimated total water use for all wells that were fracked from 2005 through mid-2013. (See Table 3.)

The greatest total water consumption occurred in Texas, at the same time the state was struggling with extreme drought. Other states with high water use include Pennsylvania, Arkansas and Colorado. The amount of water used for fracking in Colorado was enough to meet the water needs of nearly 200,000 Denver households for a year.[97]

Table 3. Water Used for Fracking[98]

State	Total Water Used since 2005 (million gallons)
Arkansas	26,000
Colorado	26,000
Kansas	670
Louisiana	12,000
Mississippi	64
Montana	450
New Mexico	1,300
North Dakota	12,000
Ohio	1,400
Oklahoma	10,000
Pennsylvania	30,000
Tennessee	130
Texas	110,000
Utah	590
Virginia	15
West Virginia	17,000
Wyoming	1,200
TOTAL	**250,000**

Air Pollution Created

Fracking created hundreds of thousands of tons of air pollution in 2012. As shown in Table 4, well-site operations during drilling and well completion generated approximately 450,000 tons of health-threatening air pollution. And that does not even include the significant emissions from ongoing operations, compressors, waste pits and truck traffic to and from drilling sites carrying supplies and personnel.

This air pollution estimate for all wells is based on emissions figures from wells in the Marcellus Shale. Different drilling targets and practices may lead to different results.[99] Additional research and improved data availability will help clarify the amount of pollution occurring in different regions.

The 2012 NO_x emissions from the early stages of fracking in Colorado were equal to 27 percent of the NO_x produced by power plants in the state, assuming fracking well emissions rates were similar to those in the Marcellus.[100] In Pennsylvania, fracking produced NO_x equal to 7 percent of that emitted in 2011 by electricity generation, a major source of smog-forming emissions.

Table 4. Estimated Air Pollution Produced from Early Stages of Fracking (Drilling and Well Completion) in 2012 (tons)

State	Particulate Matter	NO_x	Carbon Monoxide	VOCs	Sulphur Dioxide
Arkansas	400	5,300	8,100	700	20
Colorado	1,100	14,000	21,000	2,000	50
Kansas	100	1,700	2,700	200	6
Louisiana	80	1,000	1,600	100	3
Mississippi	Unavailable	Unavailable	Unavailable	Unavailable	Unavailable
Montana	100	1,300	2,000	200	4
New Mexico	300	3,600	5,400	500	10
North Dakota	1,000	13,000	19,000	2,000	40
Ohio	100	1,700	2,600	200	6
Oklahoma	Unavailable	Unavailable	Unavailable	Unavailable	Unavailable
Pennsylvania	800	10,000	15,000	1,000	30
Tennessee	Unavailable	Unavailable	Unavailable	Unavailable	Unavailable
Texas	7,800	100,000	153,000	14,000	300
Utah	400	5,700	9,000	1,000	20
Virginia	1	7	11	1	0
West Virginia	400	4,500	6,900	600	20
Wyoming	270	3,500	5,300	500	12
TOTAL	**13,000**	**170,000**	**250,000**	**23,000**	**600**

Global Warming Pollution Released

Completion of fracking wells produced global warming pollution of 100 million metric tons of carbon dioxide equivalent from 2005 to 2012, equal to emissions from 28 coal-fired power plants in a year.[101]

Using the data on the number of fracking wells, we estimated emissions from well completion using an emissions rate from a recent study by researchers at MIT. The researchers calculated that the average fracked shale gas well completed in 2010 released 110,000 pounds of methane during the first nine days of operation.[102] The researchers assumed that 70 percent of wells were operated with equipment to limit emissions, that 15 percent of wells flared gas, and that 15 percent of wells vented gas. Their calculations did not include methane emissions after the first nine days, such as during processing, transmission and distribution, nor did they include carbon dioxide emissions from trucks and drilling equipment. We used data on the number of wells fracked since 2005 (as presented in Table 1 in "Estimate of Fracking Wells") to estimate methane emissions. Table 5 presents estimated emissions from completion of fracking wells from 2005 to 2012.

In Texas, emissions from completion of fracking wells since 2005 are equal to those produced by 12 coal-fired power plants in a year.[103] Completion of wells in Pennsylvania produced emissions equal to the pollution from 1.7 million passenger vehicles in a year.[104]

This estimate of emissions from well completion is both incomplete and includes several points of uncertainty. First and foremost, it does not include emissions from ongoing operation of wells. Second, in states where regulators do not have a firm estimate of the number of fracking wells, such as in Colorado and Texas, our conservative estimate of the number of fracking wells results in an underestimate of emissions. Introducing uncertainty, this estimate treats all wells as if they were the same and have the same emissions. In reality, some wells produce gas, some produce oil, and some wells produce gas that requires additional processing.[105] Finally, even those states that track the number of fracking wells typically don't track well type.

We believe this estimate of emissions from well completions understates total emissions from fracking wells. To compare this estimate of emissions from well completion to an estimate from ongoing emissions and to avoid the problem of uncertainty regarding emissions by well type, we estimated emissions based on gas production for a few states.

Table 5. Global Warming Pollution from Completion of Fracking Wells

State	Based on Well Completion from 2005 to 2012 (metric tons of carbon dioxide-equivalent)
Arkansas	6,200,000
Colorado	23,000,000
Kansas	500,000
Louisiana	2,900,000
Mississippi	11,000
Montana	300,000
New Mexico	1,700,000
North Dakota	6,500,000
Ohio	420,000
Oklahoma	3,400,000
Pennsylvania	8,300,000
Tennessee	No estimate
Texas	40,000,000
Utah	1,700,000
Virginia	120,000
West Virginia	4,100,000
Wyoming	1,400,000
TOTAL	**100,000,000**

Researchers at Cornell have studied emissions from fracking in five unconventional gas formations.[106] The researchers estimated the methane emissions released from multiple steps in the fracking process—drilling, fracking and processing—and calculated emissions as a percentage of produced gas.[107] Using estimates of gas production by state, where available, we calculated statewide global warming pollution from fracking. For the two states where we have complete production data—Pennsylvania and North Dakota—the production-based emissions estimate is higher than the estimate based on the number of completed wells.

