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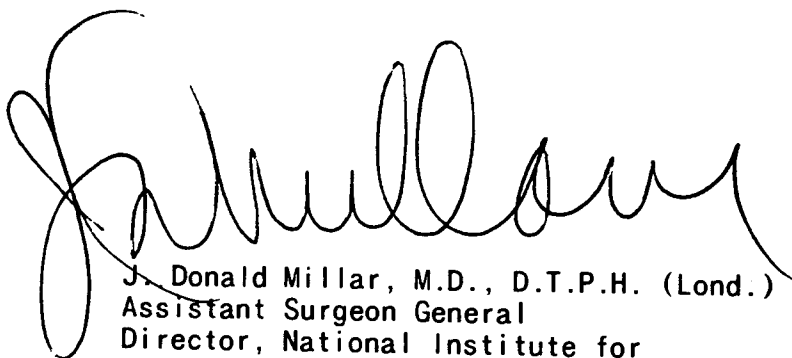
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FOREWORD

The initial Respirator Decision Logic was developed in 1975 as part of the National Institute for Occupational Safety and Health/Occupational Safety and Health Administration (NIOSH/OSHA) Standards Completion Program and was updated in 1978. Due to technical advances in respirator design and research, NIOSH has again revised the Respirator Decision Logic.

This revision retains many aspects of the original Respirator Decision Logic, but it differs in five areas: odor warning properties with respect to air-purifying cartridge/canister respirators, recognition of the problems in assigning protection factors, changes in protection factors for certain respirator classes, respirator recommendations for carcinogens, and medical recommendations.

The recognition of wide variation among workers in their sensitivities for detection of odors has led to the recommendation that employers not rely solely on currently published data on odor thresholds to ensure that workers who wear air-purifying cartridge or canister respirators are capable of smelling the contaminant at the applicable exposure limit. Recent research on in-plant respirator testing suggests that some previously assigned protection factors based on data from laboratory fit testing may not be valid. This revised Respirator Decision Logic has incorporated assigned protection factors based on data from recent in-plant research for some powered air-purifying respirators (PAPR) and some similar respirators, such as loose-fitting and tight-fitting continuous flow air-line respirators. Since NIOSH maintains that there is no safe exposure to carcinogens, only the most protective respirators should be used to protect workers from exposure to carcinogens in the workplace. Finally, specific medical recommendations are included to assist physicians in determining an individual's fitness to wear a respirator.



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CONTENTS

	<u>Page</u>
FOREWORD	iii
ACKNOWLEDGMENTS	iv
TABLES AND FIGURE	vi
I. INTRODUCTION	1
A. Background and Scope	1
B. Cautionary Statements	2
II. RESPIRATOR DECISION LOGIC	5
A. Criteria for Selecting Respirators	6
B. Restrictions and Requirements for All Respirator Usage	7
C. Respirator Decision Logic Sequence	8
D. Subparagraphs	21
1. Oxygen-Deficient Atmosphere	21
2. Exposure Limits	21
3. Immediately Dangerous to Life or Health (IDLH)	22
4. Eye Irritation	23
5. Escape Apparatus	24
6. Potential Warning Properties for Use with Cartridge/Canister Air-Purifying Respirators	26
7. Limitations of Respirators for Gases and Vapors	27
8. Assigned Protection Factors	27
9. Particulate Filter Respirators	29
10. Suggested Medical Evaluation and Criteria for Respirator Use	30
III. REFERENCES	35
IV. GLOSSARY	40
V. APPENDICES	43
A. NIOSH Policy Statement on Approval of Air-Purifying Respirators with End-of-Service-Life Indicators	43
B. NIOSH Policy Statement on Use of Single-Use and Dust and Mist Respirators for Protection Against Asbestos	47
C. Odor Warning: Background Information	48
D. Protection Factor: Background Information	50
E. Medical Aspects of Wearing Respirators: Background Information	52

TABLES

<u>Number</u>		<u>Page</u>
1.	Assigned protection factor classifications of respirators for protection against particulate exposures	13
2.	Assigned protection factor classifications of respirators for protection against gas/vapor exposures	15
3.	Assigned protection factor classifications of respirators for protection against combination gas/vapor and particulate exposures	17
4.	Selection options for escape respirators	25
5.	NIOSH recommended maximum use concentrations for gas and vapor air-purifying elements	28
6.	Suggested frequency of medical fitness determinations	32

FIGURE

<u>Number</u>		<u>Page</u>
1.	Flow Chart of Respirator Decision Logic Sequence	19

I. INTRODUCTION

A. Background and Scope

The National Institute for Occupational Safety and Health (NIOSH) routinely makes recommendations regarding the use of respirators for workers exposed to workplace environments that contain hazardous concentrations of airborne contaminants and/or oxygen-deficient atmospheres. Such recommendations are made only when engineering controls are not technically feasible, while controls are being installed or repaired, or when emergency and other temporary situations arise. Respirators are the least preferred method of worker protection from respiratory hazards because they can be unreliable if an adequate respiratory protection program is not established by the employer and because they require worker cooperation. The intent of this decision logic is to provide industrial hygienists and other professionals knowledgeable in respirator selection with a procedure for selecting suitable classes of respirators for particular concentrations of specific contaminants. In this decision logic, concerns are raised about limitations of the data used to set protection factors for several classes of respirators.

To ensure uniformity and adherence to proper respirator usage, NIOSH recommendations have been based on the Respirator Decision Logic developed jointly in 1975 by NIOSH and the Occupational Safety and Health Administration (OSHA) as part of the Standards Completion Program and updated in June 1978. That decision logic incorporated requirements contained in 30 CFR 11 and fit factor data developed by the Los Alamos National Laboratory (LANL). NIOSH has now modified that decision logic to reflect new developments that include increased use of respirators to control exposure to carcinogens in the workplace, introduction of new respiratory equipment, and reporting of field research data on workplace protection factors (WPF's).

This modified decision logic identifies the criteria necessary to determine the classes of respirators that will provide a known degree of respiratory protection for a given work environment, assuming that the respirators are used correctly. The degree of protection is related in part to protection factors. Many of the assigned protection factors (APF's) that appear in this decision logic are based on laboratory studies and should be regarded as approximate.

The selection of a specific respirator must be made by individuals knowledgeable about the limitations associated with each class of respirators and familiar with the actual workplace environment, including the job task(s) to be performed. The correct use of a respirator is just as important as the selection process if adequate worker protection is to be achieved. Without a complete respiratory protection program, workers will not receive the degree of protection anticipated from a respirator, even if it is a correct choice for the situation. Training, motivation, medical

evaluation, fit testing, and a respirator maintenance program are critical elements for the successful use of a respirator. As a minimum, compliance with 29 CFR 1910.134 is mandatory whenever respirators are used by workers, whether on a required or voluntary basis.

B. Cautionary Statements

NIOSH concerns about the use of respirators are discussed further in various parts of the document and are summarized in the following six cautionary statements:

• Assigned Protection Factors

In general, the assigned protection factors (APF's) that appear in this decision logic are not based on measurements of actual field (workplace) performance. As noted in the footnotes accompanying Tables 1, 2, and 3, in only a few instances are the APF's based on any workplace performance testing; the majority of the APF's have no workplace performance basis at all. APF's based solely on laboratory fit testing should be viewed and applied with particular caution, even when the laboratory testing involves a simulated work regimen. To date, no relation has been demonstrated between laboratory fit factors and measured workplace performance. As more performance testing of respirators is undertaken in the workplace by NIOSH and others, NIOSH may find it necessary to revise the APF's upward or downward. For the present, APF's should not be considered reliable predictors of performance levels that will be achieved during actual use, since APF's are not based on a sufficient amount of workplace testing.

• Fit Testing

No qualitative or quantitative fit tests have been demonstrated to be capable of effectively identifying inadequately fitting respirators (i.e., respirator-wearer combinations that provide less protection than the APF). The presently used fit tests (e.g., ANSI-recommended, OSHA-approved) may fail to identify individual wearers with inadequate respiratory protection. Thus fit tests should be used with caution and with recognition of their possible deficiencies. As appropriate, periodic evaluations of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection.

• QNFT Fit Factor Screening Levels

Regarding quantitative fit testing (QNFT), no studies are available to indicate what fit factor value (i.e., screening level) will ensure a high probability of identifying inadequately fitting respirators. That is, there are no studies demonstrating what fit factor values are adequate

accept/reject criteria for QNFT fit screening. When QNFT is used for fit screening, the fit factor screening level should be chosen with caution and with recognition of the uncertainty of its effectiveness. As appropriate, periodic evaluation of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection.

- **Adequate Warning Properties**

No physiological effects in humans (e.g., odor, taste, eye irritation, respiratory irritation) have been demonstrated as being capable of consistently providing respirator wearers with timely, consistent, persistent, and reliable warning of hazardous airborne concentrations inside a respirator. Individual wearers may be unable to detect the warning effect when necessary and may fail to take action necessary to protect themselves (e.g., leaving the area where respirators are necessary or changing the sorbent cartridge or canister). When warning properties must be relied on as part of a respiratory protection program, the employer should accurately, validly, and reliably screen each prospective wearer for the ability to detect the warning properties of the hazardous substance(s) at exposure levels that are less than the exposure limits for the substance(s). Warning properties should be regarded with caution and with recognition of their unreliability.

- **Service Life Information**

For essentially all gases and vapors, no adequate service life information is available to respirator wearers or to those responsible for respiratory protection programs. When this information is not available, respirators with air-purifying sorbent elements should be used with caution and with recognition of the wide variability of service lives under differing use conditions. Employers should possess valid and reliable estimates of service lives for all sorbent elements used in the respiratory protection program. Service life test data should be representative of all conditions of intended use that can be reasonably anticipated. Factors known to affect the service lives of sorbent elements include, but are not limited to, the make and model of sorbent element, airborne concentrations of contaminant(s), and relative humidity through each sorbent element. When appropriate service life data is available, any reliance on the data should be undertaken with caution and with recognition of the limitations and uncertainties of the information.

- **Determination of Protection Factor Levels Required for Adequate Protection**

Workers are never exposed to a single unvarying concentration of a contaminant. In a given work area, individual exposures may vary widely between workers, during a workshift, and between days. The range of potential exposures should be appropriately determined for all workers and for all circumstances that can be reasonably anticipated. The

highest anticipated exposure for each respirator wearer should be used to compute the protection factor required for each wearer. Required protection factors should be used with caution and with recognition of their uncertainties.

II. RESPIRATOR DECISION LOGIC

This decision logic contains a series of questions regarding situations which may require the use of respirators. (See Respirator Decision Logic Sequence, page 8.) In answering these questions, the user of this decision logic is assisted in identifying specific classes of respirators, applicable restrictions, and the appropriate respirator selection table to use. When using one of the tables to identify a suitable class of respirators, the user must keep in mind the restrictions identified in the question section of this decision logic.

This decision logic identifies the criteria necessary to determine the classes of respirators that will provide the minimum acceptable degree of protection for a chemical at a given concentration. Classes of respirators offering greater protection can usually be used in place of the minimum acceptable class of respirators. Respirator classes are consistent with respirator certification groupings as specified in 30 CFR 11.

The recommendations in this decision logic are based primarily on the physical, chemical, and toxicologic properties of the contaminant and on the limitations of each class of respirators, including filtration efficiency, air supply capability, and face seal characteristics and leakage. Thus this decision logic is limited to identifying classes of acceptable respirators, rather than individual respirators.

