

NABIR



SUMMARY PROCEEDINGS of a WORKSHOP on BIOREMEDIATION AND ITS SOCIETAL IMPLICATIONS AND CONCERNS (BASIC)

July 18-19, 1996
Airlie Center, Warrenton, Virginia

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Executive Summary

The Department of Energy (DOE), Office of Health and Environmental Research held a workshop in support of its new fundamental scientific program in Natural and Accelerated Bioremediation Research (NABIR) on July 18-19, 1996 near Warrenton, Virginia. In all, 45 invited participants from government, academia, non-profit institutions, trade organizations and the business community met to discuss ethical, legal, and social issues (ELSI) associated with the new NABIR program. The objectives of the workshop were (1) to explore what some of the societal, public policy, educational and other issues attendant to the NABIR Program might be; (2) to begin a process of public involvement; and (3) to develop an initial set of recommendations for creating a program in Bioremediation and Its Societal Issues and Concerns (BASIC) within NABIR.

Participants engaged in a very lively discussion of a broad range of specific topics. A number of direct and provocative ideas were offered. Some of these are included in the body of these proceedings. General consensus was that DOE was to be lauded for this attempt to institute a novel approach to a long-standing need to enhance public participation in the scientific enterprise.

A number of specific recommendations were made during the workshop and are included in this proceedings. Some of the more general recommendations included:

- Funding a BASIC research program integral with scientific elements
- A list of important BASIC research topics
- Ways to develop partnerships for implementation of NABIR.

Suggested performance measures included:

- An infrastructure for broad-based discussion of NABIR is in place that includes mechanisms for interaction between DOE offices and among field research centers, the scientific community and the public.
- Scientists and social scientists are working together by joint involvement in field research and other activities, as measured by joint publications.
- Environmental impacts of the NABIR Program and its field research centers have been determined in accordance with the National Environmental Policy Act (NEPA) requirements.
- Education, outreach and intellectual property strategies have been adopted and are effective.
- The public understands bioremediation, its potential, and its limitations.
- The press is supportive.
- Annual research funding for the NABIR Program increases significantly toward the original goal of \$40M to \$50M.

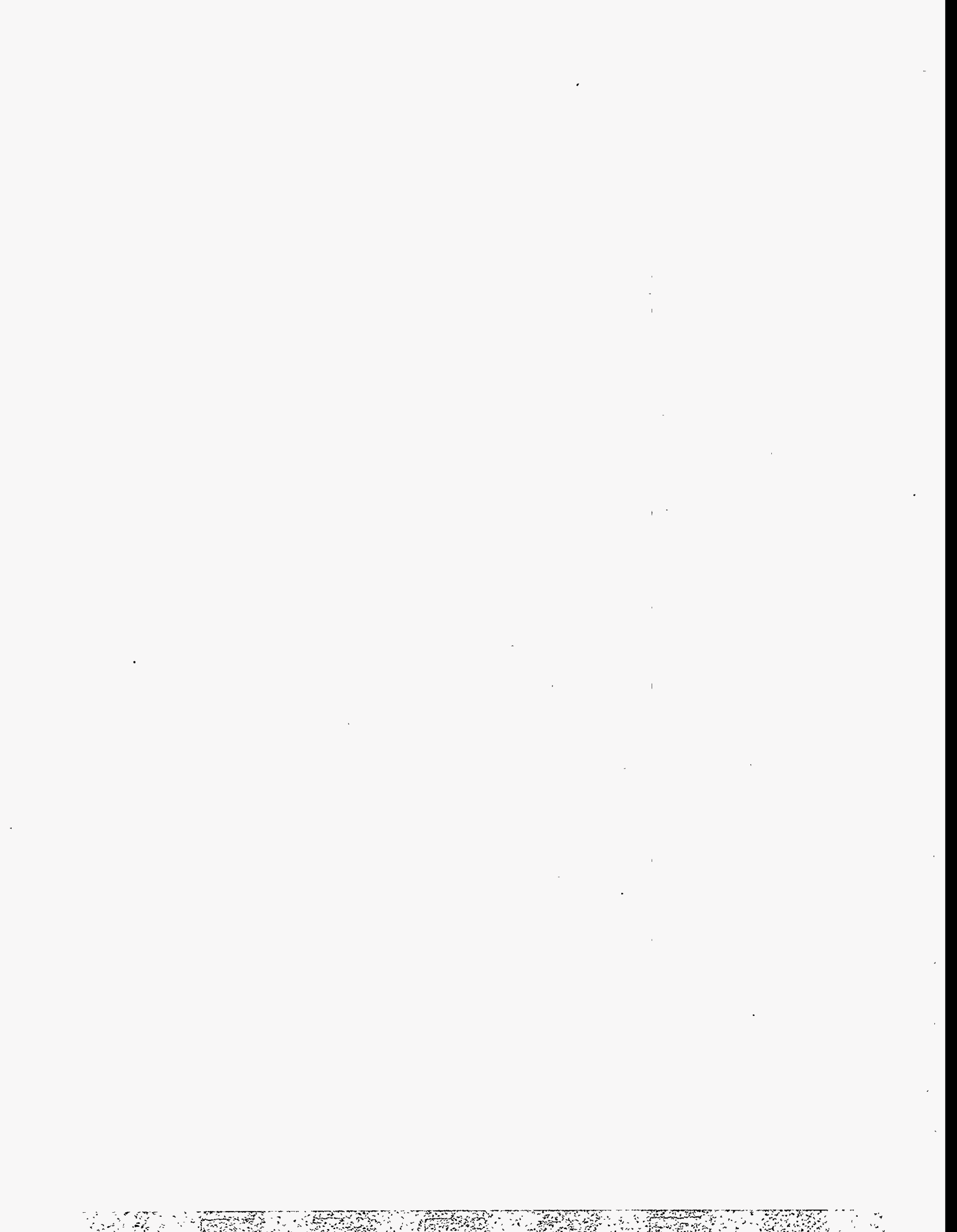


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Introduction

This document summarizes the proceedings of a workshop on Bioremediation and Its Societal Implications and Concerns (BASIC) held July 18-19, 1996 at the Airlie Center near Warrenton, Virginia. The workshop was sponsored by the Office of Health and Environmental Research (OHER), U.S. Department of Energy (DOE), as part of its fundamental research program in Natural and Accelerated Bioremediation Research (NABIR).

The information summarized in these proceedings represents the general conclusions of the workshop participants, and not the opinions of workshop organizers or sponsors. Neither are they consensus opinions, as opinions differed among participants on a number of points. The general conclusions presented below were reached through a review, synthesis, and condensation of notes taken by NABIR Program Office staff and OHER program managers throughout the workshop. Specific contributions by participants during breakout sessions are recorded in bullet form in the appropriate sections, without attribution to the contributor(s). These contributions were transcribed as faithfully as possible from notes about the original discussions. They were edited only to make them grammatically correct, parallel in structure, and understandable to someone not familiar with the NABIR Program or BASIC element.

DOE's Environmental Legacy

DOE has a 50-year legacy of environmental problems resulting from nuclear weapons manufacture and storage and from the management of radioactive wastes from commercial power plants, hospitals, universities, research institutes, and other sources. Among the most serious is widespread contamination of soil and groundwater at many DOE facilities with mixed chemical and radiological contaminants. This mixed waste contamination often occurs at great depth and over large geographic areas that can be measured in units of cubic miles (e.g., at Hanford and Savannah River).

The result is a cleanup cost that has been variously estimated in tens to hundreds of billions of dollars. The most recent estimate of "base-case" cost and duration of the cleanup effort is a total of \$230 billion in expenditures over a 75-year period (DOE 1995a). However, this and other such estimates are unreliable for many reasons. One key reason is that technical solutions are prohibitively expensive or do not even exist for many of the subsurface contaminant scenarios. For example, the recent cost estimate does not include the costs of many needed environmental restoration activities, including nuclear explosion sites and most contaminated groundwater, because no feasible cleanup technologies presently exist. Others are excluded from the cost estimates because collateral ecological damage would be too severe using existing technologies.

Thus, the DOE has identified the need for imaginative and novel *in situ* cleanup approaches (DOE, 1994). The Office of Environmental Management (EM) has responsibility for the deployment of innovative technology based on the development and application of fundamental knowledge from the scientific community. The Office of Energy Research (ER, which includes OHER), in conjunction with EM has identified bioremediation as a promising innovative approach in need of critical fundamental understanding of interrelated molecular, microbial, ecological, and biogeochemical processes.

Scope of the NABIR Program

The mission of the NABIR program is to *provide the scientific understanding needed to use natural processes and to develop methods to accelerate these processes* for the bioremediation of contaminated soils, sediments, and groundwater at DOE facilities (DOE, 1995b). NABIR focuses on bioremediation of complex contaminant mixtures, with primary emphasis on metals, radionuclides, solvents, explosives (e.g., TNT, HMX, RDX), chelating agents and organic acids. Although petroleum hydrocarbons are widespread contaminants at DOE sites, sufficient fundamental knowledge for their biological treatment (except when they are mixed with inorganics) is largely available from research efforts sponsored by the Environmental Protection Agency (EPA) and within industry.

"We are developing an operating strategy—how we will conduct NABIR."

Scientific understanding in NABIR will be gained by performing fundamental laboratory, intermediate-scale, and field-oriented research in seven principal programmatic elements, including:

- Biotransformation and Biodegradation
- Community Dynamics and Microbial Ecology
- Biogeochemical Dynamics
- Assessment
- Biomolecular Science and Engineering
- Acceleration
- System Engineering, Integration, Prediction, and Optimization.

In the future, and depending on availability of funding, it is hoped that up to three field research centers (FRCs) with supporting infrastructure will be established at DOE sites to facilitate interdisciplinary research in microbiology, geochemistry, geohydrology, environmental engineering, molecular and structural biology, and computational sciences. The FRCs will be dedicated to fundamental science for the proposed ten-year duration of the program. NABIR will develop a programmatic data management system to encourage cross-institutional as well as interdisciplinary collaboration and to provide computational methods for predicting and optimizing the effectiveness of natural and accelerated bioremediation.

Ethical, Legal, and Social Issues

Today, public involvement in environmental and societal issues is intense and widespread, reflecting more openly expressed concerns about new technologies' impacts on the public, a higher level of education, and a more effective and pervasive communication system than in the past. Within the scientific and engineering community, recognition is growing that successful

technical programs can only be developed with a solid understanding of issues pertaining to stakeholders, public acceptance and regulatory policy, intellectual property, and societal ethics. For example, DOE and the National Institutes of Health (NIH) have learned from the Human Genome Program that public debate about ethical, legal, and social issues and concerns can have a major effect on the acceptability of research results (e.g., certain genetic tests), and how the results are applied.

The NABIR Program Plan discusses the need to consider societal issues related to bioremediation in the scientific program, so as to ensure long-term success and ultimate application of the results. The goal of the BASIC element of the NABIR Program is to address these societal issues. To ensure timely identification of, and attention to, important social issues, DOE made the BASIC element the subject of its first technical workshop.

Workshop Agenda and Participants

Based on OHER experience with the human genome, global climate change, subsurface science, medical isotopes, and other fundamental research programs, the agenda (Appendix A) for the BASIC workshop was developed in advance to reflect workshop objectives and a preliminary and tentative (but by no means exhaustive) understanding of important issues and expectations. As originally drafted, the agenda included the following sessions:

“What are the BASIC questions we need to identify and address now?”

- Welcome, Introductions, and Charge to Participants
- NABIR Program Status
- Principles and Science of Current Bioremediation Technology
- NABIR Program Overview
- NABIR Scientific Program Elements and Objectives
- BASIC Program Preview. Workshop Format and Objectives
- Bioremediation: Future Potential and Scientific Needs
- BASIC Issues 1: Lessons from the Past
- BASIC Issues 2: Regulatory, Policy, Societal, Legal and Economic Issues
- Education and Public Outreach
- Intellectual Property

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- Breakout Sessions: Public Perception and Public Policy, Intellectual Property, Education and Outreach
- Summary Session.

The following sections of these proceedings summarize (A) the Charge to Workshop Participants, and (B) BASIC Performance Outcomes and Metrics, followed by summaries of the three breakout sessions: (C) Public Perception and Public Policy, (D) Intellectual Property, and (E) Education and Outreach.

The approach and style for the following sections is a distillation of salient points made by all of the participants, written as text, and based on extensive workshop notes taken by two or more people at all times during each of the sessions. While certain ideas and comments can be attributed to individuals, the text of this proceedings is written as a single voice of all participants so that, with few exceptions, individual contributions remain anonymous.

Sessions

A. Charge to Workshop Participants

The purpose of the workshop was to identify key ethical, legal, and social issues by engaging a broad community of potential stakeholders and otherwise interested and expert participants in a focused discussion. The workshop was facilitated by Dr. Daniel Drell, Program Manager with responsibility at OHER for the Ethical, Legal, and Social Impacts (ELSI) Program of the DOE Human Genome Program and for BASIC within the NABIR program. In reviewing DOE's experience with the Human Genome program and its incorporation of an ELSI component, Dr. Drell began the workshop by charging participants to learn from experiences of the genome ELSI program, and to view BASIC as an opportunity for a new approach.

"Public Promise—In five years we will evaluate BASIC with an external review."

The charge to the workshop was to discuss and provide input to a number of subject areas so that the results could be used within the NABIR program to affect a number of specific outcomes. These were:

- To develop a set of NABIR principles based on the assumption that the scientific program elements are worthy of attention.
- To foster collaboration among scientists, stakeholders, and others within and beyond NABIR, thereby facilitating internal integration and establishing partnerships to enable implementation.
- To identify and prioritize issues pertinent to launching new scientific programs in order to develop a BASIC research component.

During the discussion that accompanied and followed Dr. Drell's introductory remarks, three key issues were raised. These were:

- Metrics—How will the extent of success or failure of BASIC be measured? What peer review mechanisms, if any, will be established?
- BASIC Integration—How will a BASIC component be developed within the overall context of NABIR? Is it to be an independent or integrated program? Might it be useful to include social scientists (ELSI experts) in the process for peer review of scientific program elements and the individual projects on which they are built?
- Is there a role for BASIC in prioritizing scientific research within NABIR?

The complexity of issues is such that their resolution during the workshop was not possible. Rather, the purpose of the workshop was to identify issues and initiate the process within NABIR for adequately addressing them.

As a result of the discussion, Dr. Drell committed NABIR to establishing a set of performance outcomes and metrics against which a BASIC program of ethical, legal, and societal research, stakeholder engagement, and NABIR integration would be measured by external review in five years.

B. BASIC Performance Outcomes and Metrics

Throughout the workshop sessions, participants identified and listed potential performance outcomes and metrics for the BASIC element. The suggested performance outcomes and metrics were:

- A social infrastructure for broad-based discussion of NABIR is in place.
- Scientists and social scientists are working together by joint involvement in field research activities, as measured by joint publications.
- Environmental impacts of the NABIR Program and the field research centers have been determined in accordance with the National Environmental Policy Act (NEPA) requirements.
- Education, outreach, and intellectual property strategies have been adopted and are effective.
- The public understands bioremediation, its potential, and its limitations.
- The press is supportive.
- Annual research funding for NABIR increases significantly toward the original goal of between \$40M and \$50M during and after the third year.

"There is no a priori assumption that BASIC exists to sell NABIR. Rather, there is a need for a set of principles that we can all buy into to guide the process."

Two types of issues and concerns were identified and discussed during the workshop: (1) issues and concerns related to the establishment and implementation of a new, long-term scientific program and (2) issues and concerns related to the development and deployment of bioremediation technologies. The three sessions summarized below largely address the latter.

C. Policy and Public Perception

Public Perception

The scope and level of understanding of issues that collectively result in public perception and that, in turn, are translated into public policy, are very broad and dynamic. Public perception of bioremediation is largely associated with the larger questions of environmental stewardship, risk management, technology, and cost. To understand public perception, it is first necessary to

understand that “the” public is, in reality, “many” publics. Then it becomes possible to address the key ethical issues and concerns that underlie public perception of bioremediation and its influence on public policy.

Collective public perception reflects the heterogeneous and dynamic nature of the public. For a given contaminated DOE site at which the party responsible for cleanup is considering *in situ* remedial technology options, the public includes:

- Homeowners, businesses, service providers, and other stakeholders in the local community, such as native American tribes and local special interest groups
- Technology providers, such as Office of Technology Development (EM-50) contractors, Office of Environmental Restoration (EM-40) contractors, and the scientific community
- Broader regional interest groups
- National environmental interest groups
- Taxpayers
- Local governing bodies (i.e., municipalities and counties)
- State and federal regulatory agencies.

“The public has an irrational fear of microorganisms.”

“There is a class of people who have discovered that you can make money if you scare people about microorganisms.”

“Microbes are the invisible guardians of the earth.”

In the broadest sense of its contribution to public perception, the public also includes the DOE problem owner and, by extension, other affected or interested bodies within the federal government. Again, “the” public is, in fact, “many” publics. In the context of technology development and deployment, this multiplicity is important for conceptualizing the role of the public in planning and implementing scientific and engineering programs in an environment of shrinking federal support and increasing technical complexity.

Ethical underpinnings of public perception as they apply to bioremediation at a DOE site must be identified and understood. The scope of these ethical issues includes people’s philosophies regarding the relationship of humankind to the environment. By extension, it also includes human responsibility for ecological change both for the environment in and of itself, and for the health, safety, and enjoyment of future human populations. This ethic of environmental stewardship underlies perceptions of ecological and human health risks associated with the existing problem and the alternative remedial technologies. Additionally, issues of research practice, including openness, need to be acknowledged. Perception of risk associated with technology includes some degree of public mistrust based on past experiences with:

- Unexpected consequences (“unpleasant surprises”) of a new technology, especially potential health risks

- Failure of a technology to perform as intended
- Perceived secrecy or deception by technology providers (e.g., “better living through chemistry” associated with pollution by the chemical industry)
- Having the problem owner also be the entity that develops, purchases, and deploys the technology
- The often highly complex and difficult-to-understand nature of the science and technology itself.

Because bioremediation is a technical intersection of many disciplines including, for example, use of genetically engineered microorganisms (which can invoke fears of its own) or injection of chemical substances into groundwater, it is likely that public perception will be influenced to some extent by the perceptions and factors listed above.

Public Expectations

Public expectations associated with the selection and application of innovative technology are molded by concerns about a number of issues. With respect to a given technology, the public wants to know about:

- Its effectiveness and reliability
- Failure control—What are the possible failure scenarios and the associated contingency plans?
- Applicability to the specific use in question
- The range of potential environmental effects—this is the basis for perception of acceptable levels of risk compared to no action or the application of alternative technologies (“ecological ethics”)
- Any possible health consequences
- How to get involved in decision making
- Cost effectiveness.

“Uncritical acceptance is just as bad as uncritical rejection.”