Using our production-based method, Pennsylvania, North Dakota and Colorado had the highest emissions. Pennsylvania produced the most global warming pollution from fracking for gas. In 2012, the state created 24 million metric tons of carbon dioxide-equivalent, as much pollution as produced by seven coal-fired power plants or 5 million passenger vehicles.[108]

Photo: Gerry Dincher/Flickr.

Storage tanks can be a significant source of fugitive methane emissions.

Acres of Land Damaged

Nationally, land directly damaged for fracking totals 360,000 acres. (See Table 6.) This estimate includes the amount of land that has been cleared for roads, well sites, pipelines and related infrastructure in each state. However, the total amount of habitat and landscape affected by fracking is much greater. In treasured open spaces, a single well-pad can mar a vista seen from miles around. A study of fracking development in Pennsylvania estimated that forest fragmentation affected more than twice as much land as was directly impacted by development.[109]

Fracking activity in Colorado damaged 57,000 acres, equal to one-third of the acreage in the state's park system.[110] In Pennsylvania, the amount of land directly affected by fracking-related development since 2005 is equal to all the farmland protected since 1999 through the state's Growing Greener land preservation program.[111]

Table 6. Land Damaged for Fracking[112]

State	Acres Damaged since 2005
Arkansas	24,000
Colorado	57,000
Kansas	No estimate
Louisiana	No estimate
Mississippi	No estimate
Montana	230
New Mexico	8,900
North Dakota	50,000
Ohio	1,600
Oklahoma	22,000
Pennsylvania	33,000
Tennessee	No estimate
Texas	130,000
Utah	9,000
Virginia	460
West Virginia	16,000
Wyoming	5,000
TOTAL	**360,000**

Photo: ©Dennis Dimick/Flickr.

A grid of drilling sites and roads, similar to those used in fracking, lies across the landscape near Odessa, Texas.

In the years to come, fracking may affect a much bigger share of the landscape. According to a recent analysis by the Natural Resources Defense Council, 70 of the nation's largest oil and gas companies have leases to 141 million acres of land, bigger than the combined areas of California and Florida.[113] Moreover, as noted earlier in this report, the oil and gas industry is seeking access to even more acres of land for fracking—including areas on the doorsteps of our national parks, and inside our national forests—some of which contain sources of drinking water for millions of Americans.

Policy Recommendations

As evidenced by the data in this report, fracking is causing extensive damage to the environment and public health in states across the country. States as disparate as Colorado, North Dakota, Pennsylvania and Texas suffer from air pollution, water pollution, habitat disruption and water depletion caused by widespread fracking. Wherever fracking has occurred, it has left its mark on the environment and our well-being.

Fracking has additional impacts not documented in this report. Environmental damage includes water pollution from spills of fracking fluids and methane leaks into groundwater, as well as air pollution from toxic emissions that causes both acute and chronic health problems for people living near wells. Economic and social damage includes ruined roads and damage to farm economies.

The scale of this threat is growing almost daily, with thousands of new wells being added across the nation each year. Given the scale and severity of fracking's myriad impacts, constructing a regulatory regime sufficient to protect the environment and public health from dirty drilling—much less enforcing such safeguards at more than 80,000 wells, plus processing and waste disposal sites across the country—seems implausible at best.

In states where fracking is already underway, an immediate moratorium is in order. In all other states, **banning fracking is the prudent and necessary course to protect the environment and public health.**

- At a minimum, state officials should allow cities, towns and counties to protect their own citizens through local bans and restrictions on fracking.
- Moreover, states bordering on the fracking boom should also bar the processing of fracking waste so that they will not become dumping grounds for fracking operations next door. Vermont has already banned fracking and its waste, and similar proposals are under consideration in other states.

Where fracking is already happening, the least we should expect from our government is to **reduce the environmental and health impacts of dirty drilling as much as possible**, including:

- The federal government should close the loopholes that exempt fracking from key provisions of our federal environmental laws. For example, fracking wastewater, which often contains cancer-causing and even radioactive material, is exempt from our nation's hazardous waste laws.
- Federal and state governments should protect treasured open spaces and vital drinking water supplies from the risks of fracking. In 2011, the Obama administration's science advisory panel on fracking recommended the "[p]reservation of unique and/or sensitive areas as off limits to drilling and support infrastructure."[114] In keeping with this modest directive, dirty fracking should not be allowed near our national parks, national forests or in watersheds that supply drinking water.

- Policymakers should end worst practices. Fracking operators should no longer be allowed to use open waste pits for holding wastewater. The use of toxic chemicals should not be allowed in fracking fluids. Operators should be required to meet aggressive water use reduction goals and to recycle wastewater.

To ensure that the oil and gas industry—rather than taxpayers, communities or families—pays the costs of fracking damage, states and the Bureau of Land Management should **require robust financial assurance from operators at every well site**.

While we conclude that existing data alone is sufficient to make the case against fracking, additional data will provide a more complete picture and is critical for local communities and residents to assess ongoing damage and liability where fracking is already occurring. As this report revealed, data available on fracking are inconsistent, incomplete and difficult to analyze. To remedy this, oil and gas companies should be required to report all fracking wells drilled, all chemicals used, amount of water used, and volume of wastewater produced and toxic substances therein. Reporting should occur into an accessible, national database, with chemical use data provided 90 days before drilling begins.