After various classes of respirators are identified as being suitable for a given situation, an evaluation is made of other factors of the particular work environment so that the best respirator within the recommended classes can be chosen. In some situations, the selection of a respirator classified as providing a higher level of protection may be advisable.

To assist the user, this decision logic contains ten subparagraphs following the Respirator Decision Logic Sequence that describe respirator limitations, use of applicable exposure limits, warning properties, protection factors, oxygen limitations, and medical evaluation of suitability to wear respirators. Additional supporting information is contained in Appendices A through E. To properly use this decision logic, the user should carefully read the subparagraphs.

The assigned protection factors (APF's) used in this decision logic were based on quantitative fit factor data developed by Los Alamos National Laboratories (LANL) under contract to NIOSH and on field evaluation data gathered by NIOSH and others. Specific references and summaries of the data used to generate certain protection factors can be found in Subparagraph 8, page 28. Fit factors determined for the individual wearer of a respirator by quantitative fit testing or by any other method used to determine fit should not be substituted for the APF given for each class of respirators. However, the fit factor determined through quantitative fit testing must be greater than the APF; otherwise, the respirator cannot be used by the worker.

A. Criteria for Selecting Respirators

To use this decision logic, the user must first assemble the necessary toxicologic, safety, and other relevant information for each contaminant, including the following:

- General use conditions, including determination of contaminant(s);
- Physical, chemical, and toxicologic properties of the contaminant(s);
- Odor threshold data;
- NIOSH recommended exposure limit (REL) or when no REL exists, OSHA permissible exposure limit (PEL) or other applicable exposure limit;
- Immediately dangerous to life or health (IDLH) concentration;
- Eye irritation potential; and
- Any service life information available (for cartridges and canisters).

Obtaining complete information on all criteria needed to use this decision logic may be difficult. When conflicting or inadequate data are found, experts should be consulted before decisions are made that could affect the proper use of this decision logic. In addition, the adequacy of the respirator selected is dependent on the validity of the exposure limit used. While the decision logic can be used with any exposure limit, NIOSH recommends that an REL be used when one exists for a given contaminant. For a more detailed discussion on the use of exposure limits, especially when selecting respirators for protection against carcinogens, see Subparagraph 2, page 21.

The information obtained on general use conditions for respirators should include a description of the actual job task, including the duration and frequency, location, physical demands, and industrial processes, as well as the comfort of the respirators. Some general use conditions may preclude the use of specific types of respirators in certain circumstances because the individual must be medically and psychologically suitable to wear a given respirator for a given task, particularly if the respirator is a self-contained breathing apparatus (SCBA).

Information obtained on the service life of the cartridge/canister under conditions of intended use should be evaluated regardless of the odor warning properties of the chemicals. These evaluations should be based on all gas(es) and vapor(s) present at the temperature and relative humidity extremes (high and low) in the workplace. NIOSH recommends that when the employer or a representative of the employer conducts the tests, the challenge concentrations of the gases and vapors should be at least 10 times the maximum use concentration of the respirator. The service life value

obtained from these tests should be used to determine how long a cartridge/canister could provide protection under actual use conditions. This information can be used to set up cartridge replacement schedules and should be used in conjunction with sensory warning properties. Workers should be trained to exit the contaminated area whenever they detect the odor of the contaminant. (See Subparagraph 6, page 26, for a discussion on service life testing for chemicals with poor warning properties.)

B. Restrictions and Requirements for All Respirator Usage

The following requirements and restrictions must be considered to ensure that the respirator selected will provide adequate protection under the conditions of intended use:

1. A complete respiratory protection program should be instituted which includes regular worker training; maintenance, inspection, cleaning, and evaluation of the respirator; use of the respirator in accordance with the manufacturer's instructions; fit testing; and environmental monitoring. Whenever possible, quantitative evaluation of the protection factor in the workplace should be performed to confirm the actual degree of protection provided by the respirator to each worker. Minimum respiratory protection requirements for all contaminants can be found in the OSHA Safety and Health Standards, 29 CFR 1910.134, and in separate sections for specific contaminants (e.g., 1910.1001 for asbestos, 1910.1025 for lead, etc.).
2. Qualitative or quantitative fit tests should be provided as appropriate to ensure that the respirator fits the individual. Periodic evaluation of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection. When quantitative fit testing (QNFT) is used, the fit factor screening level should be chosen with caution and with the recognition of the uncertainty of its effectiveness since no studies have demonstrated what fit factor values provide adequate accept/reject criteria for quantitative fit screening.
3. Negative pressure respirators should not be used when facial scars or deformities interfere with the face seal.
4. No respirator (including positive pressure respirators) should be used when facial hair interferes with the face seal.
5. The respirators should be properly maintained, correctly used, and conscientiously worn.
6. The usage limitations of air-purifying elements, particularly gas and vapor cartridges, should not be exceeded.
7. The respirators must be approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (MSHA/NIOSH).

8. Workers should be instructed to leave the contaminated area immediately upon suspicion of respirator failure and then to determine the problem.

9. Workers are not exposed to a single unvarying concentration of a hazardous substance, rather individual exposures may vary throughout a workshift and between days. The highest anticipated concentration should therefore be used to compute the required protection factor for each respirator wearer.

10. Respirator wearers should be aware of the variability in human responses to the warning properties of hazardous substances. When warning properties must be relied on as part of a respiratory protection program, the employer should screen each prospective wearer for the ability to detect the warning properties of the hazardous substance(s) at exposure concentrations that are less than the REL for each given substance. (See Subparagraph 6, page 26, and Appendix C, page 48, for additional information.)

11. The assigned protection factors (APF's) that appear in this decision logic are based for the most part on laboratory studies. However, a few APF's have been validated and revised as necessary after consideration of data obtained from studies of workplace protection factors (WPF's). As more WPF testing of respirators is undertaken by NIOSH and others, the APF values may be further revised. For the present, the APF's should be regarded as approximate if they are not based on WPF's.

C. Respirator Decision Logic Sequence

After all criteria have been identified and evaluated and after the requirements and restrictions of the respiratory protection program have been met, the following sequence of questions can be used to identify the class of respirators that should provide adequate respiratory protection:

1. Is the respirator intended for use during fire fighting?

a. If yes, only a self-contained breathing apparatus (SCBA) with a full facepiece operated in pressure demand or other positive pressure mode is recommended.

b. If no, proceed to Step 2.

2. Is the respirator intended for use in an oxygen-deficient atmosphere, i.e., less than 19.5% oxygen at sea level? (Refer to Subparagraph 1, page 21, for a discussion of oxygen deficiency.)

a. If yes, any type of SCBA or supplied-air respirator (SAR) with an auxiliary SCBA is recommended. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted. If additional contaminants are present, proceed to Step 3.

b. If no, proceed to Step 3.

3. Is the respirator intended for use during emergency situations?

a. If yes, two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.

b. If no, proceed to Step 4.

4. Is the contaminant regulated by the Department of Labor as a potential occupational carcinogen or identified by NIOSH as a potential human carcinogen in the workplace, and is the contaminant detectable in the atmosphere?

a. If yes, two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. Auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.

b. If no, proceed to Step 5.

5. Is the exposure concentration of the contaminant, as determined by acceptable industrial hygiene methods, less than the NIOSH REL or other applicable exposure limit? (Whenever a worker is given a respirator to use on a voluntary basis when ambient levels are below applicable limits, OSHA requires the implementation of a complete respiratory protection program, which includes medical evaluation, training, fit testing, periodic environmental monitoring, and all other requirements in 29 CFR 1910.134.)

a. If yes, a respirator would not be required except for an escape situation. Proceed to Step 7.

b. If no, proceed to Step 6.

6. Are conditions such that a worker who is required to wear a respirator can escape from the work area and not suffer loss of life or immediate or delayed irreversible health effects if the respirator fails, i.e., are the conditions not immediately dangerous to life or health (IDLH)? (Refer to Subparagraph 3, page 22, for additional information on IDLH's.)

a. If yes, conditions are not considered to be IDLH. Proceed to Step 7.

b. If no, conditions are considered to be IDLH. Two types of respirators are recommended: a SCBA with a full facepiece operated in pressure demand or other positive pressure mode or an SAR with a full facepiece operated in pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in pressure demand or other positive pressure mode. The auxiliary SCBA must be of sufficient duration to permit escape to safety if the air supply is interrupted.

7. Is the contaminant an eye irritant, or can the contaminant cause eye damage at the exposure concentration? (Refer to Subparagraph 4, page 23, for a discussion of eye irritation and damage.)

a. If yes, a respirator equipped with a full facepiece, helmet, or hood is recommended. Proceed to Step 8.

b. If no, an orinasal respirator may still be an option, depending on the exposure concentration. Proceed to Step 8.

8. Divide the 8-hour time-weighted average (TWA) exposure concentration for the contaminant (or maximum exposure concentration for a contaminant with a ceiling limit) determined in Step 5 by the NIOSH REL or other applicable exposure limit to determine the minimum protection factor required. For escape respirators, determine the potential for generation of a hazardous condition caused by an accident or equipment failure. If a potentially hazardous condition could occur or a minimum protection factor has been calculated, proceed to Step 9.

9. If the physical state of the contaminant is a particulate (solid or liquid) during periods of respirator use, proceed to Step 10; if it is a gas or vapor, proceed to Step 11; if it is a combination of gas or vapor and particulate, proceed to Step 12.

10. Particulate Respirators

10.1. Is the particulate respirator intended only for escape purposes?

a. If yes, refer to Subparagraph 5, page 24, for a discussion and selection of "escape only" respirators.

b. If no, the particulate respirator is intended for use during normal work activities. Proceed to Step 10.2.

10.2. A filter medium that will provide protection against exposure to the particulate in question is recommended. (Refer to Subparagraph 9, page 29, for a discussion on limitations of approvals for filter media.) Proceed to Step 10.3.

10.3. Respirators that have not been previously eliminated from Table 1 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors, and to Subparagraph 9, page 29, for a discussion on limitations of filter approvals.) Maximum airborne concentrations for each level of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

11. Gas/Vapor Respirators

11.1. Is the gas/vapor respirator intended for "escape only" purposes?

a. If yes, refer to Subparagraph 5, page 24, for a discussion on selection of "escape only" respirators.

b. If no, the gas/vapor respirator is intended for use during normal work activities. Proceed to Step 11.2.

11.2. Are the warning properties for the gas/vapor contaminant adequate at or below the NIOSH REL or other applicable exposure limit? (Refer to Subparagraph 6, page 26, and Appendix C, page 48, for additional information on requirements for adequate warning properties.)

a. If yes, proceed to Step 11.3.

b. If no, an air-purifying respirator equipped with an effective end-of-service-life indicator (ESLI), a supplied-air respirator, or a self-contained breathing apparatus is recommended. (Refer to Appendix A, page 43, for additional information on approval of air-purifying respirators with ESLI's.) Proceed to Step 11.4.

11.3. An air-purifying chemical cartridge/canister respirator is recommended that has a sorbent suitable for the chemical properties of the anticipated gas/vapor contaminant(s) and for the anticipated exposure levels. (Refer to Subparagraph 7, page 27, for the recommended maximum use concentrations of air-purifying chemical cartridge/canister respirators.) Proceed to Step 11.4.