Therefore, from the perspective of the public, a minimum set of ingredients for the successful application of an innovative technology such as bioremediation would include absolute openness and honesty, sound science (in support of risk assessment and management and as foundation for the technology itself), consistent performance (a track record), clear applicability, and sound information on which to base an analysis of costs and benefits. Additionally, clear regulatory policy,

“Many concerns have their roots in past experiences, for example ‘Better living through chemistry.’”

the opportunity for public involvement and influence through two-way communication, flexibility, and a staged approach for introducing complexities are important factors. Successful engagement of the public through a two-way interactive process can also result in the public providing needed continuity through time that those in the roles of problem owner or technology provider often cannot, especially if the project has a lifespan of many years or decades, as might be the case for natural bioremediation at a given site (Bilyard et al., 1996).

Lessons Learned

Many examples of the importance of effective public involvement are available to document how public perception can be instrumental to the success or failure of deploying innovative technology. A number of examples that provide direct experience for waste management and environmental restoration are known. For example, land farming (the practice of accelerating biodegradation in surface soil by mixing and fertilization), incineration, and *in situ* vitrification (ISV) are technologies for which public perception and policy evolved from broad to narrow support, with the result that these technologies currently face extensive scrutiny and regulation, and all are deployed less often than in the past.

The special case of the release of genetically engineered microorganisms (GEMs) in agricultural settings has, in contrast, evolved in the opposite direction. Where initial public response caused significant delay, today field tests with GEMs (e.g., nitrogen-fixing bacteria) and genetically altered plants (e.g., disease-resistant corn) are widespread. Generally, people are only somewhat more concerned about GEMs than about naturally occurring microorganisms. The primary concern in either case is the possibility for ecosystem disruption—the kudzu factor. A small minority associates GEMs with science-fiction scenarios. Good science, sound risk assessment, and assurance that the microorganisms are not likely to affect human health are required for public acceptance.

“Project objectives tended to be met when there were common goals and responsibilities among the participants, the stakeholders were directly involved in planning, etc., and effective communication occurred among regulators.”

Situations also exist in which effective public engagement programs have been responsible for effective movement from consideration of technical options to deployment. For site cleanup, the Berkeley Environmental Research Center (BERC) and the Western Governors Association forum both were cited as effective programs.

Comparing these experiences, a number of successful mechanisms for public involvement that lead to successful technology deployment can be identified. They include:

- Honesty and openness
- Early and ongoing public involvement that uses public input—i.e., community participation embedded in problem identification
- Dialogue with all stakeholders
- Support for the community in establishing their own technical resource(s)

- A focus on issues that influence or are captured in value judgments
- Examination of trade-offs among time, money, and uncertainty (ecological risk and risk of failure)
- Work to strengthen responsible public institutions with long-standing involvement in community needs.

"How do we build partnerships?"

Public Policy: Federal Laws and Regulations

A key requirement of the development and, in particular, the deployment of environmental restoration technology is the need to meet statutory intent. The development and application of environmental cleanup technology, especially bioremediation technology, takes place within a regulatory framework defined at the federal level by a number of laws that often overlap or conflict when applied to a specific situation. Also, different agencies have authority for enforcement. As applied to environmental biotechnology, specifically to the use of GEMs, regulatory authority may reside with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Department of Agriculture (DOA), the National Institutes of Health (NIH), or state agencies (Bilyard et al., 1996).

U.S. environmental policy regarding bioremediation reflects the following enacted statutes:

- CERCLA (Superfund) – Comprehensive Environmental Response, Compensation, and Liability Act
- RCRA – Resource Conservation and Recovery Act
- TSCA – Toxic Substances Control Act
- FPPA – Federal Plant Protection Act
- NEPA – National Environmental Policy Act
- OSHA – Occupational Safety and Health Act.

CERCLA was designed to manage unplanned, uncontrolled releases of hazardous substances to the environment. This includes catastrophic releases and long-term legacy contamination such as is typical of DOE sites. Exceptions are oil spills and releases of other materials into bodies of water that are regulated by the Clean Water Act, rather than by CERCLA. In particular, CERCLA is supposed to provide a system for identifying contaminated sites across the country, establishing liability for those sites, and assessing the best means of remediating the sites.

RCRA provides the framework for management and disposal of solid waste materials, including hazardous and non-hazardous wastes as defined by the statute. As such, it is intended to prevent uncontrolled releases which are the subject matter of CERCLA. The law establishes a "cradle-to-grave" system to identify, store, transport, treat, and dispose of waste. Included is (1) definition of what constitutes a "hazardous" waste and (2) provisions for EPA

permitting and oversight of waste treatment, storage, and disposal (TSD) facilities. Thus RCRA applies whenever bioremediation is applied to treatment, storage, or disposal of hazardous waste. Leaking underground storage tank regulations are included under RCRA.

TSCA is designed to screen compounds that are potentially hazardous to humans or the environment before they are sold and used. Two aspects of TSCA are relevant to bioremediation. First, PCB waste is regulated under TSCA (not RCRA), so any bioremediation approach directed at PCBs must qualify as an EPA-approved alternative treatment technology designed specifically for PCBs. Second, federal authority for oversight of GEMs that are released to the environment is under TSCA.

FPPA is administered by the Animal and Plant Health Inspection Service (APHIS) at the U.S. Department of Agriculture. It might affect bioremediation if the target microorganisms were regarded as potential plant pathogens.

NEPA has relevance to bioremediation in two ways. First, NEPA applies to a major federal action (e.g., cleanup of contaminated land, whether or not the land is owned or controlled by a federal agency). Second, NEPA may give the general public an opportunity to comment on the nature of any proposed actions. The public's participation in this process should result in positive and creative improvements to the process, or the recognition that the proposed approach is unacceptable.

OSHA is implemented by the U.S. Department of Health and Human Services to regulate exposure of workers to physical and health hazards. NABIR field research activities will follow OSHA regulations.

In addition to the federal regulatory environment for bioremediation, state and local authorities may play an important role in any given situation. For example, the "Ice Minus" case in Monterey County, California resulted in a ban on testing of GEMs that lasted nearly a decade. For some environmental laws, states are authorized by the federal government to administer a federally mandated program. For the NABIR Program, field research is likely to occur in states that have a federally mandated RCRA program.

The addition of nutrients or sources of oxygen to the subsurface also has the potential to invoke additional demonstrations of compliance. For example, bioventing or air sparging (forcing air through unsaturated and saturated sediments, respectively) to enhance bioremediation may result in release of some volatile organic compounds (VOCs) to the surface, which then must be regulated under the Clean Air Act. Likewise, it is conceivable that the EPA's Safe Drinking Water Act could be important for cases in which specific chemicals would be injected into groundwater to stimulate bioremediation.

Where risk-based management approaches are used, the setting of environmental endpoints may be critical to technology deployment. In general, cleanup standards (i.e., residual

"Sometimes rules collide and you get squashed."

"Sometimes rules are inappropriately applied to your project."

"Rules are usually well-intentioned."

"Regulators are powerless to change the rules."

"Pioneers must adapt to these problems."

contamination levels) are established on a case-by-case basis by the governing regulatory framework for the site (i.e., CERCLA, RCRA corrective action). At large DOE sites, this framework is established with direct involvement of state and local authorities, stakeholders, and EPA. The potential for broader acceptance and application of innovative *in situ* approaches relies on agreement as to acceptable residual contamination levels (e.g., how clean is clean), and the time frame required to achieve them.

Specific Contributions from the Public Policy Breakout Session

In the context of the above discussions, specific contributions by participants in the breakout sessions are listed below:

- Suggested NABIR principle: Principal investigators should be encouraged to incorporate K-12 outreach and education into their proposals and programs.
- Suggested NABIR principle: NABIR proposals with BASIC components should get preference for funding for cases in which scientific quality and technical relevance is equivalent for competing project proposals.
- Suggested BASIC operating principle: BASIC requirements should be incorporated into the NABIR RFA (Request for Application/Proposal). Related questions: Is NABIR a place for strictly "ivory tower" academic research? Should the RFA be worded to have optional "BASIC" elements? Should the RFA have (1) pure research, or (2) pure research plus BASIC research tracks, with separate funding resources? Should pure research and BASIC research tracks be separately funded?
- Suggested BASIC research topic: Fate and transport of GEMs from a risk perspective, driving *back* to basic science.
- Suggested BASIC research topics: (1) Creation of a communication plan by ethicists or others, for the purpose of re-training scientists to be "involved." (2) Re-analysis of existing regulations for the purpose of identifying policy, statutory, and regulatory improvements. Related question: What kind of support (e.g., education, training) will NABIR provide to scientists regarding BASIC?
- Suggested BASIC research area: Research on risk assessment and management that is focused as risk pathways are identified. The definition of risk should be broad, including environment, safety and health risks, programmatic risks, etc.
- Comment: For regulatory overview, it should be necessary and sufficient for NABIR/BASIC research to meet or exceed regulatory requirements. Researchers need to be sensitive to community values.
- Comment: Community involvement is of great importance.
- Comment: Over time and through coordination and cooperation, BASIC can assist and complement NEPA in the public involvement area.
- Comment: Involve BASIC at each step of the NABIR Program.

- Comment: It is important to establish relationships with federal and state regulators.
- Comment: Risk issues must be integrated between NABIR and BASIC.
- Comment: The cost of deployment vs. risk reduction should be clear for bioremediation technologies. We need to be able to sort *real* from *perceived* risk issues. We *can* identify risk and cost issues quantitatively, but usually only health issues get analyzed quantitatively. Societal risks get analyzed only qualitatively.
- Comment: We need to evaluate lessons learned with respect to costs and risks as projects are conducted.
- Comment: NABIR strategies should incorporate customers (DOE and others), customers' principles, and site cleanup strategies (e.g., EM-40 national cleanup plans, site-specific plans, 10-year plans, focus area strategies). Follow-on involvement with customers, strategic and tactical objectives should be modified as needed or appropriate.
- Comment: When implementing BASIC, learn how to involve stakeholders by examining other public involvement models.
- Comment: NABIR should identify policies and procedures for the safe, responsible application of the technologies it develops.
- Comment: Community stakeholders should be included on the NABIR Executive Committee.
- Comment: NABIR desired outcomes and measurement metrics should be identified now, and a timetable should be set for periodic review.
- Comment: The next NABIR workshop needs more time for prioritization.
- Comment: Need to survey and review BASIC knowledge and experience, and condense it for field education.
- Question: How do you educate scientists to be cognizant of BASIC issues, and modify their mode of operation to accommodate those principles?
- Comment: Every NABIR project should engage the public at least four times per year (e.g., at schools, PTAs, League of Women Voters, local Rotary or business groups, etc.).
- Comment: NABIR will need to plan for ongoing consultation and coordination with stakeholders.
- Comment: BASIC should recommend public meetings to: (1) set expectations among principal investigators and (2) provide education and training to principal investigators so that they are sensitive and responsive. Related question: What are the most appropriate forums for these meetings?

- Comment: NABIR managers should talk to EM folks about stakeholder involvement to find out what the most common technology concerns and issues are.

D. Intellectual Property

Issues of intellectual property were considered at the workshop mostly in the context of NABIR's focus on fundamental science and issues relevant to collaboration with the private sector. For example, it was pointed out that while it was desirable to develop a NABIR position on treatment of intellectual property arising from a multi-institutional program, it would be problematic for at least two reasons:

- Patents protect technology, not fundamental knowledge
- Many complexities exist, such as the fact that DOE both sponsors the research and purchases its resulting technology, and hence may not offer adequate incentives to private partners who might otherwise participate in the research.

Intellectual property issues center on ownership of ideas and discoveries. The kinds of inventions and discoveries that might be patentable include novel or nonobvious processes and products. Either of these may be applicable to microbial products or to microorganisms themselves, such as GEMs. Currently, there are at least 126 issued patents directly or indirectly related to bioremediation. However, the intellectual property landscape for bioremediation technologies is in its infancy and is evolving rapidly as a result of activities within the judicial system (primarily) and the regulatory system (to a lesser extent). Hence, the ultimate value of bioremediation patents will depend on the outcome of what promises to be a protracted debate in the federal courts on legal and technical points, and to a lesser degree, accepted applications of existing environmental regulations to their use in the field. Biotechnology is one field where technical understanding within the legal community is poor, and where experience and staff at the Patent and Trademark Office (PTO) in the Commerce Department are insufficient to keep up with demand.

"Biotechnology results in very large profits, whereas bioremediation only has a 15% gross margin. You cannot hire and support a scientist on 15% profit margins. Bioremediation has a very hard time making big money because the technology is owned by everyone."

As with any technology, the manner and rate of development and implementation of bioremediation methods that may arise from DOE investments will be influenced by any policy and framework for patenting and protection that may be adopted for NABIR. Presently, the U.S. Government encourages the patenting of funded research as a means to promote technology transfer. Universities and nonprofit institutions performing research on behalf of DOE would automatically receive title to any intellectual property developed. For-profit industries performing research on behalf of DOE would receive similar rights from DOE if they complied with the requirements of the DOE waiver policy at 10 CFR 784. Even if such rights exist, they may not result in much return on investment because many DOE waste problems are unique to DOE (e.g., radionuclides and mixed wastes), and therefore DOE may be the only purchaser of the patented technology. In addition, it is very difficult to enforce process

patents, and many of NABIR's discoveries will be methods or process oriented rather than product oriented.

The highly unstable and evolving intellectual property landscape results in major questions for the NABIR Program. Some of the key questions are:

- When does it make sense to patent discoveries?
- What in the NABIR focus area is patentable? (E.g., will it be possible to patent DNA sequences?)
- What policies should NABIR adopt (if any) regarding field-of-use rights, out-of-field-of-use rights, and licensing and royalties?
- If the government is the main customer and is paying for the research, will those conditions make the patent ineffective? Alternatively, will the potential for "spillover" technologies present a need for such patents?
- What roles do patents play in technology transfer?
- Are patents necessary or effective to ensure exclusivity?
- How would holders of bioremediation patents use them to secure continued funding of R&D?
- How do patents work in regulatory settings?

Another question that is currently peripheral but ultimately pertinent to intellectual property for bioremediation is products of genomic research. Six complete microbial genomes, including three obligate or facultative pathogens (i.e., *Staphylococcus aureus*, *Mycoplasma genitalium*, *Haemophilus influenzae*), thermophilic archaea (i.e., *Methanobacterium thermoautotrophicum*, *Methanococcus jannaschii*) and a common yeast (*Saccharomyces cerevisiae*) have been sequenced in the past year, resulting in massive data sets. The challenge to the scientific community is to develop technology for deciphering and making this wealth of genome information useful. To the extent that the number of whole sequenced genomes broadens to include more bacteria, fungi, and other microorganisms of environmental significance, intellectual property issues will begin to influence bioremediation generally and NABIR in particular.

"Another misconception about bioremediation is where the expertise really exists. The expertise is not in academia or the national laboratories. It is in the private sector. There are very few exceptions."

Specific Contributions from the Intellectual Property Breakout Session

In the context of the above discussions, specific contributions by participants in the breakout sessions are listed below:

General Considerations	Research-Specific Considerations
A NABIR intellectual property (IP) plan is needed (e.g., with guidelines for joint inventorship, "what happens when" guidance, etc.).	
The IP landscape needs to be monitored.	Monitor IP landscape.
How does IP operate in this environment?	Identify and research issues and questions relevant to fundamental science (technology-independent) vs. industry-specific.
The genome sciences influence microbial biotechnology-specific IP.	How does one use this knowledge?
Does the absence of IP protection interfere with publication, advancement of science, or development of technologies?	When is IP valuable within NABIR in terms of promoting dissemination of information and technology? How dependent is value on (1) who owns it, (2) what it is, and (3) nearness to practice?
An IP education piece or model is needed. A primer might be valuable. (There may be some overlap with education and outreach here.)	Questions that might be asked and/or investigated: When should fundamental technology and/or knowledge be patented and promoted? When do exclusive vs. non-exclusive ownership rights make sense? What terms in IP agreements <i>promote</i> dissemination and product development?
What are DOE's interests as a consumer vs. a provider or inventor? Is the primary R&D sponsor also the IP developer and the customer/consumer?	Are current rules adequate to promote commercial involvement?

E. Education and Outreach

Education and public outreach have been recognized as an important component of NABIR from its inception. Workshop discussion focused largely on education and outreach as integral components of the broader NABIR Program.

Specific goals were discussed that could be incorporated into the education and outreach efforts of the BASIC element. These included:

- Provide continuity from science to application by working with the community. Partnerships with the community could provide some of this continuity, and could help nurture long-term ownership of biotechnologies.
- Identify NABIR desired outcomes and measurement metrics at the outset, with public participation.

"Tower of Babel or American Melting Pot?"

- Manage risk in partnership with the community.
- Develop an understanding of how the current and evolving intellectual property environment will influence the direction of NABIR (i.e., monitor the intellectual property landscape) and devise a plan for managing intellectual property .

Strategies for achieving these goals were also discussed, including:

"Society has lost faith in science."

"Is loss of faith in science part of a general loss of faith in institutions?"

"All politics are local politics; we need local science."

- Reconceptualize the role of the public, moving toward full involvement in science and engineering decisions, with two-way communication. Increase levels of discussion where possible.
- Tailor communication and education methods to the situation at hand. Make information available to all communities, using appropriate communication methods.
- Focus on community-specific values and value judgments.
- Involve the public early and throughout the entire program. Increase their control of the program where possible, so as to promote involvement and trust.
- Anticipate who the opponents will be and what their positions will be.
- Support the development of independent community technical resources.
- Be open and honest in all communications. Discuss positives and negatives of the program freely, and be sure to address fears.
- Communicate effectively, avoiding jargon, acronyms, and terms with negative connotations.
- Involve special interest groups.
- Publicize successes; be honest and open about failures.
- Be aware of changes in public attitude (e.g., from public opinion to public judgment).

"Language used in NEPA documentation about the NABIR Program could scare the public. Words like 'reactor vessels,' 'field release,' and 'suicide genes' are examples."

Recommendations and Conclusions for BASIC

In the context of the above discussions, specific recommendations and conclusions were made by participants during the general sessions and in the breakout sessions. These are listed below:

- The following guidance is recommended for development of the BASIC research program and the call for proposals:
 - 1) BASIC should be a stand-alone program within NABIR.
 - 2) A public survey should be undertaken to identify the factors that will limit implementation of the NABIR Program.
 - 3) Field research sites must develop a public interface and input program.
 - 4) Public input should be institutionalized.
- The following activities are recommended for inclusion in the public education efforts:
 - 1) Expand the definition and involvement of stakeholders.
 - 2) Include a more diverse stakeholder group in policy development and implementation activities.
 - 3) Integrate public education objectives into the NABIR RFA.
- The following activities are recommended for inclusion in outreach efforts:
 - 1) Develop a broad-based public communication program.
 - 2) Validate educators as key stakeholders.
 - 3) Use interdisciplinary-based curriculum materials.
 - 4) Commit to a long-term strategy for funding education.
 - 5) Develop public education and institutional education assessment tools.
 - 6) Integrate education within the NABIR RFA.
- When implementing the NABIR Program, it will be important to:
 - 1) Establish a line of communication with and from the public.
 - 2) Make information about informatics and database development widely accessible.
 - 3) Incorporate public advocacy groups into NABIR's operating system.