Methodology

This report seeks to estimate the cumulative impacts of fracking for oil and gas in the United States. We attempted to limit the scope of the data included in the report to wells using high-volume hydraulic fracturing with horizontal drilling, because that new technology has the greatest environmental impacts and its use is increasing rapidly. However, the definition of and data collection practices for unconventional drilling vary significantly from state to state, making it difficult—and in some cases impossible—to limit our study only to those wells that have been developed using high-volume fracking.

To ensure that our estimates included the most comprehensive data possible, we began by collecting—largely from state oil and gas regulators, as described below—data on all unconventional drilling targets and practices (excluding acidization). Where possible, we then narrowed the data to include only those wells using high-volume hydraulic fracturing involving more than 100,000 gallons of water and/or horizontal drilling. In many states, the information needed to identify these wells was lacking. In those states, we included all wells using unconventional drilling practices in the data. In the section "Number of Wells, Wastewater and Produced Gas," we explain what types of drilling are included in the data for each state.

For data on water use and for teasing apart state data on conventional and unconventional wells, we relied heavily on the work done by SkyTruth to make data reported by the fracking industry more accessible. Oil and gas drilling companies report some of their fracking activities to the FracFocus website, providing information on individual wells in separate PDF files. SkyTruth compiles these individual PDFs and extracts the data "as is," placing the data into a standard machine-readable database that can be downloaded and analyzed. We downloaded SkyTruth's *Fracking Chemical Database* from frack.skytruth.org/fracking-chemical-database/frack-chemical-data-download on 12 June 2013. References below to SkyTruth data or API numbers from SkyTruth refer to this database.

The data we were able to collect undercounts the scope of fracking and its damage, for several reasons. First, when the data were unclear, we made conservative assumptions and chose conservative methodologies. Second, the FracFocus data we drew upon for some of our calculations are incomplete (see text box "Problems with FracFocus Data").

Our analysis does not include data from several states where fracking is a subject of policy debates, including Michigan and California. In those states, the data show that little to no fracking has occurred using high volumes of water because oil and gas companies have not yet begun to combine horizontal drilling with fracking. In these states, hydraulic fracturing has taken place in vertical wells, which require far less water.

Problems with FracFocus Data

Data collected on the FracFocus website have several limitations: FracFocus does not include all fracking wells in the nation, the data that are provided can be of poor quality, and loopholes in reporting requirements enable companies to hide some information.

The FracFocus website does not include data on all fracking wells. The website came into operation in 2011, after thousands of wells had already been fracked and in most cases operators have not retroactively entered information on older wells. Furthermore, in many states, reporting to FracFocus is voluntary and therefore the website does not cover all wells fracked since 2011. Only Colorado, Louisiana, Montana, New Mexico, North Dakota, Oklahoma, Pennsylvania, Texas and Utah require reporting to FracFocus.[115] In most of those states, however, the reporting requirement was adopted in 2012 or later and therefore not all earlier fracking activity is included on FracFocus.

Table 7. FracFocus Contains an Incomplete Count of Fracking Wells (Using More than 100,000 Gallons of Water)

	Count from FracFocus		Count Based on State Data	
State	**Fracking Wells since 2005**	**Fracking Wells in 2012**	**Fracking Wells since 2005**	**Fracking Wells in 2012**
Arkansas	1,461	611	4,910	719
Colorado	4,996	2,308	18,168	1,896
Kansas	150	108	407	236
Louisiana	1,078	346	2,327	139
Mississippi	5	3	9	Unavailable
Montana	264	174	264	174
New Mexico	916	515	1,353	482
North Dakota	2,654	1,653	5,166	1,713
Ohio	156	121	334	234
Oklahoma	2,097	1,270	2,694	Unavailable
Pennsylvania	2,668	1,295	6,651	1,349
Tennessee	2	0	30	Unavailable
Texas	16,916	9,893	33,753	13,540
Utah	1,336	765	1,336	765
Virginia	5	3	95	1
West Virginia	280	170	3,275	610
Wyoming	1,126	468	1,126	468
TOTAL	**36,457**	**19,923**	**81,898**	**22,326**

We compared the data we collected from states with the data included in FracFocus. SkyTruth's database of FracFocus data contains records for approximately 36,000 unique wells that used more than 100,000 gallons of water. Based on data we collected directly from states, we tallied more than 80,000 wells from the beginning of 2005 through mid-2013. Table 7 shows the state-by-state differences between our figures and those derived from FracFocus.

Further evidence of how much data are missing from FracFocus comes from a comparison of water use in all Texas wells reported to FracFocus by individual oil and gas companies versus water use calculated for the Texas Oil & Gas Association. This comparison shows that the figures in FracFocus in 2011 might be 50 percent too low. According to Jean-Philippe Nicot, et al., for the Texas Oil & Gas Association, *Oil & Gas Water Use in Texas: Update to the 2011 Mining Water Use Report*, September 2012, fracking used 81,500 acre-feet of water in Texas in 2011 and consumed 68,400 acre-feet. In contrast, the data from SkyTruth's compilation of FracFocus data suggest total use was 46,500 acre-feet in 2011. Reporting by Texas operators was voluntary at this point, and in 2011 only half of Texas wells were reported to FracFocus, according to Leslie Savage, Chief Geologist, Oil and Gas Division of the Texas Railroad Commission, personal communication, 20 June 2013.

Second, the quality and scope of the data are inconsistent. Typographical errors and incorrect chemical identifying numbers mean some of the data are unusable.

Finally, companies are not required to report all the chemicals they use in the fracking process. Through a trade-secrets exemption, drilling companies can mask the identities of chemicals. In some states, up to 32 percent of the chemicals used are not disclosed because companies claim they are trade secrets, per SkyTruth, *SkyTruth Releases Fracking Chemical Database*, 14 November 2012.

Number of Wells, Wastewater and Produced Gas

We obtained most of our data on a state by state basis for the number of wells, the amount of wastewater produced, and the amount of gas produced.