11.4. Respirators that have not been previously eliminated from Table 2 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors.) Maximum airborne concentrations for each class of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. The calculated maximum use concentration limits should not exceed the limitations noted in Subparagraph 7, page 27. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

12. Combination Particulate and Gas/Vapor Respirators

12.1. Is the combination respirator intended for "escape only" purposes?

a. If yes, refer to Subparagraph 5, page 24, for a discussion and selection of "escape only" respirators.

b. If no, the combination respirator is intended for use during normal work activities. Proceed to Step 12.2.

12.2. Does the gas/vapor contaminant have adequate warning properties at or below the NIOSH REL or other applicable exposure limit? (Refer to Subparagraph 6, page 26, and Appendix C, page 48, for additional information on requirements for adequate warning properties.)

a. If yes, proceed to Step 12.3.

b. If no, either an air-purifying respirator equipped with an effective ESLI (Appendix A, page 43), a supplied-air respirator, or a self-contained respirator is recommended. Proceed to Step 12.4.

12.3. An air-purifying chemical cartridge/canister is recommended that has a particulate prefilter suitable for the specific type(s) of gas/vapor and particulate contaminant(s) and for the exposure concentrations. (Refer to Subparagraphs 7, page 27, and Subparagraph 9, page 29, for recommended maximum use concentrations and filter limitations.) Proceed to Step 12.4.

12.4. Respirators that have not been previously eliminated from Table 3 and that have APF's equal to or greater than the minimum protection factor determined in Step 8 are recommended. (Refer to Subparagraph 8, page 28, and Appendix D, page 50, for a discussion of protection factors and Subparagraph 9, page 29, for a discussion on limitations of filter approvals.) Maximum airborne concentrations for each level of respiratory protection can be calculated by multiplying the NIOSH REL or other applicable exposure limit by the APF for that class of respirators. The calculated maximum use concentration limits should not exceed the limitations noted in Subparagraph 7, page 27. Workers wearing respirators should meet the medical guidelines discussed in Subparagraph 10, page 30.

Table 1.--Assigned protection factor classifications of respirators for protection against particulate exposures¹

Assigned protection factor	Type of respirator
5	Single-use (see definition in Glossary) or quarter mask ² respirator
10	Any air-purifying half-mask respirator including disposable ³ (see definition in Glossary) equipped with any type of particulate filter except single use ^{2,4} Any air-purifying full facepiece respirator equipped with any type of particulate filter ⁵
25	Any powered air-purifying respirator equipped with a hood or helmet and any type of particulate filter ⁴ Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode ⁴
50	Any air-purifying full facepiece respirator equipped with a high efficiency filter ² Any powered air-purifying respirator equipped with a tight-fitting facepiece and a high efficiency filter ⁴ Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode ² Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode ⁴

- 1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m³.
- 2 The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 An APF factor of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test.
- 4 APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].
- 5 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

Table 1.--Assigned protection factor classifications of respirators for protection against particulate exposures¹--Continued

Assigned protection factor	Type of respirator
50 cont.	Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode ²
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode ²
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode ²
10,000	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode ²
	Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode ²

- 1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m³.
- 2 The assigned protection factors (APF's) were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 An APF of 10 can be assigned to disposable particulate respirators if they have been properly fitted using a quantitative fit test.
- 4 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].
- 5 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

Table 2.--Assigned protection factor classifications of respirators for protection against gas/vapor exposures

Assigned protection factor ¹	Type of respirator
10	<p>Any air-purifying half mask respirator (including disposable) equipped with appropriate gas/vapor cartridges²</p> <p>Any supplied-air respirator equipped with a half mask and operated in a demand (negative pressure) mode²</p>
25	<p>Any powered air-purifying respirator with a loose-fitting hood or helmet³</p> <p>Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode³</p>
50	<p>Any air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or gas mask (canister respirator)²</p> <p>Any powered air-purifying respirator equipped with a tight-fitting facepiece and appropriate gas/vapor cartridges or canisters³</p> <p>Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode²</p> <p>Any supplied-air respirator equipped with a tight-fitting facepiece operated in a continuous flow mode³</p> <p>Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode²</p>
1,000	<p>Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode²</p>

- 1 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
- 2 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 3 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

Table 2.--Assigned protection factor classifications of respirators for protection against gas/vapor exposures--Continued

Assigned protection factor ¹	Type of respirator
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode ²
10,000	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode ²
	Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode ²

¹ The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.

² The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].

³ The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

Table 3.--Assigned protection factor classifications of respirators for protection against combination gas/vapor and particulate exposures¹

Assigned protection factor ²	Type of respirator
10	<p>Any air-purifying half-mask respirator equipped with appropriate gas/vapor cartridges in combination with any type of particulate filter³</p> <p>Any full facepiece respirator with appropriate gas/vapor cartridges in combination with a dust or mist or fume; dust and mist; or dust, mist, and fume filter⁴</p> <p>Any supplied-air respirator equipped with a half-mask and operated in a demand (negative pressure) mode³</p>
25	<p>Any powered air-purifying respirator equipped with a loose-fitting hood or helmet⁵</p> <p>Any supplied-air respirator equipped with a hood or helmet and operated in a continuous flow mode⁵</p>
50	<p>Any air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with a high efficiency filter or an appropriate canister incorporating a high efficiency filter³</p> <p>Any powered air-purifying respirator with a tight-fitting facepiece equipped with appropriate gas/vapor cartridges in combination with a high efficiency filter or an appropriate canister incorporating a high efficiency filter⁵</p> <p>Any supplied-air respirator equipped with a full facepiece and operated in a demand (negative pressure) mode³</p>

1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m³.

2 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.

3 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].

4 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.

5 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

**Table 3.--Assigned protection factor classifications of respirators for protection against combination gas/vapor and particulate exposures¹--
Continued**

Assigned protection factor ²	Type of respirator
50 cont.	<p>Any supplied-air respirator equipped with a tight-fitting facepiece and operated in a continuous flow mode⁵</p> <p>Any self-contained respirator equipped with a full facepiece and operated in a demand (negative pressure) mode³</p>
1,000	Any supplied-air respirator equipped with a half-mask and operated in a pressure demand or other positive pressure mode ³
2,000	Any supplied-air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode ³
10,000	<p>Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode³</p> <p>Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode³</p>

- 1 Only high efficiency filters are permitted for protection against particulates having exposure limits less than 0.05 mg/m³.
- 2 The assigned protection factor (APF) for a given class of air-purifying respirators may be further reduced by considering the maximum use concentrations for each type of gas and vapor air-purifying element.
- 3 The APF's were determined by Los Alamos National Laboratories (LANL) by conducting quantitative fit testing on a panel of human volunteers [6].
- 4 The APF was based on consideration of efficiency of dust, fume, and/or mist filters.
- 5 The APF's were based on workplace protection factor (WPF) data or laboratory data more recently reported than the LANL data [7-11, 14-17].

The Respirator Decision Logic Sequence is presented in Figure 1 in the form of a flow chart. This flow chart can be used to identify suitable classes of respirators for adequate protection against specific environmental conditions. Refer to the corresponding narrative section for additional information pertaining to a specific part of the flow chart.