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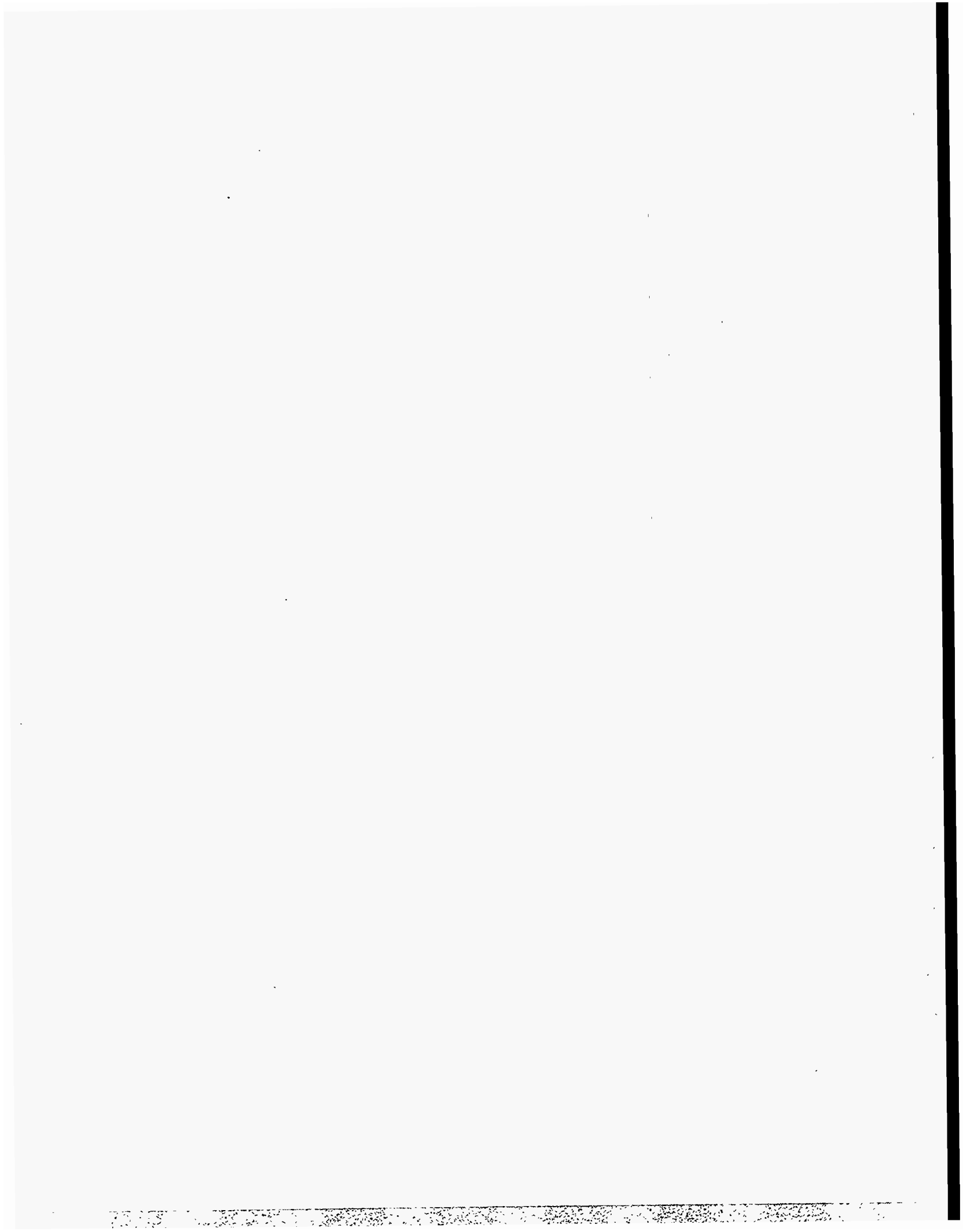
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Afterword

BASIC will not be a program to "sell" bioremediation to a suspicious public. Rather, it is intended to make the NABIR Program better, by at all times honestly and openly communicating what its goals are, what its successes and failures are (it will have both), how it works, and how it fits within the broader scope of environmental biology directed at addressing DOE's cleanup challenges. NABIR is a fundamental research program designed to explore aspects of bioremediation about which we do not know very much. The public, who are paying for the program through their taxes, have an absolute right to know what is happening and to be involved in the process of making it happen.

The potential promise of bioremediation, influenced by advances in human and microbial genome research, is vast. So too are the challenges from the 50-year history of nuclear weapons production that contributed to America's pre-eminent position as the strongest nation in the world today. With that position, though, comes the responsibility to clean up the wastes created along the way. There are no guarantees that novel bioremediation strategies will solve all of the enormous waste cleanup problems that we have. However, we would not be acting responsibly if we did not explore aggressively, with honesty and candor, what bioremediation could do for us. BASIC will be an ongoing process, integrated within NABIR, to constantly ensure that the program is transparent to the citizenry.



APPENDIX A
WORKSHOP AGENDA



Appendix A

Agenda

Workshop on Bioremediation and Its Social Implications and Concerns (BASIC)

DOE Program in Natural and Accelerated Bioremediation Research (NABIR)

July 18–19, 1996
Airlie House, Virginia

Workshop Goal: The goal of the workshop is to develop an understanding of societal, economic, legal and other issues that are important to bioremediation research and development, and to identify language for an RFA, a set of principles for NABIR, and a strategic direction for BASIC to ensure that NABIR successfully achieves its immediate and long-term goals.

Proposed Format: The BASIC workshop will include participation by invitation only. NABIR program managers (OHER), NABIR program element science team leaders (STLs), the NABIR program office and select customers, technical experts and stakeholders will participate. The total number of participants should be as small as possible to foster effective interaction and maintain focus. Participants would be arranged in either a circular or U-shaped format. Speakers and participants can be invited to submit, ahead of time, prepared materials that they feel would contribute to the discussions and the NABIR Program Office will attempt to assemble any such materials into a binder for distribution at, and after, the workshop. Each session will have a coordinator and one or two scribes. The coordinators will guide the discussions and the scribes will develop a set of notes for collation, distribution, and use following the workshop.

Day 1

- 1:00–1:15 p.m. **Welcome. Introductions and Charge to Participants.**
Jay Grimes/John Houghton/Dan Drell, DOE Office of Health and
Environmental Research
- 1:15–1:30 **NABIR Program Status**
John Houghton, DOE Office of Health and Environmental Research
Objective: The objective is to provide an overview of the current status of
NABIR.
- 1:30–2:30 **Principles and Science of Current Bioremediation Technology**
F. Blaine Metting, NABIR Program Office, Pacific Northwest National
Laboratory (40 min + 20 min discussion)
Objective: The objective is to provide an overview of the current status of
bioremediation technology and its application in the field.

- 2:30–2:45 **NABIR Program Overview**
D. Jay Grimes, DOE Office of Health and Environmental Research
Objective: The objective is to describe the NABIR program and its long-term goals in the context of fundamental research in the Office of Health and Environmental Research.
- 2:45–3:30 **NABIR’s Scientific Program Elements and Objectives**
Sally Benson, NABIR Program Office, Ernest Orlando Lawrence Berkeley National Laboratory
Scope: The presentation will communicate the scientific objectives and technical focus within each of the seven program elements in the context of the key cross-cutting themes of field research, mixed contamination, and *in situ* remediation.
- 3:30–3:45 *Break*
- 3:45–4:15 **BASIC Program Preview. Workshop Format and Objectives.**
Dan Drell, DOE Office of Health and Environmental Research
Objective: The objective is to articulate the desired outcomes for the workshop, describe the interactive format to be used to achieve the outcomes, and note the relevant lessons from the Genome ELSI experience.
Scope: Participants will understand (1) that OHER intends to use the results of the workshop to identify a set of underlying principles and concepts for the development of NABIR’s program, (2) how the BASIC program is intended to support OHER programmatic and DOE site cleanup goals, and (3) how the format for the workshop is intended to focus presentations and interactive discussions on achieving the desired outcomes.
- 4:15–5:30 **Bioremediation: Future Potential and Scientific Needs**
Moderator: Daniel Abramowicz (bioremediation), General Electric
Presenters: Ronald Unterman (bioremediation), Envirogen, Inc.; Jennie Hunter-Cevera (industrial microbiology), NABIR Program Office, Ernest Orlando Lawrence Berkeley National Laboratory; Burt Ensley (phytoremediation), Phytotech, Inc.
Objective: The objective is to describe selected scientific activities in order to build a common understanding of the future potential of bioremediation and of industrial bioprocesses that will benefit from basic science focused on bioremediation.
Scope: Presenters will each take 15 minutes to communicate their perspective on current research relevant to DOE environmental restoration needs in order to stimulate discussion. A moderated 30-minute open discussion session will follow.
- 5:30–7:30 *Dinner (with speaker TBD)*

7:30–9:15

BASIC Issues Session 1: Lessons from the Past

Session Moderator: David Feldman, University of Tennessee

Panelists: Gary Jacobs and Robert Burlage, Oak Ridge National Laboratory

Objective: The objective of this session is to review recent past experiences with bioremediation and relevant field releases of microorganisms to elicit relevant lessons for NABIR.

Scope/Format: Individuals with experiences of field releases will briefly (15 min) present these experiences and what they believe to be lessons learned. Each presentation will be followed by 10 minutes of general discussion.

Day 2

8:30–10:30 a.m.

BASIC Session 2: Regulatory, Policy, Societal, Legal, and Economic Issues

Objective: The objective of this extended session, covering a number of issues, is to identify critical regulatory, policy, societal, legal, and other issues that come within the BASIC category and which potentially could enhance or complicate the development and utilization of strategies for implementing the NABIR program.

Format: The format remains as for the previous session with brief subject presentations (15 min) followed by moderated group discussion (10 min).

Issue 1: The Regulatory Climate. What is the current regulatory environment within which the NABIR program must operate?

Issue 2: Public Policy. What is current public policy and its implications for NABIR?

Panelists: Gordon Bilyard (stakeholder issues), Pacific Northwest National Laboratory; Susan Arnold (regulatory issues), Oak Ridge National Laboratory; Janice Longstreth (public policy—invited), Waste Policy Institute.

10:30–10:45

Break

10:45–11:45

Issue 3: Education and Public Outreach. What are the potential mechanisms for effective education, public awareness, and public involvement? What should the message(s) be?

Session Moderator for Issue 3: Sonya Hammond, State of California Extension Service

Panelists: Kate Devine, *Biotreatment News*; Betty Mansfield, Oak Ridge National Laboratory; Manuel Perry, Lawrence Livermore National Laboratory.

11:45 a.m.–
12:45 p.m.

Issue 4: Intellectual Property and NABIR

What is anticipated? Who owns what? What precedents and means exist for developing intellectual property from government-funded research?

Session Moderator: Rebecca Eisenberg, University of Michigan

Panelists: Pete Pesenti, DOE Office of Technology Research; Burt Ensley, Phytotech, Inc.

12:45–1:30 *Lunch*

1:30–3:00 p.m. **Breakout Sessions**

Participants will break out into three groups for this session:

- Regulatory, Policy and Societal Issues. Chair: Kate Probst
- Intellectual Property. Chair: Rebecca Eisenberg
- Education and Outreach and Guidelines for NABIR. Chair: Carl Anthony, Earth Island Institute

For the first two breakout groups, participants will be asked to develop a comprehensive list of issues. Each issue will be defined and assigned a weight as to its potential impact and importance on NABIR.

For the third breakout group on guidelines, which will encompass education and outreach, participants will be tasked with developing a first set of NABIR principles and guidelines.

3:00–3:15 *Break*

3:15–5:00 **Summary Session**

Objective: The objective of the closing session is to review workshop results and to identify a course of action for BASIC. The deliverables should be a prioritized list of BASIC issues that NABIR will address and a statement of principles (part of a workshop report that will be prepared for publication, and which would be used to guide the BASIC research program).

Scope: Each of the three breakout groups will report back with the results from their individual sessions. These presentations will be the basis for general discussion leading toward fulfillment of the stated objectives.

Session Chair: Dan Drell (OHER)

5:00 p.m. *Adjourn*

APPENDIX B
LIST OF PARTICIPANTS

Appendix B

List of Participants

Daniel A. Abramowicz, General Electric Co.

Susan E. Arnold, Oak Ridge National Laboratory

Eve Bach, Arc Ecology

Paul Bayer, Department of Energy (DOE), Office of Health and Environmental Research (OHER)

Sally M. Benson, Ernest Orlando Lawrence Berkeley National Laboratory

Gordon R. Bilyard, Pacific Northwest National Laboratory

Robert S. Burlage, Oak Ridge National Laboratory

Ronald L. Crawford, University of Idaho

Katherine Devine, *Biotreatment News*

Stephen L. Domotor, DOE, Office of Environmental Management

Daniel W. Drell, DOE, Office of Health and Environmental Research

Rebecca S. Eisenberg, University of Michigan Law School

Burt D. Ensley, Phytotech, Inc.

David Lewis Feldman, University of Tennessee–Knoxville

Jeffrey L. Fox, *ASM News*, *Nature Biotechnology*

Carl W. Gehrs, Oak Ridge National Laboratory

David Giamporcaro, U.S. Environmental Protection Agency

Darrell Jay Grimes, DOE, Office of Health and Environmental Research

Sonya V. Hammond, University of California Cooperative Extension

Michael A. Heitkamp, Monsanto Company

Clarence R. Hickey, DOE, Office of Energy Research

John C. Houghton, DOE, Office of Health and Environmental Research

Jennie C. Hunter-Cevera, Ernest Orlando Lawrence Berkeley National Laboratory

Gary K. Jacobs, Oak Ridge National Laboratory

Seth W. Kullman, University of California, Davis

Alice M. H. Lin, Office of Management and Budget, Energy and Science Branch

Janice D. Longstreth, Waste Policy Institute

Betty Mansfield, Oak Ridge National Laboratory

F. Blaine Metting, Jr., Pacific Northwest National Laboratory

Curtis R. Olsen, DOE, Office of Health and Environmental Research

Appendix B

Sue Palk, DOE, Office of the Assistant General Counsel for Intellectual Property and
Technology Transfer

Manuel Perry, Futures and Planning Consultant

Peter T. Pesenti, Pacific Northwest National Laboratory

Katherine N. Probst, Center for Risk Management

Philip Sayre, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics

William J. Smith, Allied Technology Group, Inc.

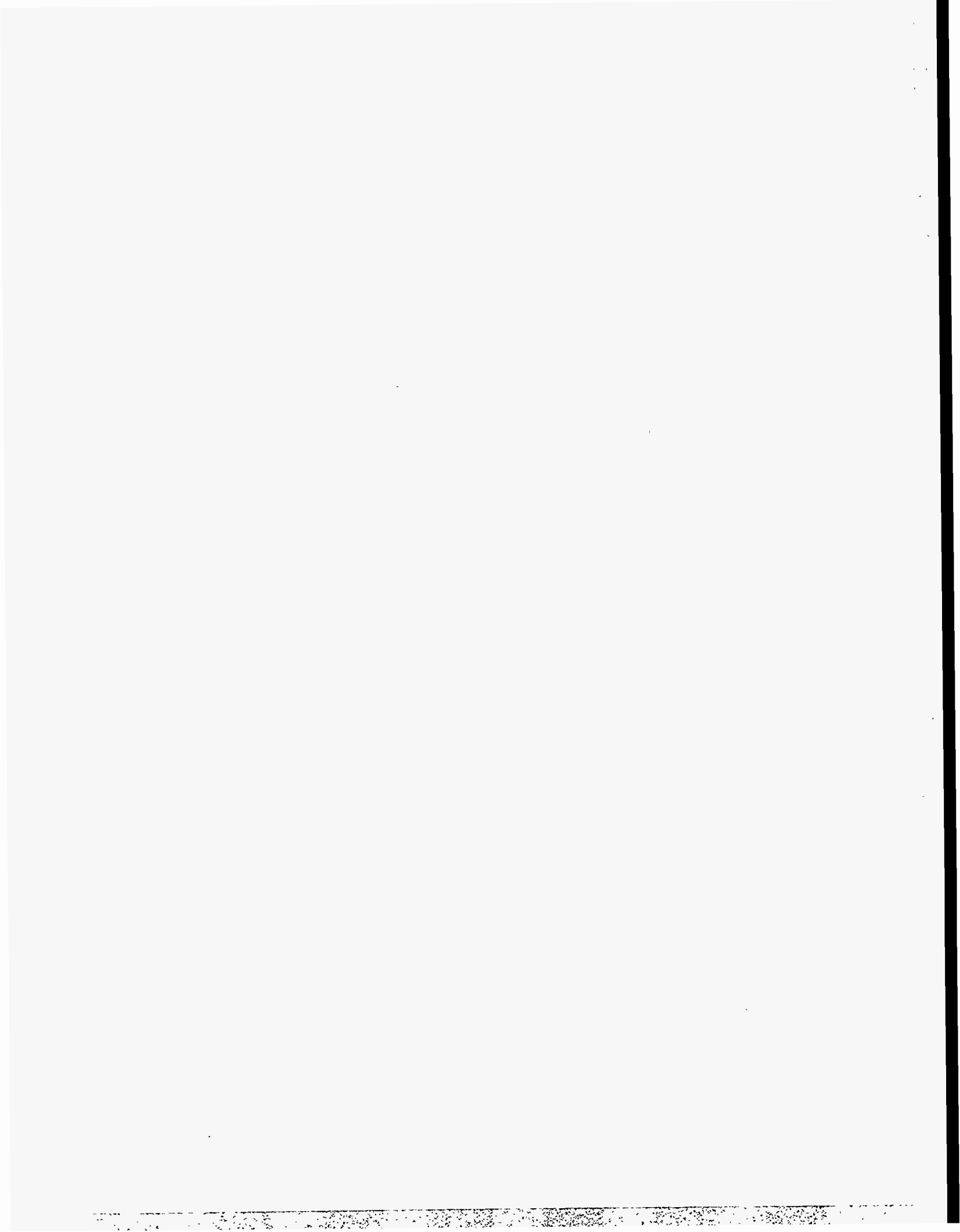
David G. Thomassen, DOE, Office of Health and Environmental Research

Ronald Unterman, Envirogen, Inc.