Arkansas

Data on well completions in Arkansas came from Arkansas Oil and Gas Commission, *Fayetteville Well Completion Report*, downloaded from www.aogc2.state.ar.us/FayettevilleShaleInfo/regularly%20updated%20docs/B-43%20Field%20-%20Well%20Completions.pdf, 4 June 2013. Essentially all these wells are fracked, per James Vinson, Webmaster, Little Rock Office, Arkansas Oil & Gas Commission, personal communication, 4 June 2013. We included wells with no date listed for "Date of 1st Prod" when they had other remarks indicating they were drilled in the past few years.

Our calculation of the volume of flowback and produced water in Arkansas is based on a finding in J.A. Veil, Environmental Science Division, Argonne National Laboratory, for the U.S. Department of Energy, Office of Fossil Energy, National Energy Technology Laboratory, *Water Management Practices Used by Fayetteville Shale Gas Producers*, June 2011. Veil reports that one producer in the Fayetteville Shale estimates that "the combined return volume of flowback water and subsequent produced water for the Fayetteville shale is … about 25%." We multiplied this by data on water consumed to frack Fayetteville shale wells in 2012.

Colorado

Colorado does not track fracking wells separately from other oil and gas wells. To estimate the number of fracking wells in the state, we counted the number of wells in Weld, Boulder, Garfield and Mesa counties with spud dates of 2005 or later. Data on well completions came from Colorado Oil and Gas Conservation

Commission, *2013 Production Summary*, accessed at cogcc.state.co.us/, 3 September 2013, and guidance on which counties to include came from Diana Burn, Eastern Colorado Engineering Supervisor, Colorado Oil and Gas Commission, personal communication, 4 September 2013. Many wells in Weld and Boulder counties use fracking to tap the Niobrara and Codell formations, while wells in Garfield and Mesa counties target the Piceance Basin. We excluded wells from all other counties because those wells use lower volumes of water due to shallower wells, foam fracking, or recompletion of existing wells.

Our estimate of gas production and produced water volumes came from Colorado Oil and Gas Conservation Commission, *2012 Annual Production Summary* (Access database), downloaded 25 June 2013. We selected for gas and water production data from all wells drilled in Weld, Garfield, Boulder and Mesa counties since 2005 as described above.

Kansas

We obtained data on all horizontal wells from Kansas Geological Survey, *Oil and Gas Well Database*, accessed at chasm.kgs.ku.edu, 30 May 2013. We counted only those wells with a listed spud date. We were unable to obtain an estimate of wastewater produced.

Louisiana

We obtained data on shale wells drilled in the Haynesville formation from Louisiana Department of Natural Resources, *Haynesville Shale Wells* (spreadsheet), updated 13 June 2013. We counted only those wells with a spud date. The majority of fracking in Louisiana is occurring in the Haynesville shale, per Michael Peikert, Manager, Environmental Section of Engineering Division at the Department of Natural Resource's Office of Conservation, personal communication, early June 2013.

Data on produced water are not available in Louisiana.

Mississippi

Mississippi began requiring permits for fracking wells only in March 2013. Therefore, we used data provided to FracFocus by oil and gas companies involved in fracking. We used the "Find a Well" function on the FracFocus website to search for wells in Mississippi as of 18 June 2013. Reporting to the FracFocus website is voluntary for companies in Mississippi, so the website likely undercounts fracking wells in the state.

Monthly data on produced water are available well by well from the Mississippi Oil and Gas Board's website (http://gis.ogb.state.ms.us/MSOGBOnline/) using individual API numbers. We looked up three wells, one of which has been abandoned, and used the volume of produced water to calculate a state average.

Montana

Our count of fracking wells came from the FracFocus database. We screened for wells that reported using more than 100,000 gallons of water, and counted 264 wells.

This estimate is conservative. A tally of new horizontal and recompleted horizontal wells in Montana Board of Oil and Gas Conservation, *Horizontal Well Completion Count*, accessed at www.bogc.dnrc.mt.gov, 29 May 2013 turned up 1,052 wells, which may include some coalbed methane wells.

To obtain an estimate of produced water, we downloaded the list of API numbers in Montana reported to FracFocus and compiled by SkyTruth. We provided that list of API numbers, which started in 2011, to Jim Halvorson, Petroleum Geologist, Montana Board of Oil and Gas, who queried the state's database for all produced water reports associated with those API numbers in a spreadsheet on 27 June 2013. We summed the produced water figures for the 12-month period ending 31 May 2013.

New Mexico

We calculated the total number of fracking wells in New Mexico in two different ways and chose to use the lower estimate to be conservative.

We counted 1,353 fracking wells by downloading a list of all permitted wells in the state from New Mexico Energy, Minerals and Natural Resources Department, Oil Conservation Division, *OCD Data and Statistics*, 12 June 2013. We selected all wells with an "H" (for hydraulically fractured) at the end of the well name, per a conversation with Phillip Goetze, New Mexico Oil Conservation Division, 25 June 2013. We further screened the wells to include just those with a status of "Active," "Plugged" or "Zone Plugged." We included wells that were identified as "New (Not drilled or compl)" if those records otherwise contained information suggesting the well has been completed (by listing days in production in 2011, 2012, or 2013). This count included a few wells started before 2005.

We counted 1,803 fracking wells by reviewing the list of hydraulic fracturing fluid disclosure forms submitted by drillers for approval before fracking a well. We obtained the list from New Mexico Oil Conservation Division, *Action Status Permitting Database*, 13 June 2013. The requirement to submit these forms began in 2012, so this count doesn't include wells from 2011 and earlier. This approach was based on a conversation with Laurie Hewig, Administrative Bureau Chief, New Mexico Oil Conservation Division, 13 June 2013.