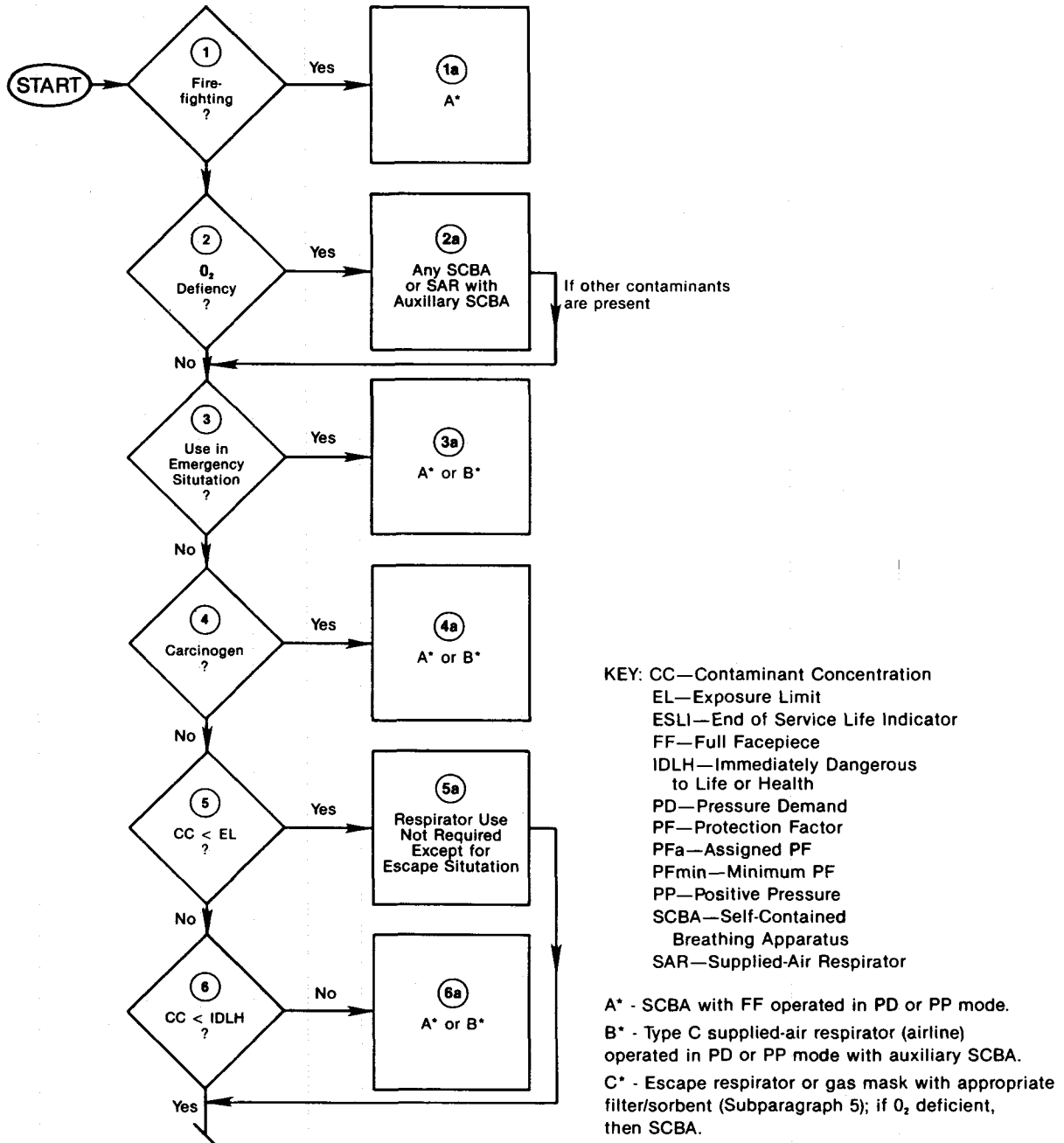


Figure 1. — Flow Chart of Respirator Decision Logic Sequence

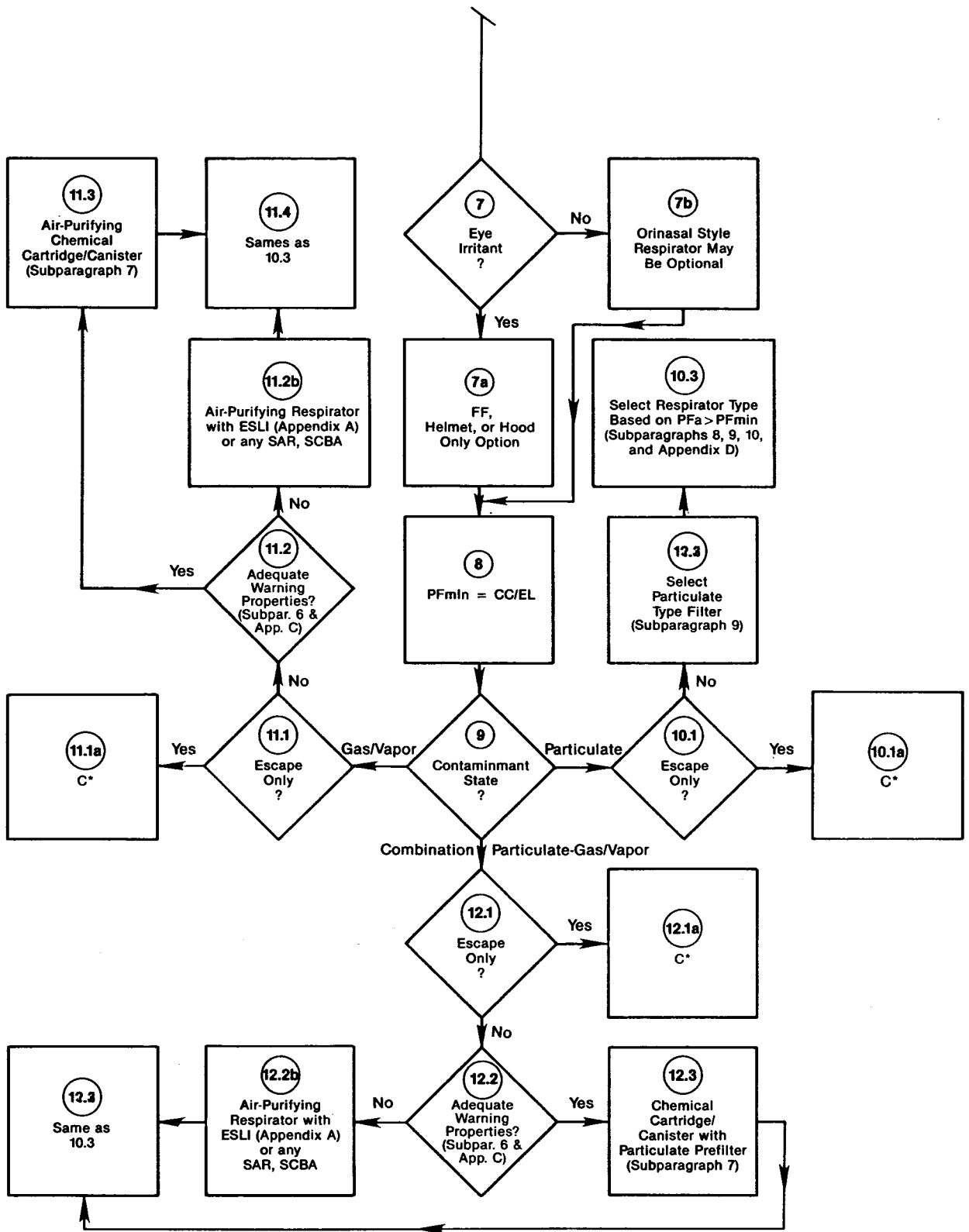


Figure 1. — Flow Chart of Respirator Decision Logic Sequence — Continued

D. Subparagraphs

The following subparagraphs provide additional information to assist the reader in using the Respirator Decision Logic Sequence:

Subparagraph 1: Oxygen-Deficient Atmosphere

The National Institute for Occupational Safety and Health (NIOSH) defines an oxygen-deficient atmosphere as any atmosphere containing oxygen at a concentration below 19.5% at sea level [1]. NIOSH certification of air-line or air-purifying respirators is limited to those respirators used in atmospheres containing at least 19.5% oxygen, except for those air-line respirators equipped with auxiliary self-contained breathing apparatus (SCBA).

The minimum requirement of 19.5% oxygen at sea level provides an adequate amount of oxygen for most work assignments and includes a safety factor. The safety factor is needed because oxygen-deficient atmospheres offer little warning of the danger, and the continuous measurement of an oxygen-deficient atmosphere is difficult.

At oxygen concentrations below 16% at sea level, decreased mental effectiveness, visual acuity, and muscular coordination occur. At oxygen concentrations below 10%, loss of consciousness may occur, and below 6% oxygen, death will result. Often only mild subjective changes are noted by individuals exposed to low concentrations of oxygen, and collapse can occur without warning [2,3,4].

Since oxygen-deficient atmospheres are life-threatening, only the most reliable respirators are recommended; the most reliable respirators are the self-contained breathing apparatus or the supplied-air respirators with auxiliary self-contained units. Because a high protection factor is not necessary to ensure an adequate supply of oxygen even in an atmosphere containing no oxygen, any certified self-contained unit is adequate. All aspects of a respiratory protection program must be instituted for these recommendations to be valid.

Subparagraph 2: Exposure Limits

The majority of the OSHA PEL's were adopted from the American Conference of Governmental Industrial Hygienists (ACGIH) TLVs® published in 1968. The difficulty in changing PEL's through promulgation of standards when new toxicologic information is identified has caused many standards to become outdated. The effectiveness of this decision logic is limited to the adequacy of the selected exposure limits in protecting the health of workers. Exposure limits based on a thorough evaluation of more recent or extensive data should be given priority.

For all chemicals that cause irritation or systemic effects but do not cause carcinogenic effects, it is currently believed that a threshold exposure

concentration exists such that virtually all persons in the working population (with the possible exception of hypersensitive individuals) would experience no adverse health effects.

For many carcinogenic substances, most available data provide no evidence for the existence of a threshold exposure concentration below which the substance would be safe. As with noncarcinogenic substances, there appears to be a dose-response relationship for carcinogenic substances. If no threshold exists for a carcinogen, then there is no safe exposure concentration; however, lower exposures would be associated with lower risks.

For some carcinogens, NIOSH attempts to identify the lowest REL on the basis of the quantitative detection limit for the method used to monitor exposures. For other carcinogens, NIOSH does not identify a precise exposure limit but recommends instead that the employer control worker exposures to the lowest feasible limit.

Regardless of the selected exposure limit for a carcinogen, the best engineering controls and work practices should be instituted. Respirators should not be used as a substitute for proper control measures. When respiratory protection is required to achieve the lowest exposure concentration, then only the most effective respirators should be used. Two types of respirators are recommended: a full facepiece SCBA operated in a pressure-demand or other positive pressure mode or a full facepiece supplied-air respirator (SAR) operated in a pressure-demand or other positive pressure mode in combination with a SCBA operated in a pressure demand or other positive pressure mode. The practicality of each situation must be assessed to determine the most technically feasible protection for the worker.

Other variables such as the specific situation, worker, or job may influence the selection of the appropriate exposure limit for a given contaminant. For example, the effects of some hazardous substances may be increased due to exposure to other contaminants present in the workplace or the general environment or to medications or personal habits of the worker. Such factors, which would affect the toxicity of a contaminant, would not have been considered in the determination of the specific exposure limit. Also, some substances are absorbed by direct contact with the skin and mucous membranes, thus potentially increasing the total exposure.

Subparagraph 3: Immediately Dangerous to Life or Health (IDLH)

An IDLH exposure condition is defined in this decision logic as one that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment. The purpose of establishing an IDLH exposure level is to ensure that the worker can escape from a given contaminated environment in the event of failure of the respiratory protection equipment. The IDLH is considered a maximum level

above which only a highly reliable breathing apparatus providing maximum worker protection is permitted. Any appropriate approved respirator may be used to its maximum use concentration up to the IDLH concentration.

In establishing the IDLH concentration, the following conditions must be assured:

- a. The ability to escape without loss of life or immediate or delayed irreversible health effects. (Thirty minutes is considered the maximum time for escape so as to provide some margin of safety in calculating the IDLH.)
- b. The prevention of severe eye or respiratory irritation or other reactions that would hinder escape.

Sources of information for determining whether the exposure limit for a contaminant represents an IDLH condition are as follows:

- a. Specific IDLH guidelines provided in the literature such as the American Industrial Hygiene Association (AIHA) Hygienic Guides and the NIOSH Pocket Guide for Hazardous Chemical Substances (previous editions were published jointly by NIOSH and OSHA), and/or
- b. Human exposure and effects data, and/or
- c. Animal exposure and effects data, and/or
- d. Where such data specific to the contaminant are lacking, toxicologic data from analogous substances and chronic animal exposure data may be considered.

Subparagraph 4: Eye Irritation

Eye protection in the form of respirators with full facepieces, helmets, or hoods is required for routine exposures to airborne contaminants that cause any irritation to the mucous membranes of the conjunctivae or the cornea or cause any reflex tearing. Eye protection is required for contaminants that cause minor subjective effects as well as for those that cause any damage, including disintegration and sloughing of conjunctival or corneal epithelium, edema, or ulceration. NIOSH is not aware of any standards for gas-tight goggles that would permit NIOSH to recommend such goggles as providing adequate eye protection.

For escape, some eye irritation is permissible if the severity of irritation does not inhibit the escape and if no irreversible scarring or ulceration of the eyes or conjunctivae is likely.

When data on threshold levels for eye irritation are insufficient, quarter- or half-mask respirators can be used, provided that the worker experiences

no eye discomfort and no pathologic eye effects develop. Workers should be told that if any eye discomfort is experienced, they will be provided with respirators that have full facepieces, helmets, or hoods and that provide protection equivalent to the quarter- or half-mask respirators.

Subparagraph S: Escape Apparatus

Escape devices have a single function: to allow a person working in a normally safe environment sufficient time to escape from suddenly occurring respiratory hazards.

Escape devices can be separated into two categories: air-purifying respirators and self-contained breathing apparatus. Air-purifying respirators remove contaminants from the air by sorbent and/or filter media, but because they do not provide air, these respirators cannot be used in an oxygen-deficient atmosphere. Air-purifying escape respirators include the escape gas mask (canister) respirator, the gas mask (canister) respirator, and the filter self-rescuer. The escape gas mask consists of a half-mask or a mouthpiece respirator. The mouthpiece respirator can be used for short periods of time to escape from low concentrations of organic vapor or acid gas. The escape gas mask, which utilizes a half-mask, filters contaminants from the air. These respirators may also be used to escape from low concentrations of organic vapor or acid gas. Escape gas mask respirators equipped with full facepieces can also be used for escape from IDLH conditions but not from oxygen-deficient atmospheres. No air-purifying device is suitable for escape from a potentially oxygen-deficient atmosphere. The filter self-rescue unit is the mouthpiece device, which is designed to protect specifically against less than 1% carbon monoxide.

A self-contained breathing apparatus (SCBA) provides air to the user for escape from oxygen-deficient environments. Escape SCBA devices are commonly used with full facepieces or hoods and, depending on the supply of air, are usually rated as 3- to 60-minute units. Self-contained self-rescuer (SCSR) devices have been approved by MSHA/NIOSH for escape from mines, but these devices may also have application in other similar environments. SCSR's are mouthpiece respirators that provide a source of oxygen-enriched air for up to 60 minutes. All SCBA devices can be used in oxygen-deficient atmospheres.