David C. White, University of Tennessee, Oak Ridge National Laboratory

Frank J. Wobber, DOE, Office of Energy Research (not at workshop)

APPENDIX C
BIOGRAPHICAL SKETCHES
OF PARTICIPANTS



Appendix C

Biographical Sketches of Participants

Daniel A. Abramowicz

Dr. Abramowicz is manager of the Environmental Laboratory at GE Corporate Research and Development, directing research focused on remediation, pollution prevention, and product stewardship. He is also adjunct professor in the Biology Department of Rensselaer Polytechnic Institute. He received a B.S. in Chemistry and a B.A. in Mathematics and Computer Science from Saint Francis College, and earned an M.A. and a Ph.D. in Physical Chemistry at Princeton University. Dr. Abramowicz pursued research in biophysics and photosynthesis as an Allied Chemical Fellow at Princeton. He joined the GE Research and Development Center in 1984 as a staff scientist and began investigating the application of enzymes to chemical synthesis. In 1988 he was appointed Manager of the Environmental Technology Program, and in 1992 he was appointed manager of the Bioremediation Laboratory. In this role he directed research aimed at the application of microorganisms to waste treatment. Efforts included the aerobic and anaerobic biodegradation of PCBs, nitroaromatics, silicones, and hydrocarbons. Dr. Abramowicz had written 29 technical publications and edited a book on biocatalysis.

Susan E. Arnold

Ms. Arnold graduated from Tennessee Technological University with a B.S. in Political Science and earned a J.D. from the University of Tennessee College of Law. For the past four years she has been involved in environmental law at Oak Ridge National Laboratory. She provides state and federal cleanup requirements for U.S. Army sites being remediated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA/Superfund). Ms. Arnold is a member of the American Bar Association Section Committee on Solid and Hazardous Waste.

Eve Bach

Ms. Bach is the staff economist/planner at Arc Ecology in San Francisco. She has provided technical assistance to local communities undergoing military base conversion in the areas of economic and fiscal analysis and environmental impacts. Her publications include articles exploring Defense Department funding of BRAC cleanup obligations. Prior to joining the Arc staff, Ms. Bach was Assistant City Manager for Planning and Development for the City of Berkeley, California, and taught Community Planning in the Peralta Community College District.

Paul Bayer

Mr. Bayer is responsible for two aspects of the NABIR Program: establishing field research centers and overseeing National Environmental Policy Act (NEPA) documentation. He holds a B.A. in Biology from James Madison University, an M.S. in Biology from Western Kentucky University, and an Environmental Issues Certificate from the U.S. Department of Agriculture Graduate School. Mr. Bayer joined the U.S. Department of Energy, Office of Health and Environmental Research (OHER) in January 1995. Prior to joining DOE, he worked for a federal government contractor for seven years supporting the DOE offices of Fossil Energy; Environment, Safety and Health; Energy Efficiency; and the Policy Office on a wide range of topics including fossil energy biotechnology, health effects of non-ionizing radiation, and NEPA document reviews.

Sally M. Benson

Dr. Benson co-authored the NABIR Program Plan and is the leader of the NABIR Program Office team. She is director of the Earth Sciences Division at Ernest Orlando Lawrence Berkeley National Laboratory, and is a visiting professor of earth sciences at Clemson University, where she teaches a summer field camp in hydrogeology at the DOE Westinghouse Savannah River Site. She received a B.A. in Geology from Columbia University and an M.S. and Ph.D. from the Materials Sciences and Mineral Engineering Department, University of California, Berkeley. Since 1977 Dr. Benson has performed research related to energy and environmental issues, including geothermal energy sources, natural gas storage, and agricultural pollution. More recently she has focused on environmental problems associated with the Department of Energy Weapons Production Complex. Dr. Benson is co-author of over 55 technical and review articles, book chapters, and technical reports.

Gordon R. Bilyard

Dr. Bilyard received an M.S. in Marine Zoology from the University of Maine and a Ph.D. in Biological Oceanography from Oregon State University. He subsequently worked on pollution ecology of the marine environment and compliance of point-source pollutant discharges with the Clean Water Act. Since joining Pacific Northwest National Laboratory in 1989, Dr. Bilyard has worked in environmental management, environmental policy analysis and planning, stakeholder-focused strategic planning, ecological risk assessment, and environmental risk-based standards.

Robert S. Burlage

Dr. Burlage is a staff scientist in the Environmental Sciences Division of Oak Ridge National Laboratory. He received a Ph.D. in Microbiology from the University of Tennessee. His research interests include bioremediation of hazardous wastes and the molecular biology of microorganisms, particularly in regard to microbial ecology under natural conditions. Dr. Burlage is the principal investigator for a project involving the field release of a genetically engineered bacterial strain for bioremediation research. This field release took place on the Oak Ridge Reservation during the summer of 1996.

Ronald L. Crawford

Dr. Crawford is a NABIR science team leader with particular interests in biotransformation and biodegradation, acceleration, and biomolecular science and engineering. He is professor of microbiology at the University of Idaho (UI), where he directs an internationally recognized research team in environmental biotechnology. He received an M.S. and a Ph.D. in Bacteriology from the University of Wisconsin. Dr. Crawford is co-director of UI's Center for Hazardous Waste Remediation Research and director of the Institute for Molecular and Agricultural Genetic Engineering, and was formerly head of the Department of Bacteriology and Biochemistry. Before coming to UI, Dr. Crawford was professor of microbiology at the Gray Freshwater Biological Institute at the University of Minnesota, where he conducted research on environmental microbiology and hazardous waste treatment. He has broad expertise in the biodegradation of hazardous chemicals, bioreactor design and use, development of microbial encapsulation technologies, and subsurface microbiology. He has over 20 years of experience in isolating and characterizing microorganisms that degrade natural and synthetic chemicals, and in designing microbiological systems for commercial-scale treatment of contaminated soil and water. Dr. Crawford has authored over 125 journal articles and several book chapters.

Katherine Devine

Ms. Devine is founder and president of the Washington, D.C.-based environmental consulting and publishing company, DEVO Enterprises, Inc., and founder, publisher, and editor of the magazine *Biotreatment News*. The magazine covers commercial and research activities in the public and private sectors as well as regulatory and policy issues concerning environmental biotechnology. Her consulting activities are focused on business development activities and concerns, including technology transfer, regulatory and policy matters, and product and service market assessments. Ms. Devine's past experience includes over 10 years as a regulatory impact analyst and program manager at U.S. Environmental Protection Agency headquarters. She has a B.S. in Biology and an M.S. in Economics, and has authored over 25 papers on environmental biotechnology.

Stephen L. Domotor

Mr. Domotor is a scientific research program manager with the Department of Energy's Environmental Management Science Program, Office of Science and Technology, Office of Environmental Management. He serves as NABIR's liaison with the Office of Environmental Management. He has an M.S. in Marine, Estuarine, and Environmental Science, with research and program management expertise in radioecology, assessment of environmental and health-related impacts from the operations of nuclear facilities, and development of innovative technologies for waste management. Mr. Domotor previously worked in DOE's Office of Waste Management as the science and technology team leader. Prior to working at the DOE, he was an environmental radiochemist and director of the Radioecology Laboratory for the State of Maryland's Power Plant Research Program.

Daniel W. Drell

Dr. Drell is manager of the NABIR Bioremediation and its Societal Implications and Concerns (BASIC) program. He received an undergraduate degree in Biology from Harvard and a Ph.D. in Immunology from the University of Alberta, Canada. He has done postgraduate research in developmental genetics, reproductive immunology, monoclonal antibody production, and autoimmune diseases. Dr. Drell is currently a member of the Human Genome Management Group in the Health Effects and Life Sciences Research Division of the DOE Office of Health and Environmental Research (OHER). His responsibilities include the Ethical, Legal, and Social Implications (ELSI) part of the DOE Human Genome Program; Small Business Innovative Research (SBIR) for the DOE Genome Program; the Single Chromosome Workshop program (coordinated with the National Center for Human Genome Research at the National Institutes of Health); most workshop applications that the Health Effects Division receives; and coordination of publications for the DOE Genome Program.

Rebecca S. Eisenberg

Ms. Eisenberg is a professor of law at the University of Michigan Law School. Her field of specialization is biotechnology patent issues. She is currently studying patents and technology transfer in the Human Genome Project under a DOE grant. She is a member of the National Institutes of Health-DOE working group on Ethical, Legal, and Social Issues (ELSI) in human genome research.

Burt D. Ensley

Dr. Ensley is president and CEO of Phytotech, Inc., an environmental biotechnology company involved in the development and commercialization of technology using plants for the remediation of contaminated soil and water. He received B.S. and M.S. degrees from the

University of New Mexico and a Ph.D. in Microbiology from the University of Georgia. Dr. Ensley was formerly research manager at Amgen, Inc. and director of advanced technology at Envirogen, Inc. He was responsible for directing research, field demonstrations, and evaluation of biological and physical/chemical hazardous waste treatment technologies.

David Lewis Feldman

Dr. Feldman is senior research associate in the Energy, Environment and Resources Center at the University of Tennessee–Knoxville, teaches in the graduate program in Environmental Policy, and is adjunct professor of Political Science. He is also a research team leader for the National Center for Environmental Decision-Making Research, a National Science Foundation-funded center at UT. He received a B.A. in Political Science and English from Kent State University and an M.A. and Ph.D. in political science from the University of Missouri–Columbia. Dr. Feldman's research interests include public involvement in natural resource and technological decisions, international activities to address global environmental problems, and environmental policy and management. He has written several books on energy and environmental issues, and his articles have appeared in over 20 journals.

Jeffrey L. Fox

Dr. Fox is a science writer and editor based in Washington, D.C. He also serves as current topics and features editor for *ASM News* and contributing editor for *Nature Biotechnology*. Before going free-lance, he was a senior writer for *Science* and senior editor for *Chemical & Engineering News*. He received a B.A. in English from Oakland University in Rochester, Michigan, and a Ph.D. in Biochemistry and Biophysics from the University of California, Davis.

Carl W. Gehrs

Dr. Gehrs is a member of the NABIR Program Office team and helped launch the program. He is director of the Center for Biotechnology at Oak Ridge National Laboratory, with responsibility for all research efforts in bioprocessing, biomedical, and environmental biotechnology. He oversees more than 200 principal investigators representing all directorates of the laboratory. Dr. Gehrs has a Ph.D. from the University of Oklahoma focusing on limnology and population dynamics of plankton. He has broad research interests and publication areas and has served on and chaired several national, international, and interagency committees.

David Giamporcaro

Mr. Giamporcaro is section chief of the TSCA Biotechnology Program, New Chemicals Branch, U.S. Environmental Protection Agency.

Darrell Jay Grimes

Dr. Grimes is co-manager of the NABIR program and manager of two program elements: Biotransformation and Biodegradation, and Community Dynamics and Microbial Ecology. He is a microbiologist and program manager in DOE's Office of Health and Environmental Research, Office of Energy Research. Dr. Grimes received a B.A. and M.A. in Biology from Drake University and was awarded a Ph.D. in Microbiology from Colorado State University. He joined DOE in 1990 to work in the Subsurface Science and Ocean Margins Programs; in 1994 he became program manager of the Microbial Genome Program. From 1991 to 1993, Dr. Grimes

served as executive secretary of the Biotechnology Research Subcommittee of the Committee on Life Sciences and Health, Federal Coordinating Council for Science, Engineering, and Technology. In 1995 he became a senior partner to the Interagency Environmental Technologies Office, National Science and Technology Council (NSTC), Executive Office of the President. Dr. Grimes chaired the Marine Biotechnology Working Group of the NSTC, and he currently chairs the NSTC Bioremediation Working Group. He was previously director of the Institute of Marine Science and Ocean Engineering and of the New Hampshire Sea Grant College Program, University of New Hampshire, where he was also a professor of microbiology. Dr. Grimes has authored more than 150 technical publications. He frequently serves as a consultant and expert witness on water-borne diseases.

Sonya V. Hammond

Ms. Hammond is the University of California Cooperative Extension county director for Monterey and Santa Cruz counties. Monterey County is the third-largest agricultural producer in California, with 1995 production in excess of \$2 billion. The area is world-famous for its vegetable production technology. Her areas of interest are biotechnology, public policy, and agricultural economic development. Ms. Hammond received a master's degree in International Management from the American Graduate School of International Management, and an M.A. in French from the University of California, Santa Barbara. She previously served as controller for a packing company, having responsibility for risk management and environmental compliance.

Michael A. Heitkamp

Dr. Heitkamp is an associate science fellow in the Environmental Sciences Center at Monsanto Company, where he is responsible for development of new *in situ* microbial technologies for multiple bioremediation applications. He received a B.S. in Biological Sciences from the University of Missouri, an M.S. in Veterinary Microbiology from the University of Missouri School of Veterinary Medicine, and a Ph.D. in Interdisciplinary Toxicology from the University of Arkansas for Medical Sciences. Dr. Heitkamp has been active in environmental microbiology for over 18 years, with training and experience spanning microbial toxicology, microbial ecology, chemical biodegradation, development of novel chemical-degrading microorganisms, determination of chemical pathways for microbial degradation, and the lab-scale and pilot-scale testing of new high-performance biotreatment technologies for liquid wastes and air emissions. He previously was research microbiologist for the National Center for Toxicological Research, U.S. Food and Drug Administration, and for the Columbia National Contaminant Research Laboratory, U.S. Department of the Interior. He has authored dozens of technical papers and presentations.

Clarence R. Hickey

Mr. Hickey is a National Environmental Policy Act (NEPA) compliance officer for the DOE Office of Energy Research. In this capacity he assesses the environmental impact of DOE operations on the environment. He received a B.S. in Biology from Grove City College in Pennsylvania and an M.S. in Marine Science from Long Island University. Mr. Hickey has past experience as a fishery biologist for the U.S. Nuclear Regulatory Commission and for private industry. He has conducted basic and applied research on marine ecosystems, and has taught marine biology and beach ecology. He has authored many journal publications on marine fisheries and ichthyology.

John C. Houghton

Dr. Houghton co-manages the NABIR Program and manages the Assessment program element. As a program manager for DOE's Office of Health and Environmental Research, he also manages the Integrated Assessment of Global Climate Change program, as well as other research in acid precipitation and environmental technology life-cycle analysis. Dr. Houghton received a B.S. in Geology from Stanford University and a Ph.D. in Environmental Systems Engineering from Harvard University. He came to DOE from ARCO's research laboratory, where he directed a group that assessed undiscovered petroleum resources and developed computerized mapping applications. From 1981 to 1990, Dr. Houghton served in several positions in the U.S. Geological Survey, including director of the Geographic Information Systems Research Laboratory, deputy assistant director for research, and research scientist developing new statistical techniques for resource estimation. From 1979 to 1981, Dr. Houghton served as senior policy analyst in the Office of Science and Technology Policy, where he was responsible for natural resource issues, including acid precipitation, water resources policy, and nonfuel minerals policy. Prior to OSTP, he was a research scientist in MIT's Energy Laboratory, where he co-authored a text on the economics of depletable resources.

Jennie C. Hunter-Cevera

Dr. Hunter-Cevera co-authored the NABIR Program Plan and is a member of the NABIR Program Office team. She directs the Center for Environmental Biotechnology at Ernest Orlando Lawrence Berkeley National Laboratory. She received an M.S. in Microbial Ecology from West Virginia University and a Ph.D. in Microbial Biochemistry from Rutgers University. Dr. Hunter-Cevera joined Berkeley Lab in 1994 to establish an integrative research program in environmental biotechnology that examines natural augmentation, structure-function relationships, monitoring, ecotoxicity, health risk assessment, and the molecular evolution of microorganisms in damaged sites. Before coming to Berkeley Lab, Dr. Hunter-Cevera started her own consulting company, The Biotic Network, and co-founded a small research company, Blue Sky Research. Her research with these companies resulted in several new potential antifungals and biopesticides. As a senior scientist at Geobiotics, she discovered a novel metal cyanide degrading enzyme produced by *Xanthomonas* bacteria. From 1980 to 1990 she was the director of Fermentation Research and Development at Cetus Corporation. While employed at E. R. Squibb and Sons, she discovered a novel class of antibiotics, the monobactams. Dr. Hunter-Cevera holds two patents in biocatalysis and has written several papers on microbial ecology and physiology. She is a senior editor of the *Journal of Industrial Microbiology*, past president of the Society for Industrial Microbiology (SIM), and recipient of the 1996 SIM Charles Porter Award.

Gary K. Jacobs

Dr. Jacobs is a section head in the Environmental Sciences Division at Oak Ridge National Laboratory, where he has been performing geochemical research for 13 years. He received a Ph.D. in Geochemistry from Penn State University. His expertise is in complementary laboratory, field, and computational studies of contaminant mobility, geochemical modeling of water-rock interactions, and groundwater geochemistry. Dr. Jacobs has also conducted research in co-contaminant geochemistry, microbial ecology, and *in situ* remediation. He has authored several journal articles.

Seth W. Kullman

Mr. Kullman is assistant supervisor of undergraduate research in the Department of Environmental Toxicology at the University of California, Davis. He holds a B.A. in Cellular

and Molecular Biology from Sonoma State University and expects to receive his Ph.D. in Pharmacology and Toxicology in September 1996. His areas of specialization are environmental toxicology—fate and distribution of xenobiotics in the environment; ecological toxicology—biochemical and molecular effects of xenobiotics on biota; and environmental microbiology—biochemical and molecular analysis of xenobiotic metabolism. Mr. Kullman has planned and implemented strategies for bioremediation of petroleum products through enrichment of indigenous microbial populations. He has also examined and identified benthic invertebrates as indicator species of marine pollution in San Francisco Bay. Mr. Kullman co-authored a laboratory manual on bioremediation for the Department of Defense, as well as several journal articles and presentations.

Alice M. H. Lin

Ms. Lin is a program examiner/policy analyst intern with the Office of Management and Budget, Energy and Science Branch. She received a B.S. in Molecular Biology from the Massachusetts Institute of Technology and expects to receive an M.P.P. in Science and Technology Policy from Harvard University's John F. Kennedy School of Government in 1997. She is currently performing program assessment of DOE's Human Genome Program for OMB. Her interests include bioethics policy and public perception of genetic technology. She has participated in laboratory research on viruses, retroviruses, and hemophilia.

Janice D. Longstreth

Dr. Longstreth is a board-certified toxicologist and Diplomate of the American Board of Toxicology. She holds an M.S. in Biochemistry and Nutrition and a Ph.D. in Biomedical Sciences. Dr. Longstreth has over 25 years of experience in biomedical sciences with more than 15 years in environmental health risk assessment and risk management. She has conducted research in microbiology, nutritional pathology, immunotoxicology, and public health, with an emphasis on developing methods to detect infectious or communicable agents and understand the mechanisms by which they compromise the immune system. As a staff scientist, manager and/or principal at Dynamac, ICF-Clement International, Pacific Northwest Laboratories, and the Waste Policy Institute, she developed expertise in risk assessment and management of infectious agents and toxic and hazardous materials/wastes; oncology; immunotoxicology; information management; and risk assessment of stratospheric ozone depletion and global climate change.