To estimate produced water, we used water production data reported in New Mexico Energy, Minerals and Natural Resources Department, Oil Conservation Division, *OCD Data and Statistics*, 12 June 2013, and filtered as described above. We obtained gas production figures in the same manner.

North Dakota

We obtained data on fracking wells in North Dakota from North Dakota Oil and Gas Division, *Bakken Horizontal Wells by Producing Zone*, accessed at www.dmr.nd.gov, 29 May 2013. We assumed that all horizontal wells are fracked and that all fracking in the state happens in the Bakken Shale. We obtained data on produced water from this same data source. However, reported production data are cumulative by well and we could not calculate production by all fracking wells over a one-year period. Therefore, our tally of water includes multiple years of production.

Data on gas production from fracking wells comes from North Dakota Industrial Commission, Department of Mineral Resources, *North Dakota Monthly Gas Production and Sales*, accessed at www.dmr.nd.gov/oilgas/stats/Gas1990ToPresent.pdf, 9 August 2013. We tallied production in 2012 only.

Ohio

For Ohio, we included data for wells drilled in both the Marcellus and Utica shales from the Ohio Department of Natural Resources, Division of Oil & Gas Resources. The state separates shale well permit activity into Marcellus and Utica categories, and presents it in spreadsheets entitled *Cumulative Permitting Activity*, available at oilandgas.ohiodnr.gov/shale#SHALE, with well sites permitted through 2 May 2013.

Produced water and gas information for the Utica came from Ohio Department of Natural Resources, Division of Oil & Gas Resources, *2012 Utica Shale Production Report*, 16 May 2013. Data on production from the 11 drilled Marcellus wells came from Ohio Department of Natural Resources, Division of Oil & Gas Resources, *Ohio Oil & Gas Well Database*, accessed at http://oilandgas.ohiodnr.gov/well-information/oil-gas-well-database, 24 June 2013. We used the API numbers from Ohio Department of Natural Resources, Division of Oil & Gas Resources, *Marcellus Shale Horizontal Wells*, 6 July 2013.

Oklahoma

Our count of fracking wells in Oklahoma came from a database downloaded from FracTracker, *Oklahoma Shale Wells (3-18-2013)*, accessed at www.fractracker.org/downloads/, 28 June 2013. The database does not contain any date information.

Pennsylvania

We included data for all unconventional wells with spud dates of January 1, 2005 and later from Pennsylvania Department of Environmental Protection, *Oil and Gas Reports: SPUD Data Report*, www.portal.state.pa.us, 29 May 2013.

Data on gas and water produced in 2012 from Pennsylvania's fracking wells came from the Pennsylvania Department of Environmental Protection, *PA DEP Oil & Gas Reporting Website—Statewide Data Downloads by Reporting Period*, accessed at www.paoilandgasreporting.state.pa.us/publicreports/Modules/DataExports/DataExports.aspx, 24 June 2013. Our produced water tally included "Drilling Fluid Waste," "Fracing Fluid Waste" and "Produced Fluid."

Tennessee

Our estimate of the number of fracking wells came from Ron Clendening, Geologist, Oil & Gas Contacts, Division of Geology, Tennessee Department of the Environment and Conservation, personal communication, 8 July 2013. We were unable to obtain an estimate of wastewater or gas production.

Texas

Texas began keeping track of fracking wells in February 2012. To compile an estimate of fracking wells since 2005, we used several data sources.

- 2005-2009: We assume that from 2005 through 2009, the bulk of fracking activity in Texas occurred in the Barnett Shale and was barely beginning elsewhere. A total of 8,746 new horizontal wells were drilled in the Barnett Shale from 2005 through 2009, per *Powell Barnett Shale Newsletter*, 18 April 2010, as cited in Zhongmin Wang and Alan Krupnick, *A Retrospective Review of Shale Gas Development in the United States*, Resources for the Future, 2013. The Eagle Ford Shale was first drilled in 2008 and by 2009 there were 107 producing oil and gas wells, per Texas Railroad Commission, *Eagle Ford Information*, accessed at www.rrc.state.tx.us/eagleford/, 3 September 2013.
- 2010: Nearly 40 percent of wells drilled in 2010 were fracked using more than 100,000 gallons of water, per Table 7 of Jean-Philippe Nicot, et al., Bureau of Economic Geology, Jackson School of Geosciences, University of Texas at Austin, for the Texas Water Development Board, *Current and Projected Water Use in the Texas Mining and Oil and Gas Industry*, June 2011. We multiplied 39.7 percent times the 8,133 "new drill dry/completions" in 2010, per Railroad Commission of Texas, *Summary of Drilling, Completion and Plugging Reports*, accessed at www.rrc.state.tx.us/data/drilling/drillingsummary/index.php, 19 July 2013.
- January 2011 through January 2012: We calculated the number of fracking wells in this period by multiplying the number of wells drilled by an estimate of the percentage of those wells that were fracked. The number of "new drill dry/completions" came from Railroad Commission of Texas, *Summary of Drilling, Completion and Plugging Reports,* accessed at www.rrc.state.tx.us/data/drilling/drillingsummary/index.php, 3 September 2013. We interpolated between 2010 and February 2012 using the percentage of wells that were fracked using the 2010 estimate of 39.7 percent, described above, and the percent fracked from February 2012 to April 2013, described below.
- February 2012 through April 2013: Beginning in February 2012, drilling companies in Texas have been required to report their drilling activities

to FracFocus. Per SkyTruth, 19,678 wells were fracked in Texas in that period that used more than 100,000 gallons of water. This number of wells equals 82.5 percent of all "new drill dry/completions" in the same period in Railroad Commission of Texas, *Summary of Drilling, Completion and Plugging Reports*, accessed at www.rrc.state.tx.us/data/drilling/drillingsummary/index.php, 3 September 2013.