When selecting escape apparatus, careful consideration must be given to potential eye irritation. This consideration is important for determining whether a gas mask or SCBA equipped with a full facepiece should be selected rather than a device equipped with a half-mask or mouthpiece.

The majority of gas masks or escape gas masks can be used in situations involving gas(es), vapor(s), or particulates. For escape from particulate-contaminated environments, an air-purifying element must be selected that will provide protection against the given type of particulate. The information in Table 4 should be used to select the appropriate escape apparatus.

Table 4.--Selection options for escape respirators

Escape conditions	Type of respirator
Short distance to exit, no obstacles (no oxygen deficiency)	Any escape gas mask ¹ (canister respirator) or gas mask ² (canister respirator)
	Any escape self-contained breathing apparatus having a suitable service life ³
	Any acceptable device for entry into emergency situations
Long distance to exit or obstacles along the way (no oxygen deficiency)	Any gas mask ²
	Any escape self-contained breathing apparatus having a suitable service life ³
	Any self-contained self-rescuer having a suitable service life
Potential oxygen deficiency	Any escape self-contained breathing apparatus having a suitable service life ³
	Any self-contained self-rescuer having a suitable service life

¹ An escape gas mask is a respirator designed for use during escape only from immediately dangerous to life or health (IDLH) or non-IDLH atmospheres. It may consist of a half mask facepiece or mouthpiece, appropriate air-purifying element for the contaminant, and associated connections. Maximum use concentrations for these types of respirators are designated by the manufacturer.

² A gas mask consists of a full facepiece and either chin-style or front- or back-mounted canisters with associated connections. Maximum use concentrations for canister air-purifying elements are listed in Table 5.

³ Escape self-contained breathing apparatus can have rated service lives of 3 to 60 minutes. All acceptable devices for entry into emergency situations can also be used.

Subparagraph 6: Potential Warning Properties for Use With Cartridge/Canister Air-Purifying Respirators

For the purpose of this decision logic, warning properties are defined according to odor, taste, eye irritation, or respiratory irritation. Adequate warning properties imply that the gas or vapor of interest has a persistent odor or irritant effect at concentrations at or below the OSHA PEL or NIOSH REL. Recognition of an odor depends on a person's sensory ability to detect it. Since the range of odor recognition thresholds within a population is very large, odor recognition should not be relied on as the only means for determining that a cartridge or canister is no longer effectively removing a contaminant from the air. A more detailed discussion of variability of odor detection within a population is provided in Appendix C.

NIOSH recommends that the employer ensure that each worker who is required to wear an air-purifying cartridge or canister respirator is capable of recognizing the odor of the substance of concern at a concentration at or below the applicable exposure limit. Such a determination will necessitate that an odor screening test be conducted on each individual for each substance of concern in the particular workplace.

It is recognized that existing screening tests are subjective in nature and not sufficiently sensitive and that conducting screening tests for a group of workers exposed to several substances may be impractical. Therefore, NIOSH knows of no compelling reason not to develop quantitative service life test data to supplement or replace odor screening test results if it can be demonstrated that such a procedure will afford the wearer a level of protection at least equivalent to that indicated by odor screening. Even when service life test data are used, the employer and the respirator wearer should not ignore the usefulness of sensory detection properties (for those who can detect the contaminant's presence) to serve as a warning that the cartridge/canister has failed or that the integrity of the respirator face seal has been compromised.

It is important to realize that 30 CFR 11 [specifically, 30 CFR 11.90(b) (note 4) for gas masks (canister respirators) and 30 CFR 11.150 (note 7) for chemical cartridge respirators], which provides for approval of air-purifying (organic vapor) devices, prohibits their approval for use against organic vapors with poor warning properties unless there is an OSHA standard which permits their use. A more detailed discussion appears in Appendix C.

A recent policy decision by NIOSH allows the use of respirators with effective end-of-service-life indicators for protection against contaminants with poor warning properties, provided that certain conditions are met. These conditions are described in that policy statement, which is reproduced in Appendix A.

Subparagraph 7: Limitations of Respirators for Gases and Vapors

Air-purifying respirators cannot be used in IDLH atmospheres or in atmospheres containing less than 19.5% oxygen by volume. Gas masks (canister respirators) may be used for escape if the atmosphere is not oxygen-deficient.

If, after the APF is multiplied by the REL or other applicable exposure limit (APF X REL), the product exceeds the IDLH value, then the IDLH value shall be the maximum use concentration. (See Tables 1, 2, and 3.) In addition, there are maximum use concentrations associated with all gas and vapor air-purifying elements. (See Table 5.)

Air-purifying devices should not be allowed for either entry into or escape from hazardous environments when supporting evidence exists to demonstrate that unreasonably short service life would occur at the maximum use concentration.

Where there is reason to suspect that a sorbent has a high heat of reaction with a substance, use of that sorbent is not recommended. For such a substance, only non-oxidizable sorbents should be allowed.

Air-purifying respirators cannot be used for protection against gases and vapors with poor warning properties unless the respirator is approved with an effective ESLI. (See Appendix A.)

Although limited in number, there are specific air-purifying respirators that are approved by MSHA/NIOSH for protection against gases and vapors when respirators approved for a given class of contaminants (e.g., organic vapors) cannot be used due to sorbent deficiencies.

Subparagraph 8: Assigned Protection Factors (APF's)

APF's (sometimes referred to in the literature as respirator protection factors), which appear in the 1975 and 1978 versions of the OSHA/NIOSH Respirator Decision Logic, in the 1980 American National Standards Institute (ANSI) standards for respiratory protection, and in all OSHA health standards, are based on quantitative fit testing (QNFT) of respirators [6]. (See definition of fit factors in Appendix D.) No data have been reported in the literature to demonstrate that the results of QNFT are sufficiently indicative of the protection that a given respirator provides in the workplace. Recent studies by NIOSH [7-9] and others [10-12] have suggested that fit factors do not correlate with the workplace protection factors provided by powered air-purifying respirators (PAPR's) and negative pressure half-mask respirators. (See definition of workplace protection factors in Appendix D.)

Table 5.--NIOSH recommended maximum use concentrations (expressed in ppm) for gas and vapor air-purifying elements

Classification of gas and vapor air-purifying elements

Type of gas or vapor	Cartridge(s)	Chin-style canister	Front- or back-mounted canister
Organic vapors	1,000*	5,000†	20,000†
Acid gases			
Sulfur dioxide (SO ₂)	50	100	100
Chlorine (Cl ₂)	10	25	25
Hydrochloric (HCl)	50	100	100
Ammonia (NH ₃)	300	500	500
Methyl amine (CH ₃ NH ₂)	100	--	--
Carbon monoxide (CO)	NA	NA	1,500

* Maximum use concentration will be 1,000 ppm or the immediately dangerous to life or health (IDLH) value for the specific organic vapor, whichever is lower.

† Maximum use concentration for "entry into" will be limited to the value listed or to the IDLH value for the specific organic vapor, whichever is lower.

APF's that are still based on the fit factors determined by Los Alamos National Laboratories (LANL) can be used for those classes of respirators for which no WPF data or simulated workplace protection factor (SWPF) data are available. However, as WPF data are developed, these APF's will be revised, as have the current APF's for powered air-purifying respirators (PAPR's) [7-9,11,14-16]. It should be noted that a number of studies [17-20] on the workplace performance of respirators have appeared in the literature. However, the results of these studies are of little value for establishing APF's because their protocols did not require proper fit or correct use and conscientious wearing of the respirator while in-facepiece sampling was done. A notable exception is the study by Revoir (1974) [21].

When WPF data existed, NIOSH utilized the point estimate equation proposed by Myers et al. [13] to help establish the APF's recommended in this decision logic. The point estimate equation is as follows:

$$\text{protection factor (PF)} = \mu g / Sg^{Zp}$$

where μg = the geometric mean of the measured WPF

Sg = the geometric standard deviation of the measured WPF

Zp = the value corresponding to the selected proportion (p) on the log-normal probability distribution

When WPF data existed, NIOSH selected a confidence limit of $p=0.95$. Thus for a given set of data and given class of respirators, NIOSH would expect that 95% of the WPF's would exceed the calculated point estimate value.

Despite the fact that some of the PF's have a statistical basis, they are still only estimates of an approximate level of protection. It must not be assumed that the numerical values of the APF's presented in this decision logic represent the absolute minimum level of protection that would be achieved for all workers in all jobs against all respiratory hazards. The industrial hygienist or other professional responsible for providing respiratory protection or evaluating respiratory protection programs is therefore encouraged to evaluate as accurately as possible the actual protection being provided by the respirator.

Subparagraph 9: Particulate Filter Respirators

MSHA/NIOSH particulate respirators are certified according to seven basic categories. These categories consist of the following types of exposures:

- **Dusts:** Airborne exposure limit not less than 0.05 mg/m³ or 2 mppcf (see Appendix B);
- **Fumes:** Airborne exposure limit not less than 0.05 mg/m³ or 2 mppcf;
- **Mists:** Airborne exposure limit not less than 0.05 mg/m³ or 2 mppcf (see Appendix B);
- **Dusts, Fumes, and Mists:** Airborne exposure limit less than 0.05 mg/m³ or 2 mppcf and radionuclides;
- **Radon Daughters;**
- **Asbestos-Containing Dusts and Mists** (see Appendix B); and
- **Single-Use Dust and Mist Respirators** (see Appendix B).

Subparagraph 10: Suggested Medical Evaluation and Criteria for Respirator Use

The following NIOSH recommendations allow latitude for the physician in determining a medical evaluation for a specific situation. More specific guidelines may become available as knowledge increases regarding human stresses from the complex interactions of worker health status, respirator usage, and job tasks. While some of the following recommendations should be part of any medical evaluation of workers who wear respirators, others are identified as being applicable for specific situations.

a. A Physician Should Make the Determination of Fitness to Wear a Respirator by Considering the Worker's Health, the Type of Respirator, and the Conditions of Respirator Use.

The recommendation above satisfies OSHA regulations and leaves the final decision of an individual's fitness to wear a respirator to the person who is best qualified to evaluate the multiple clinical and other variables. Much of the clinical and other data could be gathered by other personnel. It should be emphasized that the clinical examination alone is only one part of the fitness determination and that collaboration with foremen, industrial hygienists, and others may often be needed to better assess the work conditions and other factors that affect an individual's fitness to wear a respirator.

b. A Medical History and At Least a Limited Physical Examination are Recommended.

The medical history and physical examination should emphasize the evaluation of the cardiopulmonary system and should elicit any history of respirator use. The history is an important tool in medical diagnosis and can be used to detect most problems that might require further

evaluation. Objectives of the physical examination should be to confirm the clinical impression based on the history and to detect important medical conditions (such as hypertension) that may be essentially asymptomatic.

c. While Chest X-Ray and/or Spirometry May Be Medically Indicated in Some Fitness Determinations, These Should Not Be Routinely Performed.

In most cases, the hazardous situations requiring the wearing of respirators will also mandate periodic chest X-ray and/or spirometry for exposed workers. When such information is available, it should be used in the determination of fitness to wear respirators. (See Recommendation h, page 33.)