Betty Mansfield

Ms. Mansfield leads the Human Genome Management Information System (HGMIS) for the DOE Human Genome Program at Oak Ridge National Laboratory. As the primary clearinghouse for information on the Human Genome Project, the mission of HGMIS is to facilitate genome research and public understanding of that research by communicating project goals, outcomes, and generated resources to genome researchers and the greater biomedical research community, to the interested public, and to professionals who further interpret and re-disseminate the information for specific groups. Ms. Mansfield has B.S. and M.S. degrees in Biology from James Madison University. Before coming to HGMIS when it was initiated in 1989, she contributed to research in chemical carcinogenesis. She worked out two-dimensional gel electrophoresis and computing techniques and demonstrated protein changes in tissues undergoing transformation both to and from the malignant state.

F. Blaine Metting, Jr.

Dr. Metting co-authored the NABIR Program Plan and is a member of the NABIR Program Office team. He is senior program manager for biotechnology and environmental sciences at Pacific Northwest National Laboratory, where he coordinates and shares responsibility for programs in bioremediation research and a laboratory initiative in microbial biotechnology. He has a liberal arts degree from Whitman College and a doctorate in botany from Washington State University. Dr. Metting co-founded an agricultural biotechnology company and helped build a profitable specialty fertilizer business prior to his career in environmental science. Following a research appointment at Tufts Medical School, Dr. Metting joined an environmental engineering firm at which he was responsible for developing a bioremediation program. He joined PNNL as a senior research scientist in 1990.

Curtis R. Olsen

Dr. Olsen helped launch the NABIR program and is co-manager of four program elements: Community Dynamics and Microbial Ecology, Biogeochemical Dynamics, Acceleration, and Assessment. As a technical program manager for the DOE Office of Health and Environmental Research (OHER), Dr. Olsen manages a budget of over \$10 million in five programmatic areas: environmental radon/contamination, coastal ecosystems, ocean research, arctic ecosystems, and global change education. From 1980 to 1990 he conducted environmental research at Oak Ridge National Laboratory, where he used radionuclides and biogeochemical tracers to study the transport and fate of energy-related materials in terrestrial and aquatic systems. He received a Ph.D. in biogeochemistry from Columbia University and is the author or co-author of more than 60 scientific papers.

Sue Palk

Ms. Palk is an attorney with DOE's Office of the Assistant General Counsel for Intellectual Property and Technology Transfer. She focuses on intellectual property issues arising during research and technology transfer efforts of the Department's various programs. Prior to joining DOE, Ms. Palk was a patent examiner at the U.S. Patent and Trademark Office. Ms. Palk received a B.S. in Industrial Engineering and Operations Research from Virginia Polytechnic Institute and State University and a J.D. from the George Mason University School of Law.

Manuel Perry

Dr. Perry is a consultant with expertise in planning, forecasting, managing change, program design, policy development, and education. He was formerly the director of education programs at Lawrence Livermore National Laboratory, where he had a 27-year career. He has also worked as a research biochemist, teacher, and textbook author. Dr. Perry received a B.S. in Chemistry from San Francisco State University, an M.P.A. from California State University, Hayward, and a Ph.D. in Public Administration from the University of Southern California.

Peter T. Pesenti

Mr. Pesenti joined Battelle-Pacific Northwest National Laboratory in 1992 as a senior research engineer. His professional experience spans over 23 years in the Department of Defense in line and staff assignments in strategic planning, integrated logistics support, logistics research and development, logistics operations research, and systems development. He has worked extensively in strategic planning for technology applications and tailoring management

information systems to solve complex acquisition problems. At PNNL, his most recent focus has been on strategic planning for DOE's technology research program. In this capacity he is responsible for providing technical advice on emerging biotechnology programs of interest for industrial microbiology. Mr. Pesenti is pursuing a Ph.D. in Environmental Microbiology at George Mason University. His research interests focus on microbial metabolic processes and community relationships with application to the field of bioremediation.

Katherine N. Probst

Ms. Probst is a Senior Fellow with Resources for the Future's Center for Risk Management. She has over 15 years of experience in evaluating hazardous waste programs. Ms. Probst has a master's degree in City and Regional Planning from Harvard University. She is currently directing two major research projects: an evaluation of the role of land use in the remedy selection process for Superfund sites, and an analysis of the myriad legislative requirements governing DOE's environmental management program in order to explore whether a new integrated law is needed.

Philip Sayre

Dr. Sayre is a senior microbiologist in the U.S. Environmental Protection Agency's Office of Pollution Prevention and Toxics. He reviews recombinant microorganisms subject to the Toxic Substances Control Act (TSCA) for relevant risk issues and identifies biotechnology risk issues for EPA's Office of Research and Development. He has also reviewed biotechnology products under the National Environmental Policy Act (NEPA) for the U.S. Food and Drug Administration. Dr. Sayre is an adjunct professor in the Department of Civil, Mechanical, and Environmental Engineering at George Washington University. He received a Ph.D. in Microbiology from Georgetown University.

William J. Smith

Dr. Smith, an environmental engineer for Allied Technology Group, Inc., is project manager supporting the University of California, Berkeley Environmental Remediation Center (BERC) contract to develop and implement innovative cleanup technologies from national laboratories at the Naval Air Station-Alameda. He is a member of the U.S. Navy's Restoration Advisory Board for NAS-Alameda and was recently appointed to the U.S. Army's Restoration Advisory Board for the Oakland Army Base. Dr. Smith formed the Sierra Club's East Bay Military Base Conversion Task Force, which is working to ensure that conversion of bases in the Oakland, California, area sets an example of economically and environmentally sound base conversion. He represented the Sierra Club on the Environmental Committee of U.S. Representative Ron Dellums' East Bay Conversion and Reinvestment Commission. He received a B.S. in Chemical Engineering from Iowa State University and an M.S. and Ph.D. in Biochemical Engineering from Stanford University. Dr. Smith has experience in designing, permitting, installing, and operating *in situ* bioremediation systems.

David G. Thomassen

Dr. Thomassen is manager of the NABIR program element Biomolecular Science and Engineering. As a program manager in the Health Effects and Life Sciences Research Division of the DOE Office of Health and Environmental Research (OHER), he is responsible for managing research programs that integrate information and technologies from genome, structural biology, and molecular biology research with human health research. Dr. Thomassen has B.S. and M.S.

degrees in Zoology and Genetics from Washington State University and a Ph.D. in Genetics from the University of Wisconsin at Madison. He has conducted research on the cellular and molecular mechanisms of multistage progression to neoplasia in respiratory epithelial cells at the Inhalation Toxicology Research Institute and at the National Cancer Institute.

Ronald Unterman

Dr. Unterman is co-founder and chief scientific officer of Envirogen, Inc., an environmental biotechnology company. He directs Envirogen's research and development program, including both microbe and process development for degrading or transforming toxic and hazardous wastes. Current programs include the biodegradation of chlorinated solvents (such as TCE), PCBs, MTBE, HCFCs, industrial wastewater toxics, and air toxics; genetic engineering; the application of advanced *in situ* bioremediation techniques; and design and testing of bioreactor systems. Prior to joining Envirogen, Dr. Unterman was staff scientist and later manager of GE's Environmental Technology Program. He received a B.A. in Biology from Haverford College and a Ph.D. in Biochemistry from Columbia University.

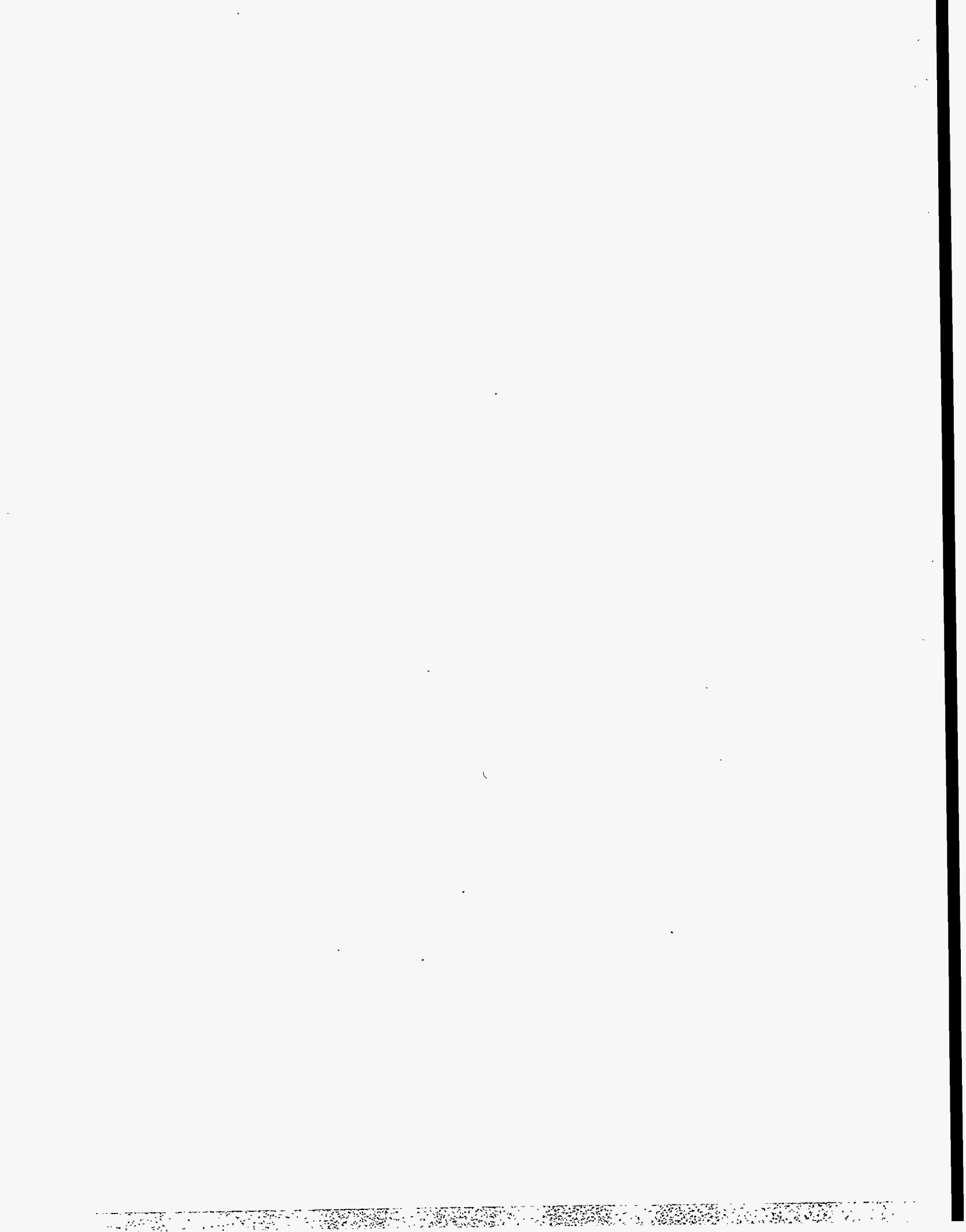
David C. White

Dr. White, a University of Tennessee, Environmental Science Division/Oak Ridge National Laboratory Distinguished Scientist, is a NABIR science team leader with particular interests in community dynamics and microbial ecology, biomolecular science and engineering, and assessment. He is a professor of Microbiology/Ecology at the University of Tennessee and executive director of the Center for Environmental Biotechnology. His research focuses on defining interactions between microbes. Under his leadership, the Laboratory developed quantitative measures of microbial viable biomass, community composition, and nutritional/physiological status based on signature lipid biomarker analysis (SLB). Dr. White received his M.D. from Tufts University and his Ph.D. from Rockefeller University.

Frank J. Wobber (not at workshop)

Dr. Wobber is manager of NABIR's Biogeochemical Dynamics and Acceleration program elements. He received an M.S. in Geology from the University of Illinois and a Ph.D. in Geology from the University of Wales, Great Britain, as a U.S. Department of State Fulbright Scholar. He has 25 years of experience in multidisciplinary natural resources and environmental research program management, including science programs for the U.S. Congress. Since 1980 he has been with the DOE Office of Energy Research (OER). Dr. Wobber conceived, designed, and implemented the OER core capability in subsurface science, which provides a base of mechanistic research to support departmental programs in site cleanup. He developed and implemented scientific initiatives in transport of organic radionuclides and mixtures, bacterial transport, subsurface heterogeneity, and deep microbiology. Dr. Wobber has received numerous awards for scientific research and research management, including an international award for leadership in geomicrobiology.

APPENDIX D
PRESENTATION GRAPHICS



Bioremediation Principles

F. Blaine Metting Jr

July 18-19, 1996 Workshop on
Bioremediation and Its Social
Issues and Concerns

**Bioremediation: The use of microorganisms
or plants to degrade or transform contaminants**

Bioremediation Marketplace

- **Over 20,000 hazardous material generators**
- **More than 5,000 WTSD facilities**
- **600,000 leaking underground storage tanks**
- **32,000 potential CERCLA sites**
- **About 6,000 contaminated federal facilities**

\$300-500M by the year 2000

The Bioremediation Industry

- **Large, diversified corporations**
- **Regional, national & international A&E firms**
- **Waste management companies**
- **Environmental consulting firms**
- **Biotechnology companies**
- **Microbial inoculant manufacturers**

Advantages of Bioremediation

- **Cost competitive with alternate technologies**
- **Contaminants can be completely destroyed**
- **It is an on-site technology**
- **In situ approaches are effective**
- **Public perception is of a “natural” process**

Disadvantages of Bioremediation

- **Not a stand alone technology**
- **Contaminants not always completely destroyed**
- **It is a highly site-specific technology**
- **In situ methods are difficult to monitor and document**
- **Bioremediation endpoints often exceed requirements**

Ex Situ Bioremediation (above ground)

In Situ Bioremediation (in place)

Biotransformation: The biological transformation of one organic compound into another (synthesis or degradation) or the alteration of the chemical species or oxidation state of inorganic molecules such as nitrate or uranium

Biodegradation: The transformation of an organic molecule to a more simple form. Complete degradation to inorganic molecules (CO₂ and H₂O) is termed
Mineralization

To succeed, Bioremediation Requires

- Presence of appropriate microorganism or consortium
- Availability of contaminants to the microorganism(s)
- Conducive environmental conditions

Bioaugmentation

The addition of microorganisms to a bioreactor or the subsurface to enable or enhance bioremediation.

- **Naturally-occurring consortia**
- **Genetically-engineered microorganisms**

Conducive Environmental Conditions

- **Electron donors and acceptors**
- **Nutrients**
- **Physical factors - Geohydrology, Geology**

Contaminants

Success to date

- Petroleum hydrocarbons
- Some solvents
- Wood preservatives
- Other pesticides
- Chemical feedstocks
- Nitrates, other inorganics
- Some PAHs (coal tars, dyes)

Potential

- Metals
- Radionuclides
- PCB mixtures
- Weathered PAHs
- Complex mixtures

Ex situ Bioremediation

- **Landfarming**
- **Slurry bioreactors**
- **Soil composting and biopiles**

In situ Bioremediation

- **Bioventing (vadose zone)**
- **Air sparging**
- **Groundwater circulation**

Bioremediation with other Technologies

- **Soil washing**
- **Soil heating**
- **Soil vapor extraction**
- **Pump and treat**

Bioremediation: Technical Status

Current Status

- Limited to surface & near surface
- Mostly small-scale applications
- Usually limited to easily manipulated conditions
- Largely restricted to “simple” contaminants

Potential

- Application to large areas and great depths
- Large-scale application
- Complex geohydrologic environments
- Complex waste mixtures

NABIR Program Overview

D. Jay Grimes

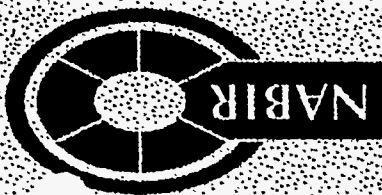
Program Coordinator

U. S. Department of Energy

Office of Health and Environmental Research

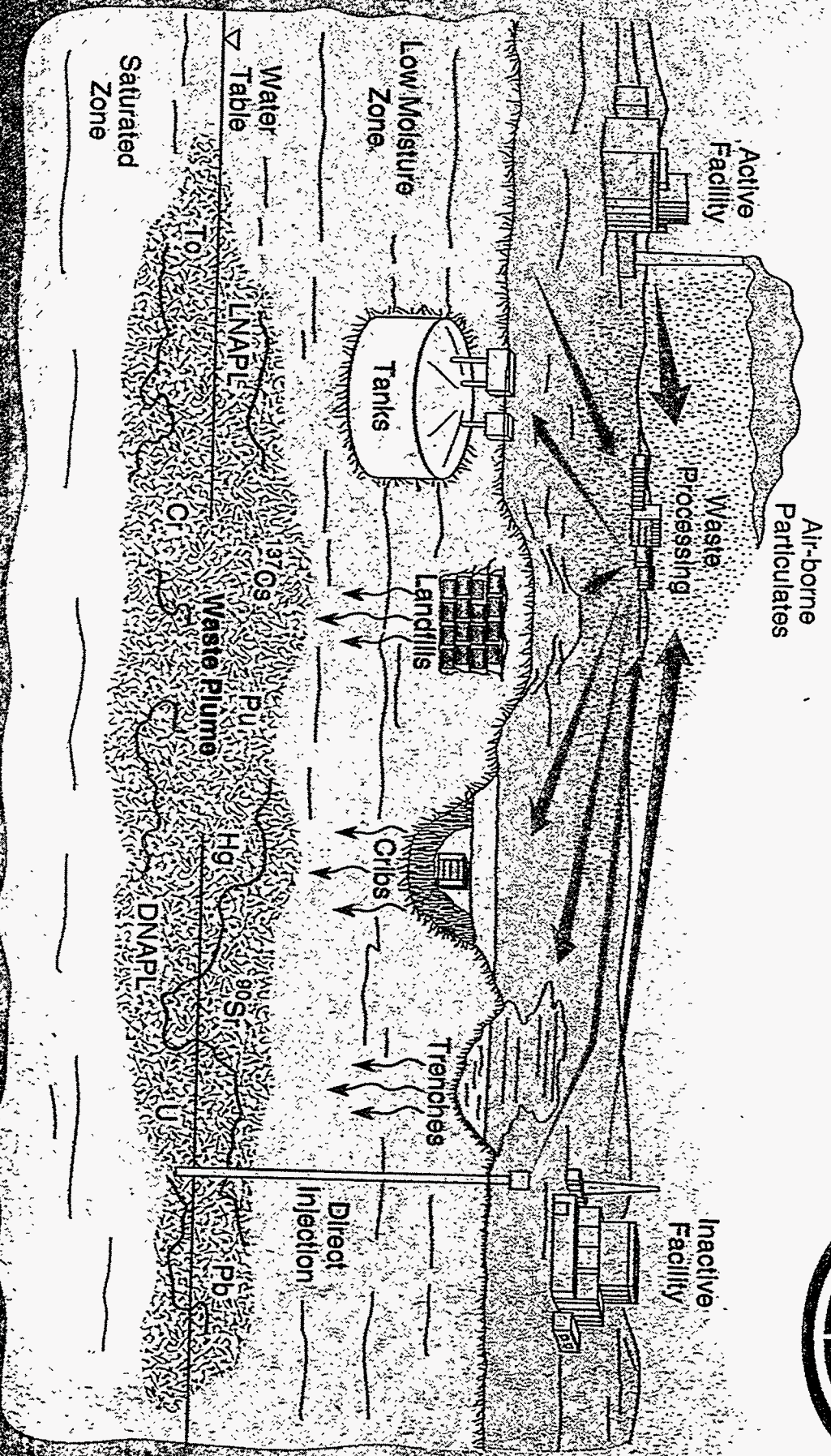
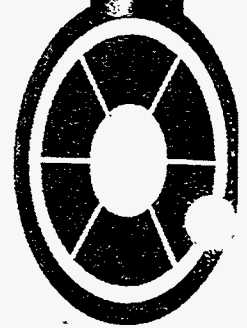
Workshop on Bioremediation and its Social Implications and Concerns
(BASIC)

July 18 - 19, 1996



Natural and Accelerated Bioremediation Research

NABIR



The DOE Agency of Environmental Purposes 2500 Billion (federal) contaminated
 resources watch and be still in the billions of contaminated soil



Definition:

The use of living organisms to reduce or eliminate environmental hazards resulting from accumulation of toxic chemicals or other hazardous waste.