Texas does not require reporting of produced water volumes. However, the state does track the volume of water that is injected into disposal wells or for enhanced recovery in other wells. Our estimate of wastewater is based on the assumption that 99 percent of all produced water is reinjected, and therefore reinjected water volumes indicate wastewater production, per Leslie Savage, P.G., Chief Geologist, Oil & Gas Division, Railroad Commission of Texas, personal communication, 18 July 2013. Ms. Savage queried the Railroad Commission's *H10 Filing System* to return results on injected saltwater volumes in 2012, which we used as the basis of our estimate. This includes both flowback and produced water.

Utah

Our count of fracking wells came from the FracFocus database. We screened for wells that reported using more than 100,000 gallons of water, and counted 1,336 wells.

We calculated gas and produced water volumes from fracking wells in Utah from Utah Department of Natural Resources, Division of Oil, Gas and Mining, *Production Data*, accessed at http://oilgas.ogm.utah.gov/Data_Center/DataCenter.cfm#download, 12 July 2013. To limit our tally to production from fracking wells, we used API numbers for all Utah wells included in SkyTruth's database from FracFocus data. Of the 1,607 wells with APIs in SkyTruth's database, we found 2012 production reports for 1,364 wells in Utah's data.

Virginia

We counted all horizontal wells included in Virginia Department of Mines, Minerals, and Energy Division of Gas and Oil Information System, *Drilling Report*, accessed at www.dmme.virginia.gov, 29 May 2013.

We were unable to obtain data on produced water. An estimated 15 to 30 percent of water and chemicals used to frack a well returns to the surface, per Virginia Department of Mines, Minerals, and Energy, Division of Gas and Oil, *Hydraulic Fracturing in Virginia and the Marcellus Shale Formation*, accessed at www.dmme.virginia.gov/DGO/HydraulicFracturing.shtml, 12 July 2013. However, we were unable to obtain data on how much formation water also is produced.

West Virginia

Our data for West Virginia includes all permitted wells targeting the Marcellus Shale. We were unable to narrow our count to drilled wells. We also chose to include wells without a listed permit date, on the assumption that any Marcellus drilling in West Virginia has occurred recently. Data is from West Virginia Department of Environmental Protection, *Resource Extraction Data Viewer*, http://tagis.dep.wv.gov/fogm/, 20 June 2013.

We tallied gas production from 2011 (the most recent year reported). We obtained 2011 production data from West Virginia Department of Environmental Protection, *Oil and Gas Production Data*, accessed from www.dep.wv.gov/oil-and-gas/databaseinfo/Pages/default.aspx, 12 July 2013. We looked up production from fracking wells by using the API numbers reported to FracFocus and compiled in SkyTruth's database. Our calculation of production is an underestimate because only 52 wells from FracFocus corresponded to wells in West Virginia's production database.

West Virginia does not collect water production data.

Wyoming

We used data on fracking wells reported to the FracFocus database to ensure we did not accidentally include coalbed methane wells. There are 1,126 wells in the FracFocus database that report using more than 100,000 gallons of water.

This figure from FracFocus is close to data we obtained through another approach. We tallied 1,273 horizontal wells since 2005 in Wyoming from FracTracker, *WY_horiz_06032013*, accessed at www.fractracker.org/data/, 28 June 2013. FracTracker obtained this list via a request to the Wyoming Oil and Gas Conservation Commission. This estimate excludes any wells that list a spud date before 2005, and includes wells with no date or that were flagged as coalbed.

Water Used

We multiplied the number of fracking wells per state since 2005 by average water use per well per state since 2011.

Average water use per well that reported using more than 100,000 gallons came from Skytruth, *Fracking Chemical Database*, accessed at http://frack.skytruth.org/fracking-chemical-database/frack-chemical-data-download, 12 June 2013. SkyTruth compiled data posted in PDFs on the FracFocus website into a database that includes water use, which can encompass freshwater, produced water and/or recycled water. The inclusion of recycled water may lead to some double-counting of water used. We included data beginning in 2011 through the most recent entries for 2013. In calculating average water consumption per well, we excluded wells that listed "None" for water use. We excluded what appeared to be duplicate entries, based on API numbers, frack date and reported water use. We also excluded two wells from Texas that reported using more than 1 billion gallons of water each, which we assumed was a data entry error by the reporting operator.

To estimate water use since 2005, we multiplied average water use per reporting well in each state by the number of fracking wells (using more than 100,000 gallons of water) in each state since 2005. The source of our well count is described in the previous section.

Air Pollution

We used data from New York State's assessment of air pollution from each well site to estimate the volume of particulate matter, smog precursors and other hazardous compounds from fracking. Though the U.S. Environmental Protection Agency recently studied air pollution from gas drilling, the data were compiled primarily from vertically rather than horizontally fracked wells and were limited to fewer types of pollutants (see EC/R, Inc., for U.S. Environmental Protection Agency, *Oil and Natural Gas Sector: Standards of Performance for Crude Oil and Natural Gas Production, Transmission, and Distribution. Background Technical Support Document for Proposed Standards*, July 2011. New York State's pollution assessment was more complete and more relevant to high-volume fracking wells.

We assume that four wells per drilling site are drilled, fracked and completed each year, per New York State Department of Environmental Conservation, *Revised Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas and Solution Mining Regulatory Program: Well Permit Issuance for Horizontal Drilling And High-Volume Hydraulic Fracturing to Develop the Marcellus Shale and Other Low-Permeability Gas Reservoirs*, 7 September 2011, 6-105. We assumed that wells produce dry gas, not wet gas, and that operators flare flowback gas instead of simply venting it. This first assumptions means our air pollution estimate may understate the problem, since wet gas wells have higher emissions, while our second assumption changes the mix of pollutants released. We multiplied the tons-per-year emissions estimates from Table 6.7 of the *Revised Draft Supplemental Generic Environmental Impact Statement* by a recent year's well completion figure for each state.