Routine chest X-rays and spirometry are not recommended solely as data for determining if a respirator should be worn. In most cases, with an essentially normal clinical examination (history and physical) these data are unlikely to influence the respirator fitness determination; additionally, the X-ray would be an unnecessary source of radiation exposure to the worker. Chest X-rays in general do not accurately reflect a person's cardiopulmonary physiologic status, and limited studies suggest that mild to moderate impairment detected by spirometry would not preclude the wearing of respirators in most cases. Thus it is recommended that chest X-ray and/or spirometry be done only when clinically indicated. (See Appendix E, page 52, for further discussion on the pulmonary effects of wearing respirators.)

d. The Recommended Periodicity of Medical Fitness Determinations Varies According to Several Factors but Could Be as Infrequent as Every 5 Years.

Federal or other applicable regulations shall be followed regarding the frequency of respirator fitness determinations. The guidelines for most work conditions for which respirators are required are shown in Table 6. These guidelines are similar to those recommended by ANSI, which recommends annual determinations after age 45 [22]. The more frequent examinations with advancing age relate to the increased prevalence of most diseases in older people. More frequent examinations are recommended for individuals performing strenuous work involving the use of SCBA. These guidelines are based on clinical judgment and, like the other recommendations in this section, should be adjusted as clinically indicated.

e. The Respirator Wearer Should Be Observed During a Trial Period to Evaluate Potential Physiological Problems

In addition to considering the physical effects of wearing respirators, the physician should determine if wearing a given respirator would cause extreme anxiety or claustrophobic reaction in the individual. This could be done during training, while the worker is wearing the respirator and

is engaged in some exercise that approximates the actual work situation.

Present regulations state that a worker should be provided the opportunity to wear the respirator "in normal air for a long familiarity period..." [23]. This trial period should also be used to evaluate the ability and tolerance of the worker to wear the respirator [24]. This trial period need not be associated with respirator fit testing and should not compromise the effectiveness of the vital fit testing procedure.

Table 6.--Suggested frequency of medical fitness determinations*

	<u>Worker age (years)</u>		
	<35	35 - 45	>45
Most work conditions requiring respirators	Every 5 yrs	Every 2 yrs	1-2 yrs
Strenuous work conditions with SCBA†	Every 3 yrs	Every 18 mos	Annually

* Interim testing would be needed if changes in health status occur.

† SCBA = self-contained breathing apparatus

f. Examining Physicians Should Realize that the Main Stress of Heavy Exercise While Using a Respirator Is Usually on the Cardiovascular System and that Heavy Respirators (e.g., Self-Contained Atmosphere Supplying) Can Substantially Increase this Stress. Accordingly, Physicians May Want To Consider Exercise Stress Tests with Electrocardiographic Monitoring When Heavy Respirators Are Used, When Cardiovascular Risk Factors Are Present, or When Extremely Stressful Conditions Are Expected.

Some respirators may weigh up to 35 pounds and may increase workloads by 20 percent. Although a lower activity level could compensate for this added stress [25], a lower activity level might not always be possible. Physicians should also be aware of other added stresses, such as heavy protective clothing and intense ambient heat, which would increase the worker's cardiac demand. As an extreme example, firefighters who use SCBA inside burning buildings may work at maximal exercise levels under life-threatening conditions. In such cases, the detection of occult cardiac disease, which might manifest itself during heavy stress, may be important. Some authors have either recommended stress testing [26] or

at least its consideration in the fitness determination [22]. Kilbom [26] has recommended stress testing at 5-year intervals for firefighters below age 40 who use SCBA and at 2-year intervals for those aged 40-50. He further suggested that firemen over age 50 not be allowed to wear SCBA.

Exercise stress testing has not been recommended for medical screening for coronary artery disease in the general population [27,28]. It has an estimated sensitivity and specificity of 78% and 69%, respectively, when the disease is defined by coronary angiography [27,29]. In a recent 6-year prospective study, stress testing to determine the potential for heart attack indicated a positive predictive value of 27% when the prevalence of disease was 3 1/2% [30,31]. While stress testing has limited effectiveness in medical screening, it could serve to detect those individuals who may not be able to complete the heavy exercise required in some jobs.

A definitive recommendation regarding exercise stress testing cannot be made at this time. Further research may determine whether this is a useful tool in selected circumstances.

g. An Important Concept Is that "General Work Limitations and Restrictions Identified for Other Work Activities Also Shall Apply for Respirator Use" [22].

In many cases, if a worker is able to do an assigned job without an increased risk to health while not wearing a respirator, the worker will in most situations not be at increased risk when performing the same job while wearing a respirator.

h. Because of the Variability in the Types of Respirators, Work Conditions, and Workers' Health Status, Many Employers May Wish to Designate Categories of Fitness To Wear Respirators, Thereby Excluding Some Workers from Strenuous Work Situations Involving the Wearing of Respirators.

Depending on the various circumstances, there could be several permissible categories of respirator usage. One possible scheme would consist of three overall categories: full respirator use, no respirator use, and limited respirator use including "escape only" respirators. The latter category excludes heavy respirators and strenuous work conditions. Before identifying the conditions that would be used to classify workers into various categories, it is critical that the physician be aware that these conditions have not been validated and are presented only for consideration. The physician should modify the use of these conditions based on actual experience, further research, and individual worker sensitivities. The physician may wish to consider the following conditions in selecting or permitting the use of respirators:

- History of spontaneous pneumothorax;
- Claustrophobia/anxiety reaction;
- Use of contact lens (for some respirators);
- Moderate or severe pulmonary disease;
- Angina pectoris, significant arrhythmias, recent myocardial infarction;
- Symptomatic or uncontrolled hypertension; and
- Age.

It seems unlikely that wearing a respirator would play any significant role in causing lung damage such as pneumothorax. However, without good evidence that wearing a respirator would not cause such lung damage, it may be prudent to prohibit the individual with a history of spontaneous pneumothorax from wearing a respirator.

Moderate lung disease is defined by the Intermountain Thoracic Society [32] as being a forced expiratory volume in one second (FEV_1) divided by the forced vital capacity (FVC) (i.e., FEV_1/FVC) of 0.45 to 0.60 or an FVC of 51 to 65% of the predicted FVC value. Similar arbitrary limits could be set for age and hypertension. It would seem more reasonable, however, to combine several risk factors into an overall estimate of fitness to wear respirators under certain conditions. Here the judgment and clinical experience of the physician are needed. Even many impaired workers would be able to work safely while wearing respirators if they could control their own work pace, including having sufficient time to rest.

Conclusion

Individual judgment is needed in determining the factors affecting an individual's fitness to wear a respirator. While many of the preceding guidelines are based on limited evidence, they should provide a useful starting point for a respirator fitness screening program. Further research is needed to validate these recommendations and others currently in use. Of particular interest would be laboratory studies involving physiologically impaired individuals and field studies conducted under actual day-to-day work conditions.

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IV. GLOSSARY

The following definitions of terms are provided to assist in the understanding and application of this decision logic.

ASSIGNED PROTECTION FACTOR (APF): See PROTECTION FACTOR.

BREAKTHROUGH: The penetration of challenge material(s) through a gas or a vapor air-purifying element. The quantity or extent of breakthrough during service life testing is often referred to as the percentage of the input concentration.

DISPOSABLE RESPIRATORS: A respirator that is discarded after the end of its recommended period of use, after excessive resistance or physical damage, or when odor breakthrough or other warning indicators render the respirator unsuitable for further use.

DUST: A solid, mechanically produced particle with a size ranging from submicroscopic to macroscopic.

EMERGENCY RESPIRATOR USE SITUATION: A situation that requires the use of respirators due to the unplanned generation of a hazardous atmosphere (often of unknown composition) caused by an accident, mechanical failure, or other means and that requires evacuation of personnel or immediate entry for rescue or corrective action.

ESCAPE GAS MASK: A gas mask that consists of a half-mask facepiece or mouthpiece, a canister, and associated connections and that is designed for use during escape only from hazardous atmospheres (see Subparagraph 5).

ESCAPE ONLY RESPIRATOR: Respiratory devices that are designed for use only during escape from hazardous atmospheres.

FILTERING FACEPIECE: A particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium. (See SINGLE-USE DUST or DUST and MIST RESPIRATORS and DISPOSABLE RESPIRATORS.)

FIT FACTOR: A quantitative measure of the fit of a specific respirator facepiece to a particular individual. (For further discussion of fit factors, refer to Appendix D.)

FUME: A solid condensation particulate, usually of a vaporized metal.

GAS: An aeriform fluid that is in a gaseous state at standard temperature and pressure.

IMMEDIATELY DANGEROUS TO LIFE OR HEALTH (IDLH): Acute respiratory exposure that poses an immediate threat of loss of life, immediate or

delayed irreversible adverse effects on health, or acute eye exposure that would prevent escape from a hazardous atmosphere.

MIST: A liquid condensation particle.

ORINASAL RESPIRATOR: A respirator that covers the nose and mouth and that generally consists of a quarter- or half-facepiece.

PLANNED or UNPLANNED ENTRY into an IDLH ENVIRONMENT, AN ENVIRONMENT OF UNKNOWN CONCENTRATION of HAZARDOUS CONTAMINANT, or an ENVIRONMENT of UNKNOWN COMPOSITION: A situation in which respiratory devices are recommended to provide adequate protection to workers entering an area where the contaminant concentration is above the IDLH or is unknown.

POTENTIAL OCCUPATIONAL CARCINOGEN: Any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory, or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance that is metabolized into one or more potential occupational carcinogens by mammals (29 CFR 1910.103, OSHA Cancer Policy).

PROTECTION FACTORS (See Appendix D):

ASSIGNED PROTECTION FACTOR (APF): The minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users.

SIMULATED WORKPLACE PROTECTION FACTOR (SWPF): A surrogate measure of the workplace protection provided by a respirator.

WORKPLACE PROTECTION FACTOR (WPF): A measure of the protection provided in the workplace by a properly functioning respirator when correctly worn and used.

RECOMMENDED EXPOSURE LIMIT (REL): An 8- or 10-hour time-weighted average (TWA) or ceiling (C) exposure concentration recommended by NIOSH that is based on an evaluation of the health effects data.

SERVICE LIFE: The length of time required for an air-purifying element to reach a specific effluent concentration. Service life is determined by the type of substance being removed, the concentration of the substance, the ambient temperature, the specific element being tested (cartridge or canister), the flow rate resistance, and the selected breakthrough value. The service life for a self-contained breathing apparatus (SCBA) is the period of time, as determined by the NIOSH certification tests, in which adequate breathing gas is supplied.

SINGLE-USE DUST or DUST AND MIST RESPIRATORS: Respirators approved for use against dusts or mists that may cause pneumoconiosis and fibrosis.

VAPOR: The gaseous state of a substance that is solid or liquid at temperatures and pressures normally encountered.

V. APPENDICES

APPENDIX A. NIOSH POLICY STATEMENT ON APPROVAL OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

NIOSH/MSHA TESTING AND CERTIFICATION OF AIR-PURIFYING RESPIRATORS WITH END-OF-SERVICE-LIFE INDICATORS

Agency: National Institute for Occupational Safety and Health (NIOSH)

Action: Notice of Acceptance of Applications for Approval of Air-Purifying
Respirators with End-of-Service-Life Indicators

Summary: 30 CFR 11; Sec. 11.150 states that NIOSH and MSHA may, after a review of the effects on wearers' health and safety, approve respirators for gases and vapors not specifically listed in that section. The current regulations also permit the use of "window indicators" for gas masks to warn the wearer when the canister will no longer remove a contaminant [11.102-5(c)(2)]. Although indicators are not mentioned in Subpart L, Chemical Cartridge Respirators, there is nothing in the regulations which explicitly prohibits their use. A NIOSH policy to allow end-of-service-life indicators (ESLI's) on air-purifying respirators for gases and vapors with adequate warning properties has already been established (Letter to All Respirator Manufacturers from Dr. Elliott Harris, June 18, 1975).