U.S. Department of Energy
Office of Energy Research
Office of Health and Environmental Research

American Academy
of Microbiology

AMERICAN
ACADEMY
OF MICROBIOLOGY

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BIOREMEDIATION
IN THE FUTURE
Update on the
bioremediation
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The Bioremediation Report
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Environmental
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for Waste
Treatment
Editors:
LARRY S. GAYL
ROBERT FOX
AND
JAMES W. DEAN

In Situ
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International Symposium on
**THE BIOPROPERTY RESULTS
OF FIELD TESTS
OF GENETICALLY-MODIFIED
PLANTS AND MICROORGANISMS**
May 11-14 1992
Geneva, Switzerland

**Field
Testing
Genetically
Modified
Organisms**
A
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Approach
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Robert Fox

Recent Reviews

Rutgers Workshop on Bioremediation, 1991

EPA Biosystems Technology Report, 1983

American Academy of Microbiology Workshop on Bioremediation, 1992

American Academy of Microbiology Workshop on Strategies and Mechanisms for Field Research, 1993

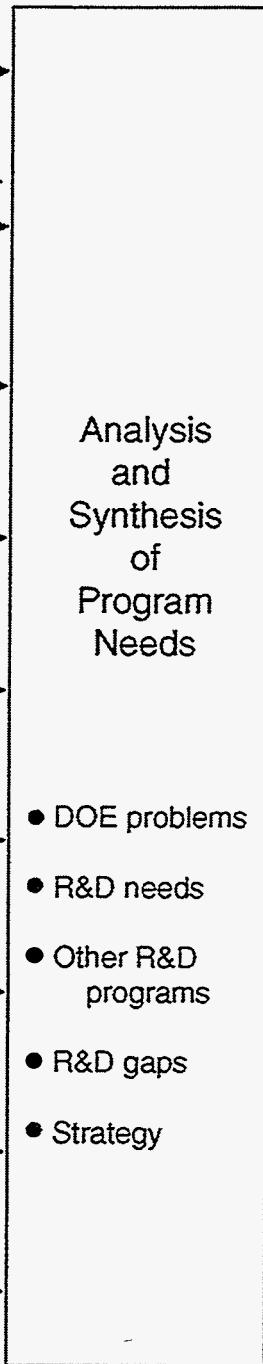
National Research Council Report on In Situ Bioremediation: When Does it Work, 1993

American Chemical Society Symposium on Bioremediation Through Phytoremediation, 1993

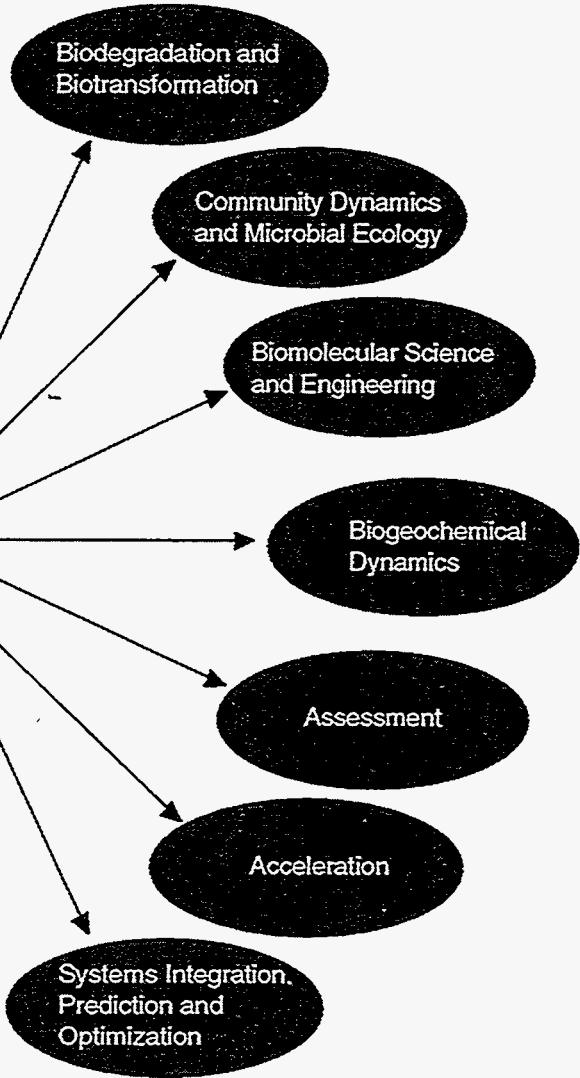
Department of Energy Workshop on Phytoremediation, 1994

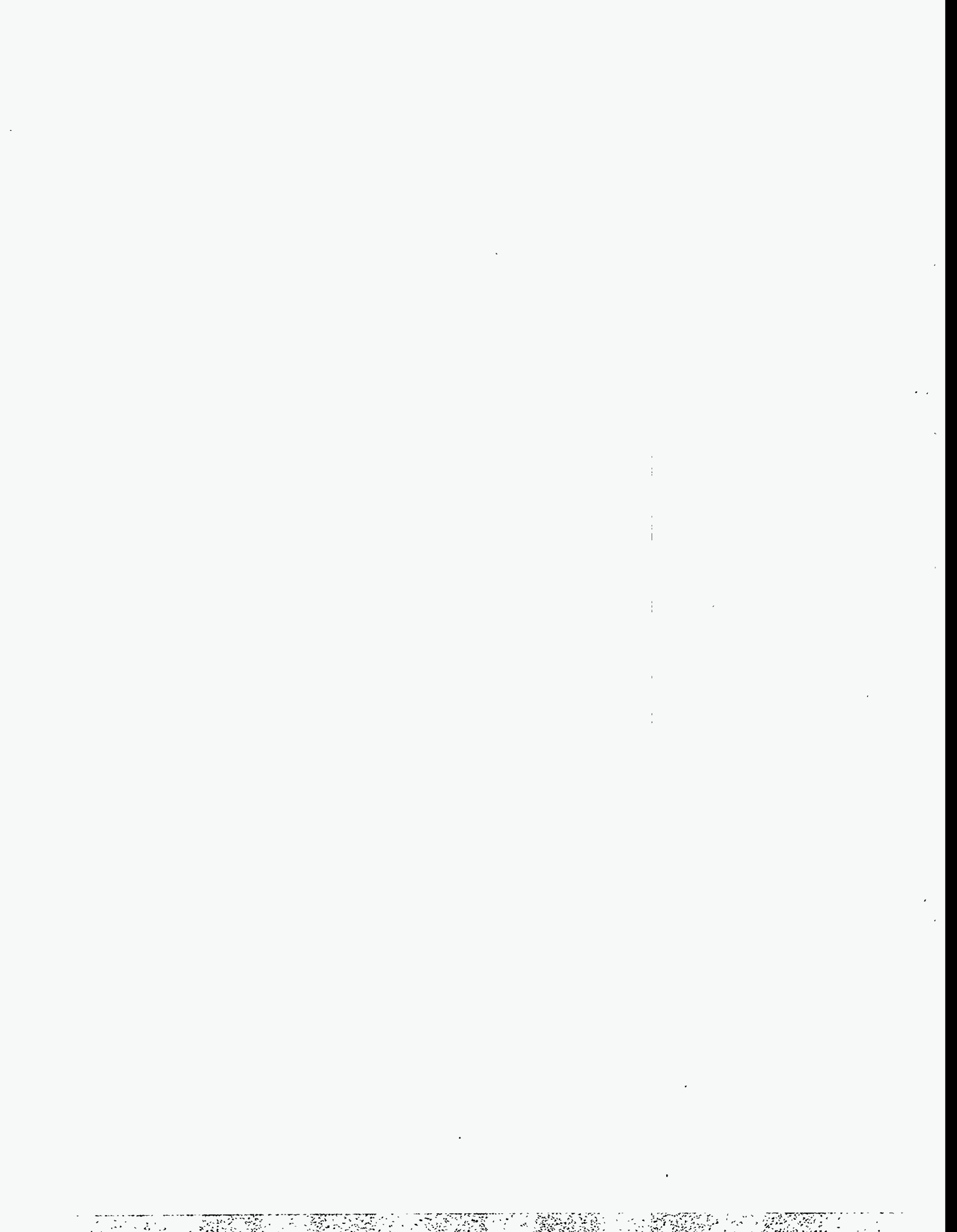
European Commission and U.S. Government Workshop on Environmental Biotechnology, 1994

National Science and Technology Council's Biotechnology Research Strategy Report, 1995



Program Elements

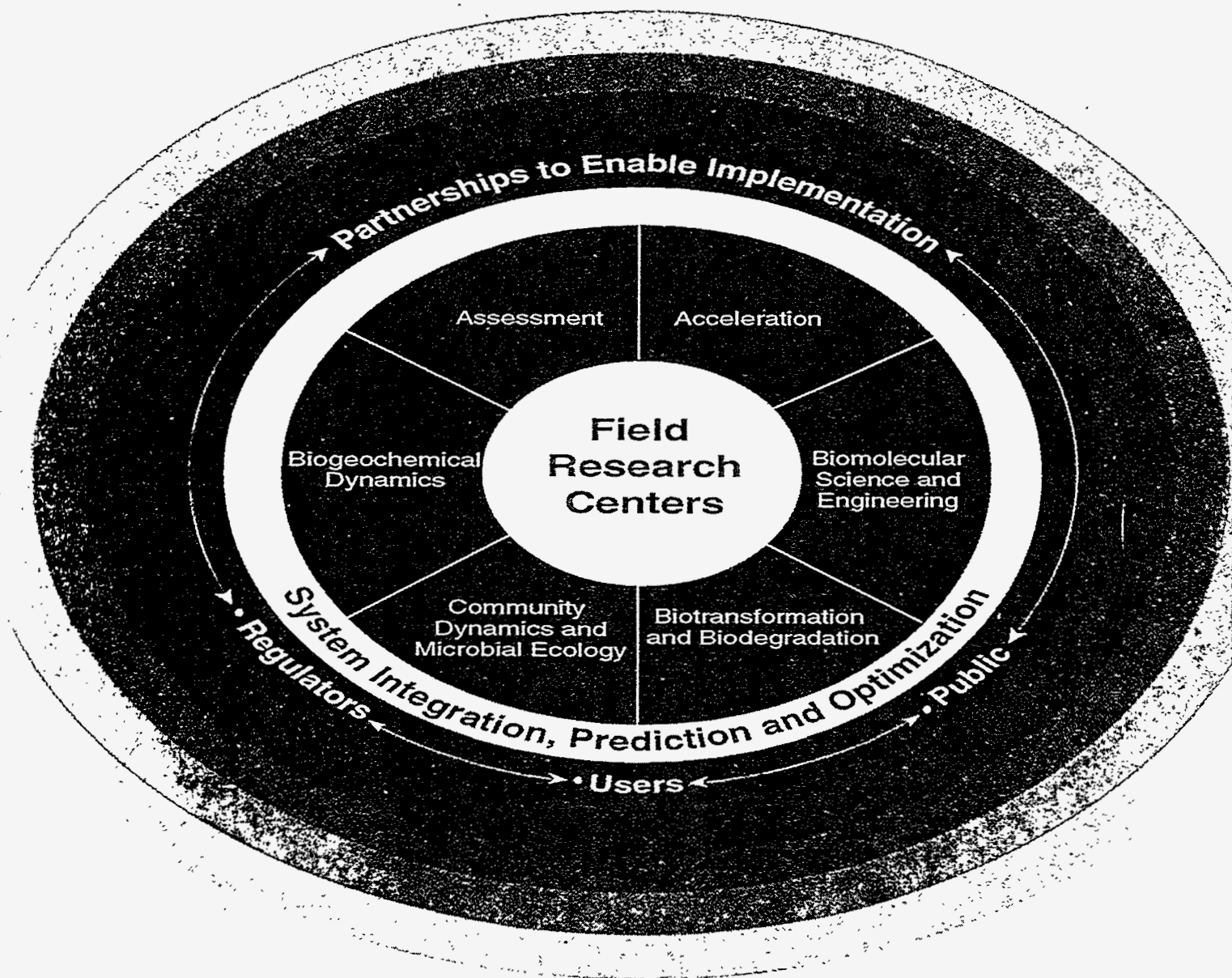




Natural and Accelerated Bioremediation Research

N A B I R

Program Plan



September 1995

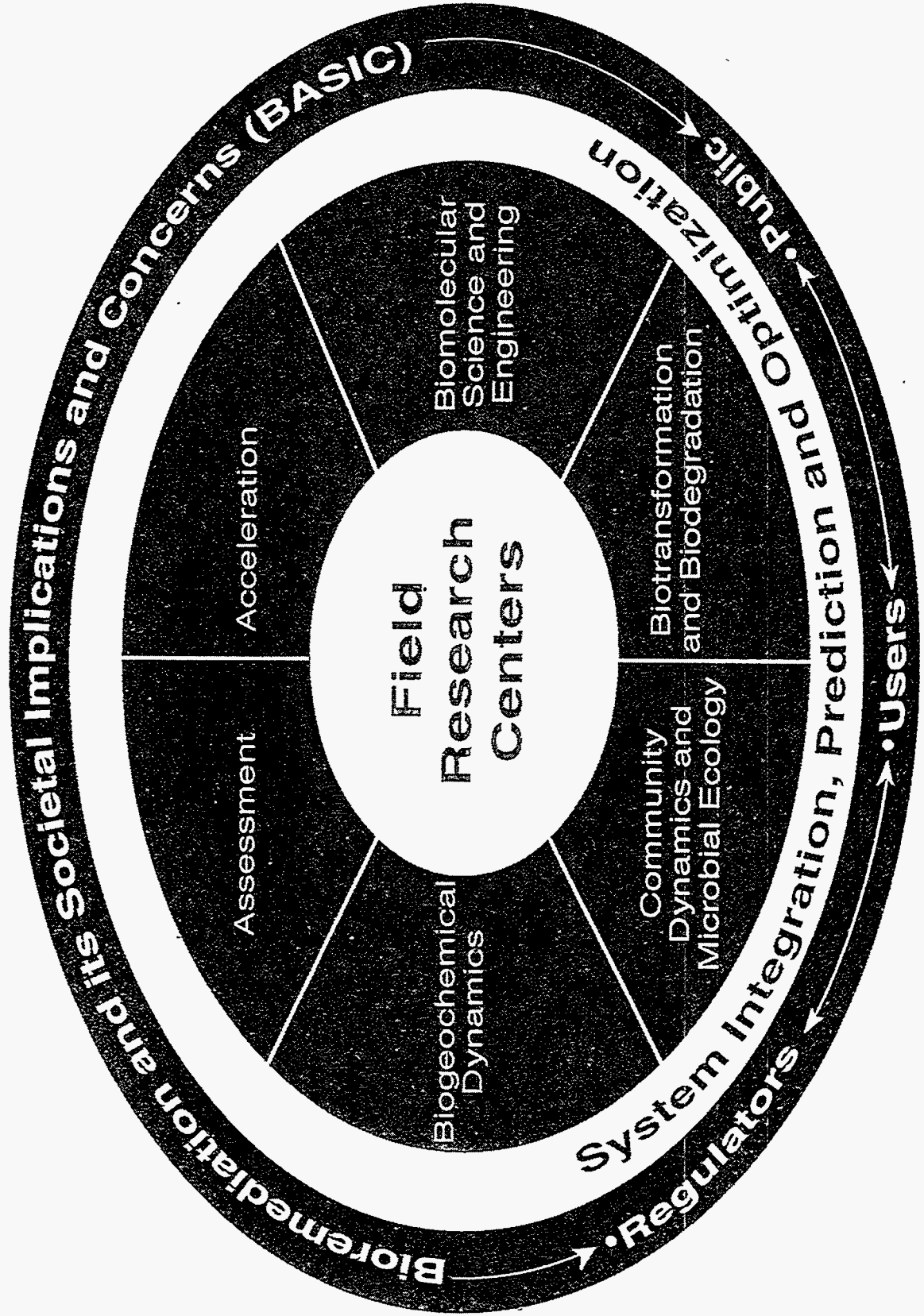


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Office of Energy Research
Office of Health and Environmental Research