This emissions estimate does not include the significant emissions from ongoing operations, compressors, and truck traffic to and from drilling sites carrying supplies and personnel.

Methane Emissions

We calculated methane emissions using two different approaches because neither approach alone provided a complete picture. The lack of data on wells drilled, gas produced and emissions per well makes it very hard to assess the extent of global warming damage from fracking. Our first approach multiplied emissions per well during completion by the number of fracking wells. Our second method multiplied emissions as a percentage of gas produced by the amount of gas produced from fracking wells.

In states with more comprehensive production data, the energy-based calculation may be more accurate because it is based on state-specific conditions. In addition, the energy-based method includes emissions from a wider range of activities involved in producing gas from fracking wells—from drilling to fracking to processing—and therefore better reflects the impact of fracking.

In states where we could obtain no or limited emissions data, the estimate based on per-well emissions during completion offers a rough emissions estimate. The per-well emission factor is conservative because it is based on a narrower definition of fracking activity (it excludes production and processing). However, it may overestimate emissions from wells that were drilled but produced little to no gas.

Emissions Based on Well Completion

We estimated methane emissions by multiplying an estimate of emissions per completion of a fracking gas well by the number of fracking wells in 2012 in each state. We estimated average emissions of 50,000 kilograms of methane per well, per Francis O'Sullivan and Sergey Paltsev, "Shale Gas Production: Potential Versus Actual Greenhouse Gas Emissions," *Environmental Research Letters*, 7:1-6, 26 November 2012, doi: 10.1088/1748-9326/7/4/044030. This estimate is a national average based on nearly 4,000 wells completed in 2010 and assumes 70 percent of wells undergo "green" completions in which fugitive emissions are captured. This likely overstates the green completions rate before 2010.

Our estimate has two limitations of note. First, it does not include methane emissions from pipelines, compressor stations, and condensate tanks, or carbon dioxide emissions from equipment used to produce gas. Second, it may not accurately reflect emissions from fracked shale wells that produce oil rather than gas. The data we obtained on well completions do not distinguish between wells fracked for oil versus gas production and therefore we have chosen to apply this estimate for shale gas wells to all wells. We spoke with two experts in the field who believe that, given the lack of better data on emissions from oil wells, is it reasonable to assume that fracked oil wells have substantial methane emissions.

We converted methane emissions to carbon dioxide equivalents using a 100-year global warming potential of 25 times that of carbon dioxide, per Federal Register, *Environmental Protection Agency, 40 CFR Part 98, 2013 Revisions to the Greenhouse Gas Reporting Rule and Proposed Confidentiality Determinations for New or Substantially Revised Data Elements; Proposed Rule*, 78(63): 19802-19877, 2 April 2013.

Emissions Based on Gas Production

We calculated methane emissions as a percentage of gas production. See the previous section for a description of how we estimated gas production in each state.

We converted cubic feet of gas production to megajoules of methane using the assumption that 78.8 percent of gas produced from unconventional wells is methane, per Robert Howarth, et al., "Methane and the Greenhouse Gas Footprint of Natural Gas from Shale Formations," *Climatic Change* 106: 679-690, 2011. (Note that other researchers have estimated the methane content of Marcellus Shale gas as high as 97.2 percent. See ICF International, Technical Assistance for New York State Department of Environmental Conservation, *Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas and Solution Mining Regulatory Program*, as cited in Mohan Jiang, et al., "Life Cycle Greenhouse Gas Emissions of Marcellus Shale Gas," *Environmental Research Letters*, 6, 034014, July-September 2011, doi:10.1088/1748-9326/6/3/034014, supplemental materials.)

We assume that 3.3 percent of the methane produced over the life of a well is lost as fugitive emissions, per Robert Howarth, et al., "Methane and the Greenhouse Gas Footprint of Natural Gas from Shale Formations," *Climatic Change* 106: 679-690, 2011, as presented in Robert Howarth, et al., *Methane Emissions from Natural Gas Systems; Background Paper Prepared for National Climate Assessment*, 25 February 2012. This estimate includes well-site and processing emissions from shale and tight-gas sands wells that produce gas. The estimate assumes significant venting of methane in the initial days after a well is fracked.

The 3.3 percent pollution rate from Howarth, et al., is higher than reported in EPA, *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990 to 2011*, 12 April 2013. However, it is in the range of one recent study that measured fugitive emissions over a gas and oil field in Colorado, finding fugitive methane emissions of 2.3 to 7.7 percent of gas produced (Gabrielle Pétron, et al., "Hydrocarbon Emissions Characterization in the Colorado Front Range: A Pilot Study," *Journal of Geophysical Research*, 117, D04304, 2012, doi:10.1029/2011JD016360, and Jeff Tollefson, "Air Sampling Reveals High Emissions from Gas Field," *Nature*, 483(7384): 139-140, 9 February 2012, doi: 10.1038/482139a). A second recent study in the same area measured methane emissions equal to 6.2 to 11.7 percent of production (Anna Karion, et al., "Methane Emissions Estimate from Airborne Measurements over a Western United States Natural Gas Field," *Geophysical Research Letters*, 27 August 2013, doi: 10.1002/grl.50811).