Use of ESLI's on chemical cartridge respirators for use against gases and vapors with poor warning properties could also be approved, because 30 CFR 11; Sec. 11.150; footnote 7 states:

"Not for use against gases or vapors with poor warning properties (except where MSHA or Occupational Safety and Health Administration standards may permit such use for a specific gas or vapor)...." Thus, air-purifying respirators with ESLI's could be approved for substances such as acrylonitrile, because the OSHA acrylonitrile standard permits the use of chemical cartridge respirators.

Under the present regulations, NIOSH can also require "any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres" [30 CFR 11; Sec. 11.63 (c)]. NIOSH must notify the applicants in writing of these additional requirements [30 CFR 11; Sec. 11.63 (d)].

The purpose of this notification is to inform respirator manufacturers and users of the NIOSH requirements for approving air-purifying respirators with

either effective passive or active ESLI's for use against gases and vapors with adequate warning properties or for use against gases and vapors with inadequate warning properties whenever there is a regulatory standard already permitting the use of air-purifying respirators.

For additional information, contact: Chief, Certification Branch, 944 Chestnut Ridge Road, Morgantown, WV 26505, (304) 291-4331.

Supplemental Information

Because human senses are not foolproof in detecting gases and vapors and because many gases and vapors found in the workplace do not have adequate warning properties, NIOSH has been investigating alternate means of detection for respirator wearers. In 1976, NIOSH adopted its current policy which allows acceptance of applications for certification of air-purifying respirators, provided that the respirators are equipped with active ESLI's for use against gases and vapors with poor warning properties and are not specifically listed in 30 CFR 11.

An active ESLI is defined as an indicator that invokes an automatic and spontaneous warning signal (e.g., flashing lights, ringing bells, etc.). An active indicator does not require monitoring by the wearer although a passive indicator (normally color change indicator) does.

During the past several years, NIOSH has received notices of concern from respirator manufacturers, regulatory agencies, and general industry regarding the Institute's policy of accepting only active ESLI's for certification. At the October 1983 Mine Health Research Advisory Council (MHRAC) meeting, NIOSH presented a document briefing on "Consideration of Use of End-of-Service-Life Indicators in Respiratory Protective Devices," and requested that MHRAC provide recommendations to the Institute with regard to the appropriateness of the use of both active and passive ESLI's. MHRAC asked their Respirator Subcommittee to review the issue.

The Respirator Subcommittee held a public meeting in Washington, D.C., on December 19, 1983, to solicit comments from interested parties. The Subcommittee reviewed the comments and then reported back to the full committee at the February 2, 1984, MHRAC meeting. Based on the public comments, the Subcommittee also suggested a few additions or modifications be made to the NIOSH proposed evaluation criteria. NIOSH incorporated the recommendations. MHRAC also recommended that active and passive ESLI's are appropriate for use with respiratory protective devices provided that criteria are established for their certification and use to ensure that the user is not exposed to increased risk as a consequence of relying upon such ESLI's.

In order for NIOSH to determine the potential effects of ESLI's on user safety and health, NIOSH recommends that all applications for approval of gas and vapor respirators with ESLI's contain the following information:

CRITERIA FOR CERTIFICATION OF END-OF-SERVICE-LIFE INDICATORS

An applicant for certification of an ESLI for use against substances with poor warning properties must provide NIOSH with the following information:

1. Data demonstrating that the ESLI is a reliable indicator of sorbent depletion ($\leq 90\%$ of service life). These shall include a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are representative of actual workplace conditions where a given respirator will be used. A minimum of two contaminant levels must be utilized: the exposure limit (PEL, REL, TLV[®], etc.) and the exposure limit multiplied by the assigned protection factor for the respirator type.
2. Data on desorption of any impregnating agents used in the indicator, including a flow-temperature study at low and high temperatures and humidities which are representative of actual workplace conditions where a given respirator will be used. Data shall be sufficient to demonstrate safe levels of desorbed agents.
3. Data on the effects of industrial interferences which are commonly found in workplaces where a given respirator will be used. Data should be sufficient to show which interferences could impair the effectiveness of the indicator and the degree of impairment, and which substances will not affect the indicator.
4. Data on any reaction products produced in the reaction between the sorbent and the contaminant gases and vapors, including the concentrations and toxicities of such products.
5. Data which predict the storage life of the indicator. (Simulated aging tests will be acceptable).

In addition to the foregoing, all passive ESLI's shall meet the following criteria:

1. A passive ESLI shall be placed on the respirator so that the ESLI is visible to the wearer.
2. If the passive indicator utilizes color change, the change shall be such that it is detectable to people with physical impairments such as color blindness.
3. If the passive indicator utilizes color change, reference colors for the initial color of the indicator and the final (end point) color of the indicator shall be placed adjacent to the indicator.

All ESLI's shall meet the following criteria:

- 1. The ESLI shall not interfere with the effectiveness of the face seal.**
- 2. The ESLI shall not change the weight distribution of the respirator to the detriment of the facepiece fit.**
- 3. The ESLI shall not interfere with required lines of sight.**
- 4. Any ESLI that is permanently installed in the respirator facepiece shall be capable of withstanding cleaning and a drop from a height of 6 feet. Replaceable ESLI must be capable of being easily removed and shall also be capable of withstanding a drop from a height of 6 feet.**
- 5. A respirator with an ESLI shall still meet all other applicable requirements set forth in 30 CFR 11.**
- 6. If the ESLI uses any electrical components, they shall conform to the provisions of the National Electrical Code and be "intrinsically safe." Where permissibility is required, the respirator shall meet the requirements for permissibility and intrinsic safety set forth in 30 CFR 18, Subpart D. Also, the electrical system shall include an automatic warning mechanism that indicates a loss of power.**
- 7. Effects of industrial substances interferences which are commonly found where a given respirator will be used and which hinder ESLI performance, shall be identified. Substances which are commonly found where the respirator is to be used must be investigated. Data sufficient to indicate whether the performance of the respirator would be affected must be submitted to NIOSH. The user shall be made aware of use conditions that could cause false positive and negative ESLI responses.**
- 8. The ESLI shall not create any hazard to the wearer's health or safety.**
- 9. Consideration shall be given to the potential impact of common human physical impairments on the effectiveness of the ESLI.**

APPENDIX B. NIOSH POLICY STATEMENT ON USE OF SINGLE-USE AND DUST AND MIST RESPIRATORS FOR PROTECTION AGAINST ASBESTOS

June 21, 1984, OSHA Public Hearings

Under Title 30, Code of Federal Regulations, Part 11 (30 CFR 11), NIOSH is required to test and certify respirators within the categories specified therein when such devices are submitted to NIOSH by applicants. Currently, 30 CFR 11, Subpart K defines a number of dust, fume, and mist respirators which may be used for protection against certain hazardous particulate atmospheres. Among the respirators defined in Subpart K are single-use dust respirators designed as respiratory protection against pneumoconiosis-producing and fibrosis-producing dusts, or dusts and mists. Subpart K lists asbestos as one of the dusts against which the single-use dust respirator is designed to protect [Subpart K, Sec. 11.130(H)]. Although at the time of the promulgation of Subpart K, it may have been assumed appropriate to list asbestos as a fibrosis-producing particulate against which the single-use disposable respirator could be reasonably expected to provide adequate protection, NIOSH is no longer confident that such an assumption is reasonable because asbestos is also a potent carcinogen.

The current requirements as (specified in 30 CFR 11) for approval of a single-use dust respirator or dust and mist respirator do not include any tests with fibrous challenge aerosol. NIOSH is currently in the process of doing a comprehensive revision of 30 CFR 11 and intends to address the issue of appropriate respiratory protection for use against asbestos, and to require that any respirator for which such approval is sought be proven to provide effective protection against asbestos. NIOSH may change the regulations included in 30 CFR 11 only in accordance with procedures set forth in the Administrative Procedures Act. In the interim, NIOSH will continue to consider applications for approval of single-use and replaceable dust/mist respirators for use against asbestos only because of the legal requirement in the current approval regulations. However, NIOSH does not recommend the use of such respirators where exposures to asbestos may occur because such a recommendation would not be prudent based on the occupational health risk.

This policy position is contained in "The Statement of the National Institute for Occupational Safety and Health--The Public Hearings on Occupational Exposure to Asbestos."

APPENDIX C. ODOR WARNING: BACKGROUND INFORMATION

It is important to realize that 30 CFR 11 prohibits the use of MSHA/NIOSH approved air-purifying (organic vapor) respirators for protection against organic vapors with poor warning properties unless there is an OSHA standard that permits such use. Specifically, 30 CFR 11, Section 11.90(b), footnote 4 gives the standards for gas masks (canister devices), while 30 CFR 11, Section 11.150, footnote 7 gives the standards for chemical cartridge respirators. Thus the "organic vapor respirator" shall be approved only for organic vapors with adequate warning properties. In addition, the requirement for adequate warning properties also applies to all MSHA/NIOSH-approved air-purifying respirators for protection against organic gases and vapors.

A recent policy decision by NIOSH allows the use of respirators for protection against contaminants with poor warning properties, provided that certain conditions are met. These conditions are outlined in the policy statement in Appendix A. MSHA/NIOSH approval may be granted for a respirator designed for use against gases and vapors with poor warning properties if the respirator incorporates an effective end-of-service-life indicator (ESLI).

However, unless the respirator incorporates an ESLI, wearers of air-purifying chemical cartridge/canister respirators must rely on adequate warning properties to alert them to the breakthrough of the sorbent in the cartridge or canister. Amoores and Hautala [33] have noted:

The ability of members of the population to detect a given odor is strongly influenced by the innate variability of different persons' olfactory powers, their prior experience with that odor, and by the degree of attention they accord to the matter.

Amoores and Hautala [33] found that on the average, 95% of a population will have a personal odor threshold that lies within the range from about one-sixteenth to sixteen times the reported mean "odor threshold" for a substance. That is, about 2.5% of a population will be able to detect a substance's odor at concentrations less than one-sixteenth of the "odor threshold" for a substance. Correspondingly, about 2.5% of the individuals will need to be exposed to concentrations exceeding by a factor of 16 the "odor threshold" in order to perceive the odor. Thus for many substances the width of distribution of personal odor threshold is over two orders of magnitude of concentration. The "odor thresholds" reported in the literature generally are the median values for wide population distributions. Also, 50% of prospective respirator wearers can detect a substance's odor only at levels that must exceed the reported "odor threshold," and about 15% cannot detect the odor at levels that exceed the "odor threshold" by fourfold [33].

OSHA incorporated into the lead standard a new isoamyl acetate qualitative fit test protocol, developed by Du Pont, which requires odor threshold

screening [29 CFR 1910.1025, Appendix D (I)(A)]. Du Pont realized that a qualitative fit test depending on odor recognition would be ineffective if every individual were not first screened for the ability to detect the odor of isoamyl acetate at some minimum concentration. This is also true for detection of the odor of the gas or vapor used to alert the wearer of sorbent element (cartridge or canister) breakthrough. Thus NIOSH recommends screening tests for workers who wear air-purifying gas or vapor respirators to determine their ability to detect the odor below the exposure limit for that gas or vapor.