NABIR

Seven Interrelated Elements



U.S. Department of Energy

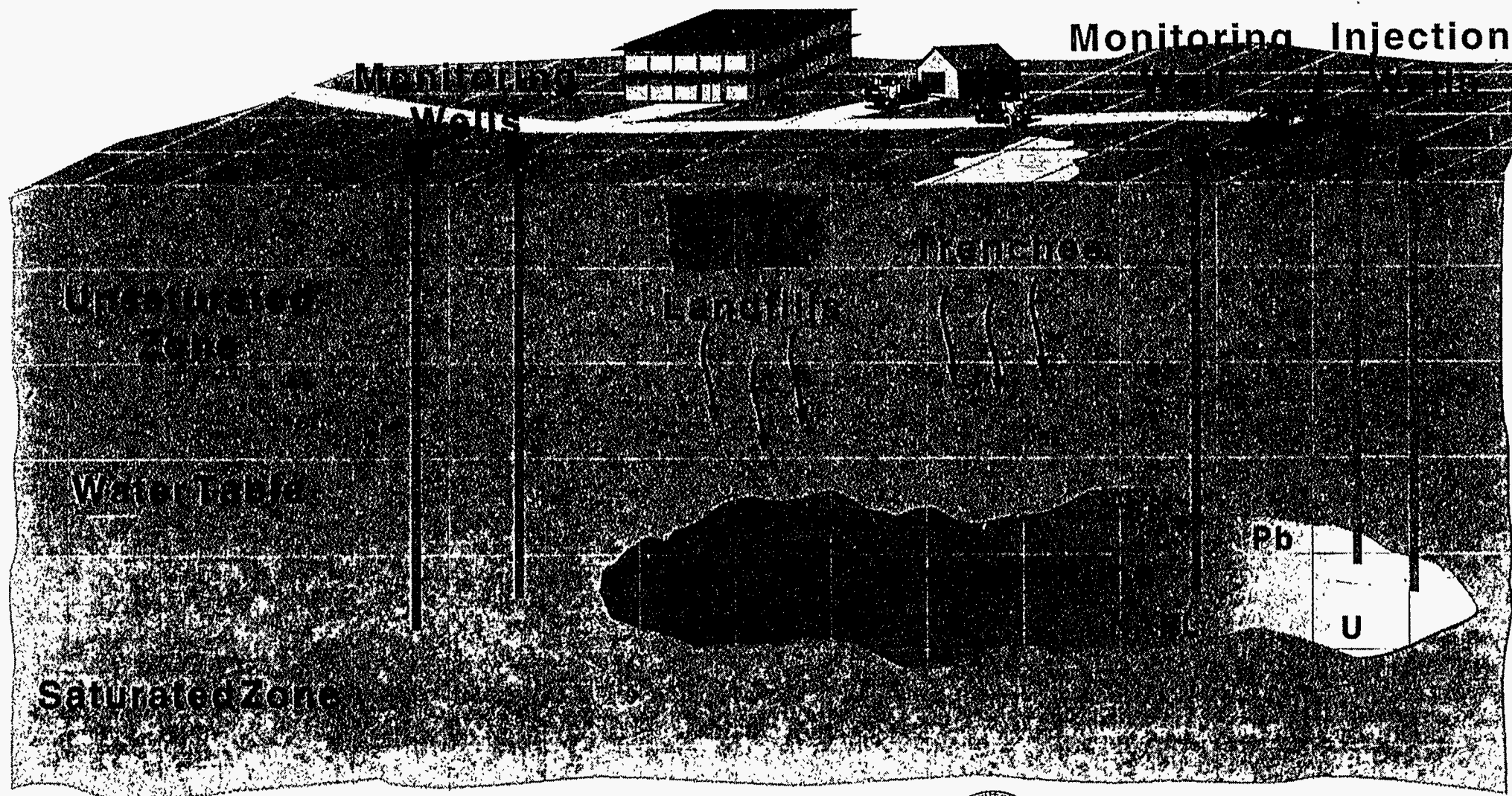


Control Site

Staging Facility and Analytical Lab

Contaminated Site

Monitoring Injection





- **Advanced Light Source**
- **Advanced Photon Source**
- **Environmental Molecular Sciences Laboratory**
- **Combustion Research Facility**
- **NABIR Field Research Centers**



- **Genomic & Structural Biology**
- **Nuclear Medicine**
- **Medical Instrumentation**
- **Environmental Research**
 - **Ocean Margins**
 - **Global Climate Change**
 - **Ecosystem Research**
 - **Subsurface Science**





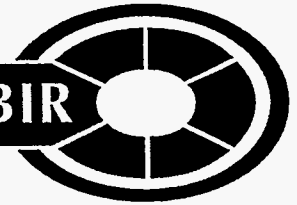
NABIR will provide the scientific understanding needed to expand the applicability of bioremediation to the mixtures of contaminants at DOE sites

- **Organics**
- **Metals**
- **Radionuclides**



Natural and Accelerated Bioremediation Research

NABIR



Scientific Program Elements and Objectives

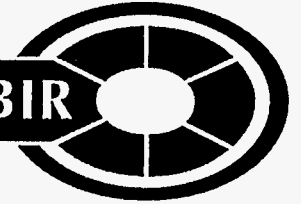
Sally M. Benson
NABIR Program Office

Ernest Orlando Lawrence Berkeley National Laboratory
Berkeley, California 94720

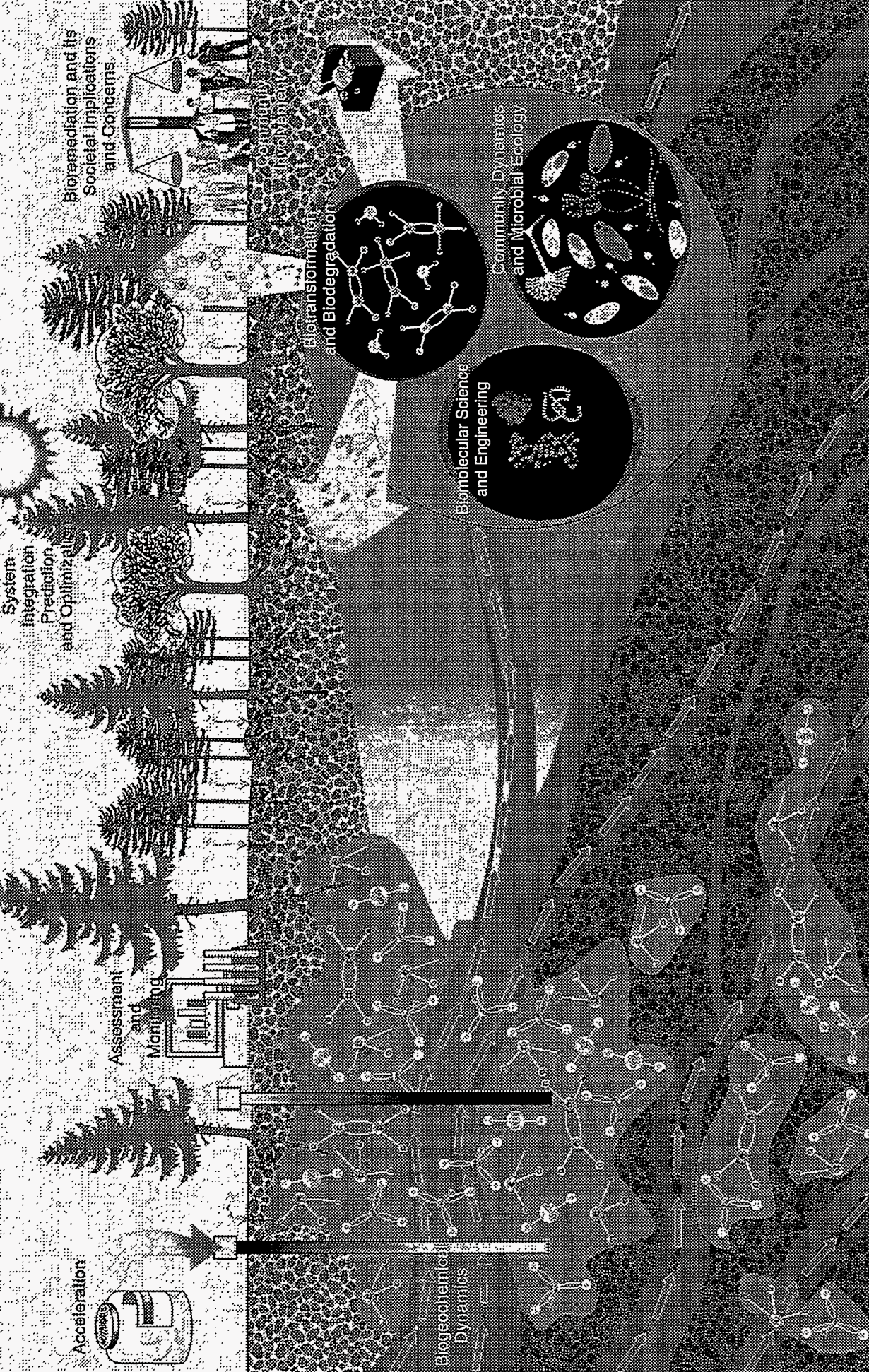
July 18-19, 1996

Why have a research program

NABIR



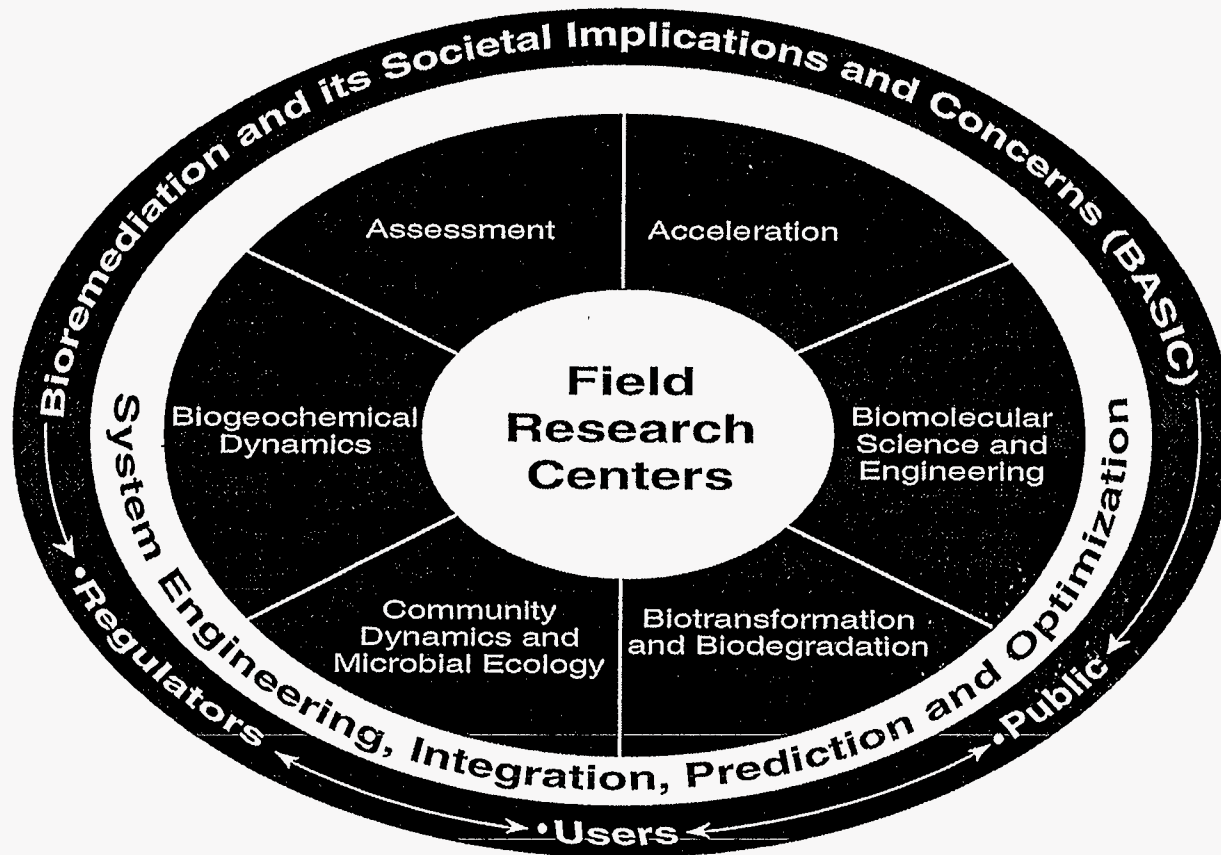
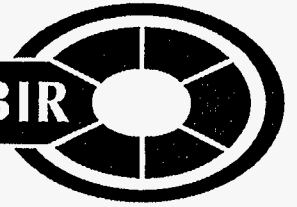
- Mixtures of contaminants pose unique challenges for bioremediation
- Soil and groundwater at DOE facilities are contaminated with radionuclides
- Laboratory results are difficult to transfer from the laboratory to the field
- Fundamental research is needed to elucidate key biological, geochemical and transport processes that contribute to bioremediation



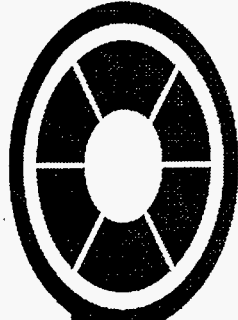
Natural and Accelerated Bioremediation Research

Seven Interrelated Elements

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Biotransformation and Biodegradation

Objective

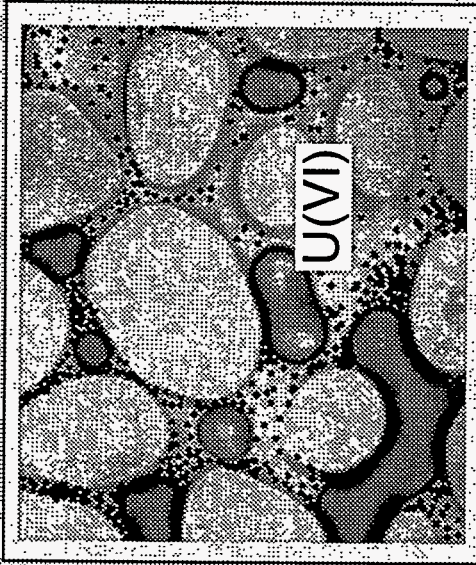
To understand the mechanisms and pathways for biotransformation and biodegradation of contaminant mixtures in order to improve the performance of bioremediation in the field.

Research Topics

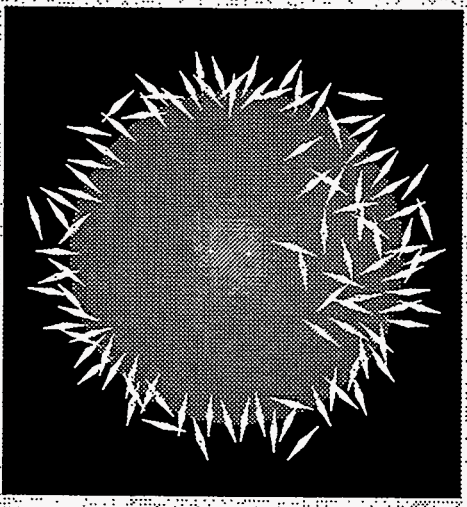
- Mechanisms for Biotransformation of Metals and Radionuclides
- Identification of Pathways, Processes, and Molecules for Degradation of Mixtures of Organic Contaminants
- Interactions between Toxic Metals, Radionuclides, and Organic Contaminants
- Kinetics of Biotransformation and Biodegradation Processes under Field Conditions



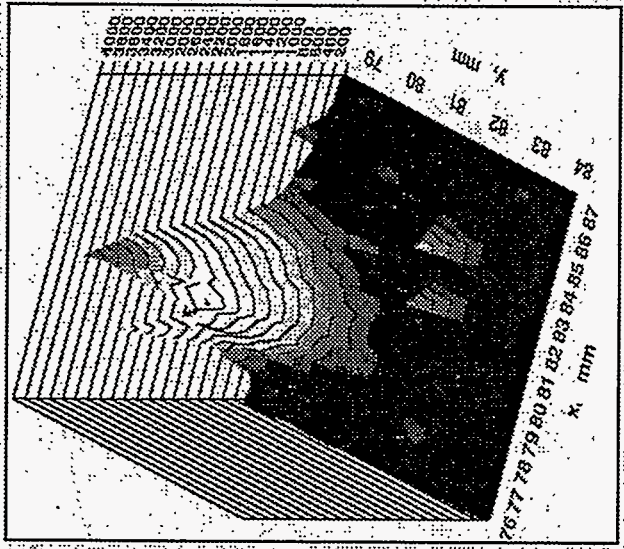
U.S. Department of Energy
Office of Energy Research
Office of Health and Environmental Research



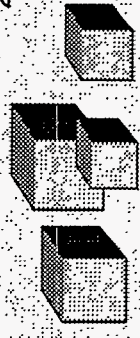
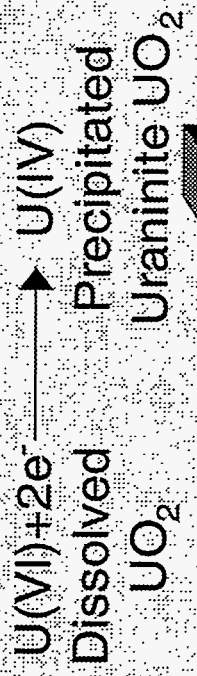
Biosorption



Kinetic and Spatial Effects

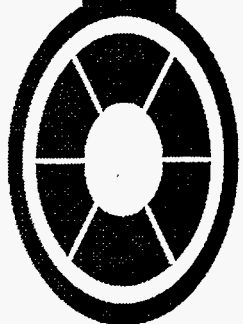


Reduction



- What biotransformation processes immobilize or mobilize uranium in subsurface environments?
- How are the processes influenced by the presence of other contaminants?
- How stable are biotransformations that immobilize uranium?