We used a slightly different method to calculate emissions for North Dakota, where a large portion of gas is flared rather than sold. We calculated emissions for the flared gas and emissions for the remaining gas separately. Because of lack of infrastructure to get gas to market, 29 percent of all gas produced in North Dakota is flared, per Lynn Helms, North Dakota Industrial Commission, Department of Mineral Resources, *Director's Cut*, 15 July 2013. We estimated emissions from this gas based on New York State Department of Environmental Conservation, *Revised Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas and Solution Mining Regulatory Program: Well Permit Issuance for Horizontal Drilling And High-Volume Hydraulic Fracturing to Develop the Marcellus Shale and Other Low-Permeability Gas Reservoirs*, 7 September 2011, 6-194. We calculated emissions from the remaining wells using Robert Howarth, et al., "Methane and the Greenhouse Gas Footprint of Natural Gas from Shale Formations," *Climatic Change* 106: 679-690, 2011, as presented in Robert Howarth, et al., *Methane Emissions from Natural Gas Systems; Background Paper Prepared for National Climate Assessment*, 25 February 2012.

Landscape Impacts

We calculated landscape impacts based on the number of wells in each state. We divided the number of wells drilled (or permitted, if only that figure was available) since the beginning of 2005 by the average number of wells per pad to obtain the number of well pads. We then multiplied the number of well pads by the size of each well pad and the roads and pipelines servicing it. Where possible, we used state-specific estimates about the number of wells per pad and the acreage damaged by pads and supporting infrastructure.

For states where most drilling is into the Marcellus Shale (**Pennsylvania** and **West Virginia**), we assumed that land disruption patterns are comparable to those in Pennsylvania, where existing drilling practices place an average of 1.8 wells per well pad. Well pads average 3.1 acres and associated infrastructure disturbs 5.7 acres. Pennsylvania data were presented in New York State Department of Environmental Conservation, *Revised Draft Supplemental Generic Environmental Impact Statement on the Oil, Gas and Solution Mining Regulatory Program: Well Permit Issuance for Horizontal Drilling And High-Volume Hydraulic Fracturing to Develop the Marcellus Shale and Other Low-Permeability Gas Reservoirs*, 7 September 2011, 6-76. We assumed **Ohio** and **Virginia** follow the same land disturbance patterns.

In **Oklahoma**, we assumed 1.1 wells per pad, and the same wellpad size and road and pipeline impacts as in Ohio and Pennsylvania.

For **Texas**, we assumed two wells per pad because the sources we consulted suggest that there are some multi-well pads but that the number of wells per pad remains small. In the Barnett, well pads hold anywhere from one to eight wells, per George King, GEK Engineering, *Multi-Well Pad Operations for Shale Gas Development, Draft Document*, 5 May 2010. In the Eagle Ford Shale, Chesapeake Energy, as of early 2013, was drilling only half of its wells on multi-well pads, per Jennifer Hiller, "Chesapeake Thinks It Has 342 Million Barrels in Eagle Ford," *Eagle Ford Fix* (blog operated by *San Antonio Express-News*), 6 May 2013. We assumed pad size is the same as in Pennsylvania (which has an average of 1.8 wells per pad). We assume road and pipeline infrastructure occupies 4.75 acres, the same as on public land in western Colorado.

For **New Mexico**, we estimated the number of wells per pad after mapping the location of fracking wells reported to FracFocus in 2012. We used the API number of those wells to obtain the latitude and longitude for each well from New Mexico Energy, Minerals and Natural Resources Department, Oil Conservation Division, *OCD Data and Statistics*, 12 June 2013. A small number of 2012 wells appear to be on multi-well pads. Given that in neighboring Texas, few wells before 2012 were drilled on multi-well pads, we assumed that New Mexico wells average 1.1 wells per pad. We assumed pad size for a single-well pad is 2.47 acres, based on the average pad size and wells per pad in Weld County, Colorado (see below). We assumed road and pipeline infrastructure occupies 4.75 acres, the same as on public land in western Colorado.

We made the same assumption for **Utah**, based on mapping the location of fracking wells and finding few multi-well pads.

For **Colorado**, we obtained estimates for acres damaged by wells in Weld County and on public land in western Colorado. By looking at the Form 2A documentation for 20 fracking wells across Weld County, we found that an average of 2.25 wells are drilled per pad and that well pads disturb an average of 5.56 acres. We could not obtain an estimate of land disturbed for roads and pipelines. We obtained this data from Colorado Oil and Gas Conservation Commission, *GISOnline*, accessed at http://dnrwebmapgdev.state.co.us/mg2012app/, 11 July 2013. Leases on federal land in western Colorado average eight wells per pad, with 7.25 acres of land disturbed per pad and an additional 4.75 acres for roads and other infrastructure, per U.S. Department of the Interior, Bureau of Land Management, Colorado State Office, Northwest Colorado Office, White River Field Office, *Draft Resource Management Plan Amendment and Environmental Impact Statement for Oil and Gas Development*, August 2012. For our calculation, we used the Weld County data for Weld and Boulder wells, and the western Colorado estimates for Garfield and Mesa wells. We used the western Colorado estimate of acreage for supporting infrastructure.

For **Wyoming**, we assumed an average of two wells per pad. Drilling in the Jonah Field is estimated to occur with single well pads and in the Pinedale Anticline with multiple wells per pad, per U.S. Department of the Interior, Bureau of Land Management, Pinedale Field Office, *Proposed Resource Management Plan and Final Environmental Impact Statement for Public Lands Administered by the Bureau of Land Management, Pinedale Field Office*, August 2008. From that same source, we used an estimate of four acres per two-well pad, and 4.9 acres for roads and pipelines per pad.

In **Montana**, we calculated land impacts based on data from current land impacts of wells in the HiLine Planning Area in north central Montana. Existing wells in the Bowdoin Dome and the rest of the HiLine Planning Area (which may not be high-volume wells) disturb an average of 0.21 acres per well pad and 0.67 acres for roads and flow lines, based on a weighted average of data presented in Table 22 of Dean Stillwell and J. David Chase, U.S. Department of the Interior, Bureau of Land Management, *Reasonable Foreseeable Development Scenario for Oil and Gas Activities on BLM-Managed Lands in the HiLine Planning Area, Montana, Final Report*, 30 October 2012. We assumed one well per pad.

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