APPENDIX D. PROTECTION FACTOR: BACKGROUND INFORMATION

The U.S. Bureau of Mines referred to the term "Decontamination Factor" in their Approval Schedule 21B, first issued in 1965, and defined it to be "the ratio of the concentration of dust, fume, or mist present in the ambient atmosphere to the concentration of dust, fume, or mist within the facepiece while the respirator is being worn." The decontamination factor is now referred to as the respirator protection factor. The original definition and application given in schedule 21B has been somewhat generalized over the years.

The protection factor of a respirator is an expression of performance based on the ratio of two measured variables, C_1 and C_0 . The variable C_1 is defined only as the measured concentration of a contaminant inside the respirator facepiece cavity, and C_0 is defined only as the measured contaminant concentration outside the respirator facepiece. The relationship between these two variables can be expressed not only as the protection factor (C_0/C_1) but also as the penetration (C_1/C_0) or efficiency $[(C_0 - C_1)/C_0]$.

The protection factor can be related to the penetration (p) and efficiency (E) as follows:

$$PF = C_0/C_1 = 1/p = 1/(1-E)$$

A further implicit condition on the PF function is that $C_1 \leq C_0$; therefore, the PF will always be greater than unity.

Protection factor assessments are made almost exclusively on man/respirator systems, while penetration and efficiency assessments are made only on component parts of the respirator system. It is important to recognize that on a man/respirator system, the measured variable C_1 becomes a complicated function of many individual sources of penetration (e.g., air-purifying element penetration, exhalation valve penetration, face seal penetration, and other inboard penetration) and those environmental conditions that would effect penetration. To deal with the multiple methods for determining and applying protection factors, a number of definitions have been proposed [13]. These definitions, described below in greater detail than in the Glossary, are as follows:

ASSIGNED PROTECTION FACTOR (APF): A special application of the general protection factor concept, APF is defined as a measure of the minimum anticipated workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to a percentage of properly fitted and trained users. The maximum specified use concentration for a respirator is generally determined by multiplying the exposure limit for the contaminant by the protection factor assigned to a specific class of respirators [13].

SIMULATED WORKPLACE PROTECTION FACTOR (SWPF): A surrogate measure of the workplace protection factor (WPF) of a respirator, SWPF differs from the WPF only in that it is measured in a laboratory simulation of a workplace setting rather than in the actual workplace. The definitions and restrictions of C_0 and C_1 are as described for the WPF. For laboratory protection factor testing to reliably estimate WPF's, a relationship must be demonstrated between the two tests. No such relationship has been identified in the literature. Until such a relationship can be shown to exist, the laboratory protection factor is of questionable use in determining or predicting the WPF [13].

WORKPLACE PROTECTION FACTOR (WPF): A measure of the actual protection provided in the workplace under the conditions of that workplace by a properly functioning respirator when correctly worn and used, WPF is defined as the ratio of the estimated contaminant concentration outside the respirator facepiece (C_0) to the contaminant concentration inside the respirator facepiece (C_1). The sampling restrictions placed on C_0 and C_1 are that both C_0 and C_1 should be TWA samples taken simultaneously while the respirator is being properly worn and used during normal work activities. In practice, the WPF would be determined by measuring the concentration inside and outside the facepiece during the activities of a normal workday [13].

FIT FACTOR: A special application of the protection factor ratio that represents a quantitative measure of the fit of a particular respirator facepiece to a particular individual, the fit factor is defined under the conditions of quantitative fit testing as the aerosol concentration in the test chamber (C_0) divided by the penetration that occurs through the respirator face seal interface (C_1) [34]. For C_1 to reflect only face seal leakage, high efficiency filters [greater than 99.97% efficient against $0.3 \mu\text{m}$ aerodynamic mass median diameter (AMMD) dioctylphthalate aerosol] are installed on the respirator. It is assumed that either no leakage or only a negligible amount of leakage into the facepiece occurs through the exhalation valve or any source other than the face seal. The fit factor is measured on a complete respirator worn by a test subject who follows a regimen of slow head movements, deep breathing, and talking; a polydispersed oil mist or sodium chloride aerosol is used that has an AMMD of approximately $0.6 \pm 0.1 \mu\text{m}$ (with a geometric standard deviation of approximately 2 to 2.4).

APPENDIX E. MEDICAL ASPECTS OF WEARING RESPIRATORS: BACKGROUND INFORMATION

In recommending medical evaluation criteria for respirator use, one should apply rigorous decision-making principles [35], using knowledge of screening test sensitivity, predictive value, etc. Unfortunately, many gaps in knowledge in this area exist. The problem is complicated by the large variety of respirators, their conditions of use, and individual differences in the physiologic and psychologic responses to them. For these reasons, the preceding guidelines (see Subparagraph 10) are to be considered as informed suggestions rather than established NIOSH policy recommendations. The following information is intended primarily to assist the physician in developing medical evaluation criteria for respirator use.

Health Effects of Wearing Respirators

Brief descriptions of the health effects associated with wearing respirators are summarized below. Interested readers are referred to recent reviews for more detailed analyses of the data [36,37].

Pulmonary: In general, the added inspiratory and expiratory resistances and dead space of most respirators cause an increased tidal volume and decreased respiratory rate and ventilation (including a small decrease in alveolar ventilation). These respirator effects have usually been small both among healthy individuals and, in limited studies, among individuals with impaired lung function [38-42]. This generalization is applicable to most respirators meeting Federal regulations when resistances (particularly expiratory resistance) are low [1,43,44]. While most studies report minimal physiologic effects during submaximal exercise, the resistances commonly lead to reduced endurance and reduced maximal exercise performance [45-49]. The dead space of a respirator (reflecting the amount of expired air that must be rebreathed before fresh air is obtained) tends to cause increased ventilation. At least one study has shown substantially increased ventilation with a full-face respirator, a type which can have a large effective dead space [50]. However, the net effect of a respirator's added resistances and dead space is usually a small decrease in ventilation [39,45,46-48,51].

The potential for adverse effects, particularly decreased cardiac output, from the positive pressure feature of some respirators has been reported [52]. However, several recent studies suggest that this is not a practical concern, at least not in healthy individuals [53-55].

Theoretically, the increased fluctuations in thoracic pressure while breathing with a respirator might constitute an increased risk to subjects with a history of spontaneous pneumothorax. Few data are available in this area. While an individual is using a negative pressure respirator with relatively high resistance during very heavy exercise, the usual maximal peak negative oral pressure during inhalation is about 15-17 cm of water [53]. Similarly, the usual maximal peak positive oral pressure

during exhalation is about 15-17 cm of water, which might occur with a respirator in a positive pressure mode, again during very heavy exercise [53]. By comparison, maximal positive pressures, such as those during a vigorous cough, can generate 200 cm of water pressure [56]. The normal maximal negative pleural pressure at full inspiration is -40 cm of water [57], and normal subjects can generate -80 to -160 cm of negative water pressure [56]. Thus while vigorous exercise with a respirator does alter pleural pressures, the risk of barotrauma would seem to be substantially less than that of the cough maneuver.

In some asthmatics, an asthmatic attack may be exacerbated or induced by a variety of factors including exercise, cold air, and stress, all of which may be associated with wearing a respirator. While most asthmatics who are able to control their condition should not have problems with respirators, a physician's judgment and a field trial may be needed in selected cases.

Cardiac: The added work of breathing from respirators is small and could not be detected in several studies [38,39]. A typical respirator might double the work of breathing from 3 to 6% of the oxygen consumption, but this is probably not of clinical significance [38]. In concordance with this view is the finding of several studies that at the same workloads heart rate does not change with the wearing of a respirator [39,54,58-60].

In contrast, the added cardiac stress due to the weight of a heavy respirator may be considerable. A self-contained breathing apparatus (SCBA), particularly one that uses compressed air cylinders, may weigh up to 35 pounds. Heavier respirators have been shown to reduce maximum external workloads by 20% and similarly increase heart rate at a given submaximal workload [46]. In addition, it should be appreciated that many uses of SCBA (e.g., for firefighting and hazardous waste site work) also necessitate the wearing of 10-25 pounds of protective clothing.

Raven et al. [40,58] found significantly higher systolic and/or diastolic blood pressures during exercise for persons wearing respirators (although increases were minimal, i.e., ≤ 10 mmHg systolic, 0-2 mmHg diastolic). Arborelius et al. [54] did not find significant differences for persons wearing respirators during exercise.

Body Temperature: Proper regulation of body temperature is primarily of concern with the closed circuit, self-contained breathing apparatus that produces oxygen via an exothermic chemical reaction. Inspired air within these respirators may reach 120°F (49°C), thus depriving the wearer of a minor cooling mechanism and causing discomfort. Obviously this can be more of a problem with heavy exercise and when ambient conditions and/or protective clothing further reduce the body's ability to lose heat. The increase in heart rate due to increasing temperature represents an additional cardiac stress.

Closed-circuit breathing units of any type have the potential for heat stress since warm expired gases (after exothermic carbon dioxide removal with or without oxygen addition) are rebreathed. Respirators with large dead space also have this potential problem, again because of partial rebreathing of warmed expired air [50].

Diminished Senses: Respirators may reduce visual fields, decrease voice clarity and loudness, and decrease hearing. Besides the potential for reduced productivity, these effects may result in reduced industrial safety. These factors may also contribute to a general feeling of stress [61].

Psychologic: This important topic is discussed in recent reviews by Morgan [61,62]. There is little doubt that virtually everyone suffers some discomfort when wearing a respirator. The large variability and the subjective nature of the psycho-physiologic aspects of wearing a respirator, however, make studies and specific recommendations difficult. Fit testing obviously serves an important additional function in providing a trial to determine if the wearer can psychologically tolerate the respirator. General experience indicates that the great majority of workers can tolerate respirators and that experience aids in this tolerance [62]. However, some individuals are likely to remain psychologically unfit for wearing respirators.

Local Irritation: Allergic skin reactions may occur occasionally from wearing a respirator, and skin occlusion may cause irritation or exacerbation of preexisting conditions such as pseudofolliculitis barbae. Facial discomfort from the pressure of the mask may occur, particularly when the fit is unsatisfactory.

In addition to the health effects associated with wearing respirators (described above) specific groups of respirator wearers may be affected by the following factors:

Perforated Tympanic Membrane: While inhalation of toxic materials through a perforated tympanic membrane (ear drum) is possible, recent evidence indicates that the airflow would be minimal and rarely if ever of clinical importance [63,64]. In highly toxic or unknown atmospheres, use of positive pressure respirators should ensure adequate protection [63].

Contact Lens: Contact lenses are generally not recommended for use with respirators, although little documented evidence exists to support this viewpoint [65]. Several possible reasons for this recommendation are noted below:

- a. Corneal irritation or abrasion might occur with the exposure. This would, of course, be a problem primarily with quarter- and half-face masks, especially with particulate exposures. However, exposures could occur with full-face respirators due to leaks or

inadvisable removal of the respirator for any reason. While corneal irritation or abrasion might also occur without contact lenses, their presence is known to substantially increase this risk.

b. The loss or misplacement of a contact lens by an individual wearing a respirator might prompt the wearer to remove the respirator, thereby resulting in exposure to the hazard as well as to the potential problems noted in "a." above.

c. The constant airflow of some respirators, such as powered air-purifying respirators (PAPR) or continuous flow air-line respirators, might irritate a contact lens wearer.