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Community Dynamics and Microbial Ecology

Objective

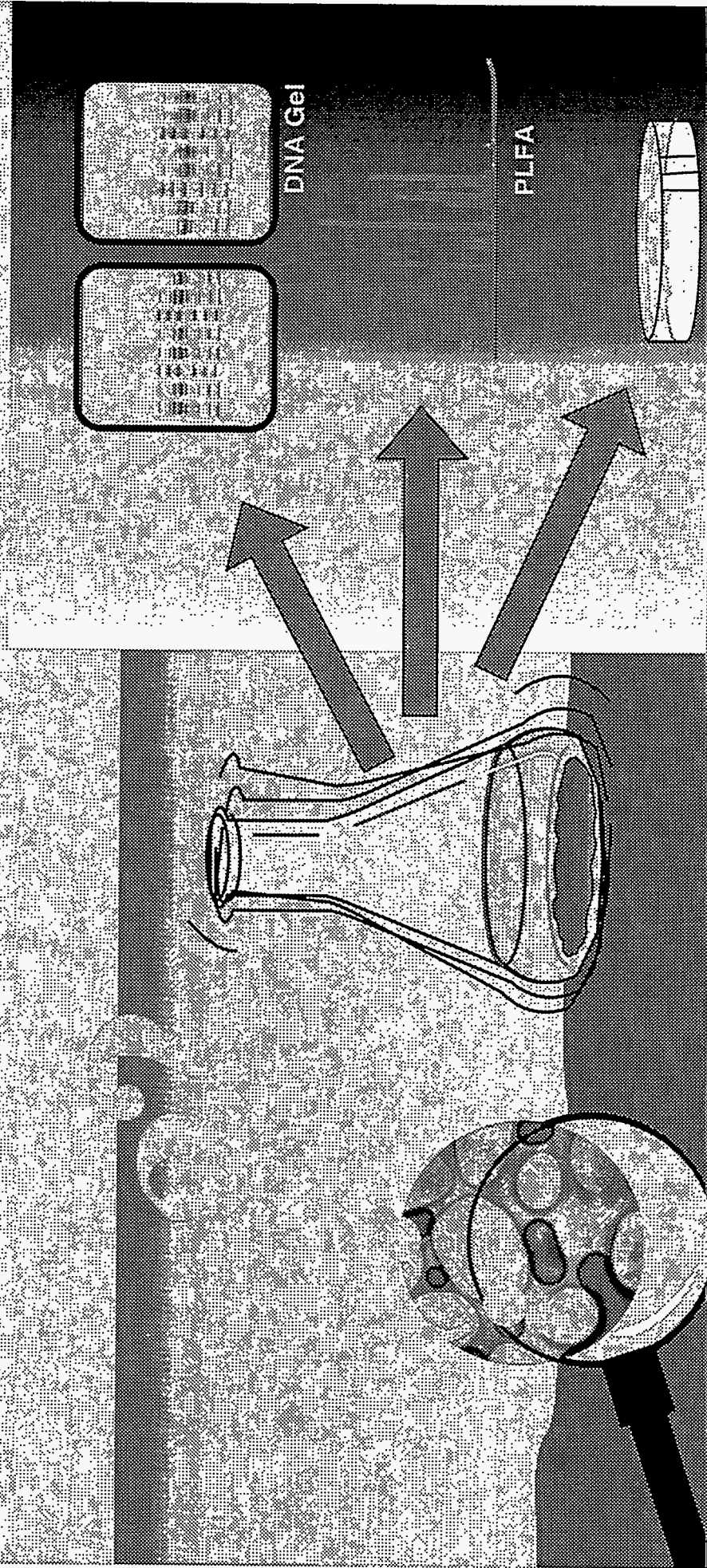
To further the understanding of the structure and function of the microbial and plant community and interactions of components in natural and amended soil and subsurface habitats containing mixed contaminants and to elucidate their role in bioremediation.

Research Topics

- Community Identification Using Molecular and Biochemical Techniques
- Molecular Evolution and Gene Transfer within the Community
- Community Structure and Function Relationships
- Influence of Environmental Factors



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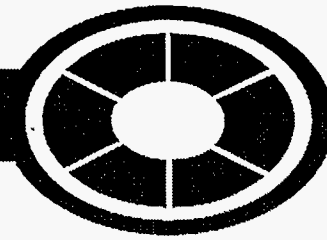


• What are the dominant microbial communities present?

• What is the influence of contaminants on the community structure and activity?

• What is the influence of changing environmental factors on community structure and activity?

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**Biomolecular
Science and
Engineering**

Objective

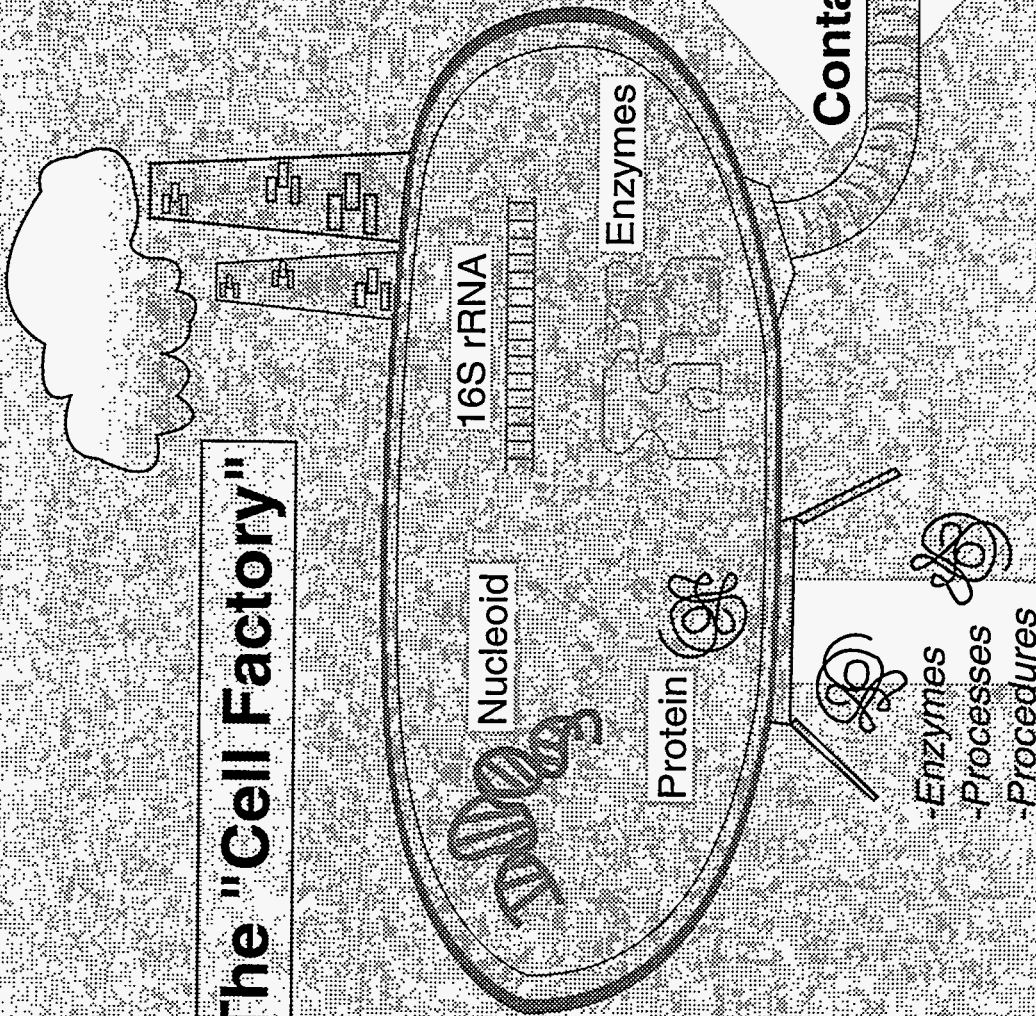
To use molecular biology to enhance our understanding of bioremediation and to genetically modify molecules and organisms to improve bioremediation activities.

Research Topics

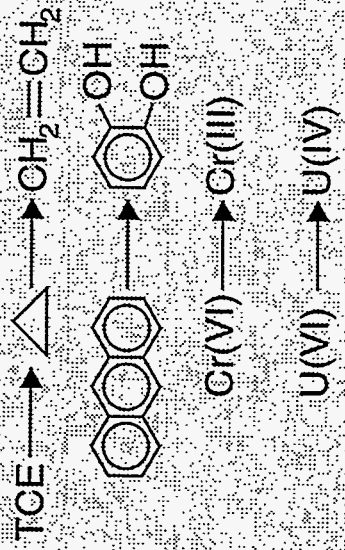
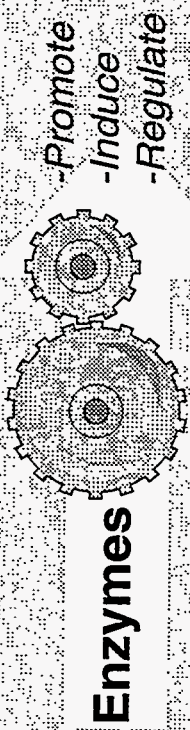
- Analysis of Genes, Proteins and Regulatory Elements for Critical Molecules in Bioremediation
- Structure and Function of Bioremediation Molecules
- Genetic Selection and Engineering of Improved Bioremediation Molecules and Organisms
- Pathway Engineering
- Cell-Free Systems for Bioremediation



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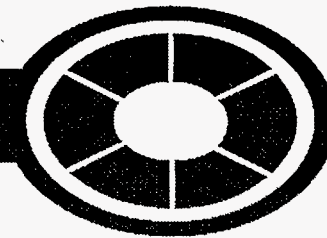
The "Cell Factory"



Detoxified Material Flows Out

- What genes regulate the production of degradative enzymes?
- What environmental factors induce such activity?
- How can we genetically modify the organism to improve its capability to biodegrade contaminants?

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Biogeochemical Dynamics

Objective

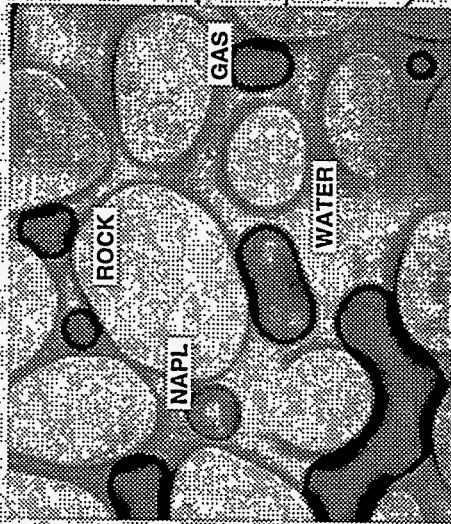
To provide a mechanistic understanding of how microorganisms and contaminants are transported under coupled and interactive physical, geochemical, and microbial processes and how underlying molecular and interfacial phenomena and natural heterogeneities control contaminant and nutrient availability and microbial and rhizosphere activity in contaminated environments.

Research Topics

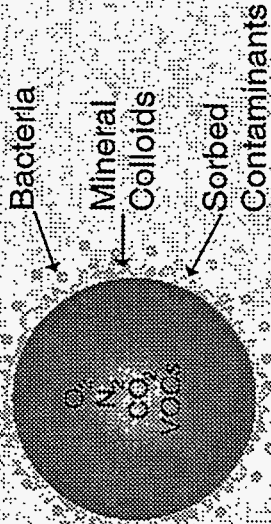
- Interfacial Phenomena
- Contaminant and Nutrient Availability
- Spatial and Temporal Heterogeneity



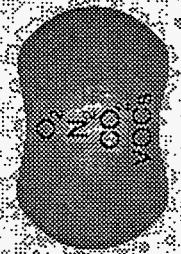
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Gas-Water Interfaces

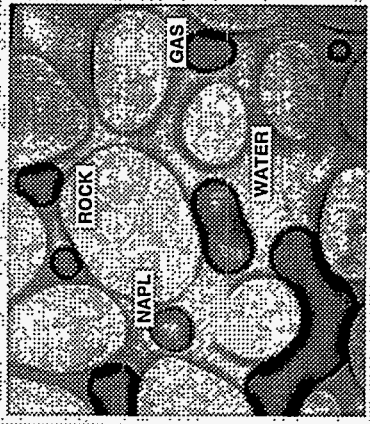


Stationary Gas Bubble

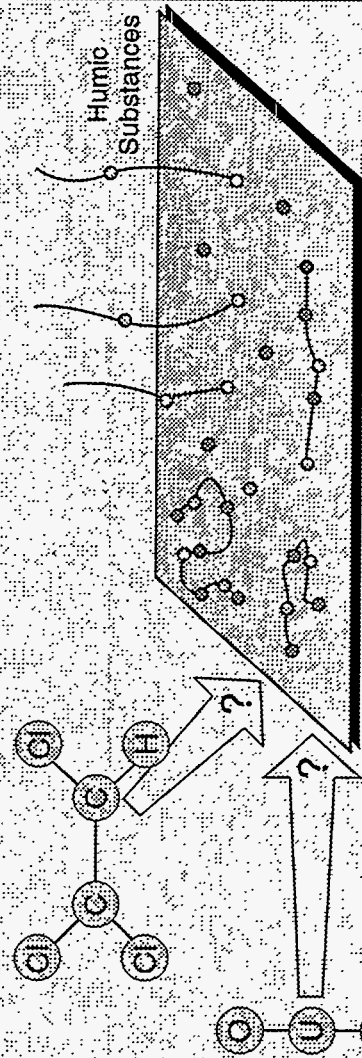


Moving Gas Bubble

NAPL-Water Interfaces

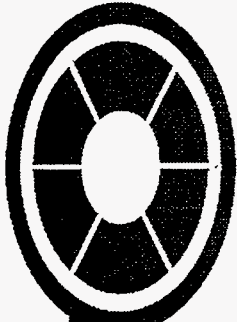


Rock-Water Interfaces



What is the Role of Interfaces on Sorption, Growth, Biodegradation, Transport, Bioavailability, Toxicity?

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Objective

To expand and validate innovative methods for measuring biodegradation rates, biotransformation processes, microbial community dynamics, electron flow, contaminant distributions, and hydrogeological and geochemical factors—and to understand the implications of these measurements.

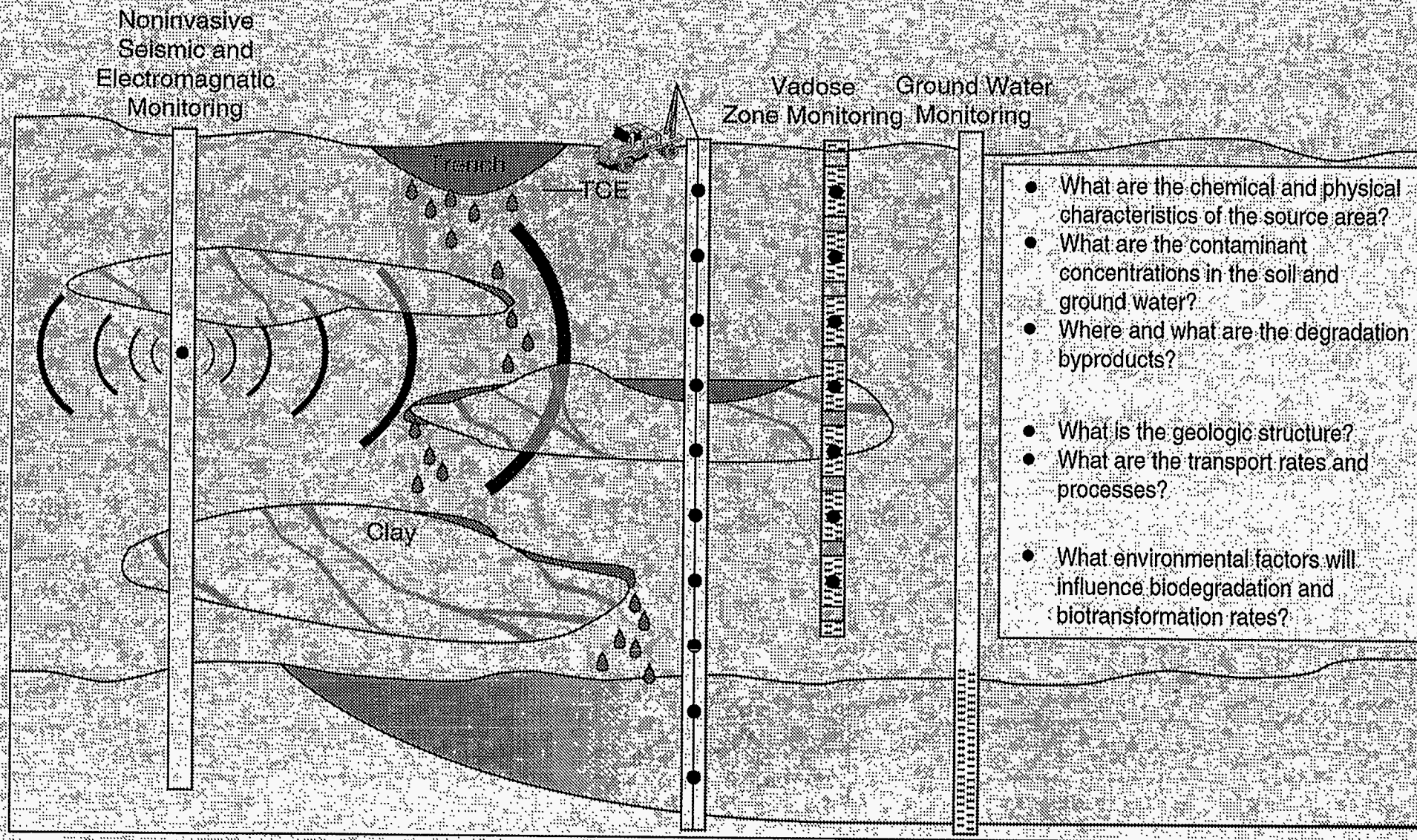
Assessment

Research Topics

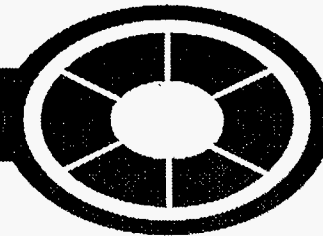
- Assessing Structure, Rate and Activity
- Geochemical, Geophysical and Hydrogeologic Characterization
- Interpretive Diagnostics
- Bioremediation End Points



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Acceleration

Objective

To develop effective methods for accelerating and optimizing in situ bioremediation processes, and where applicable, transfer this knowledge to ex situ waste treatment.

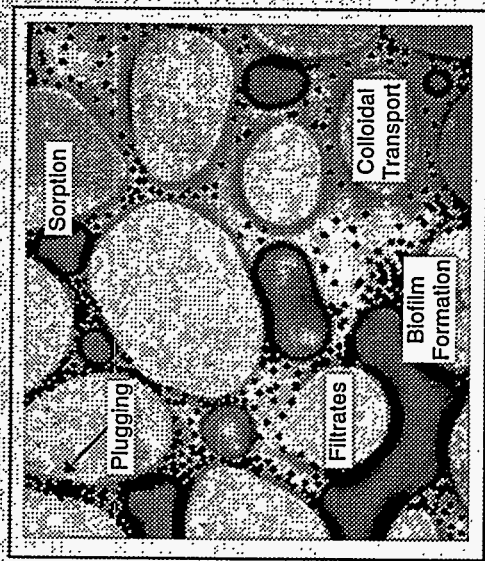
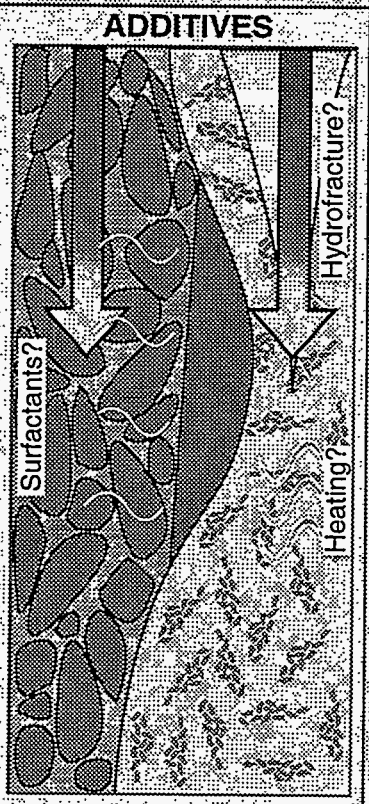
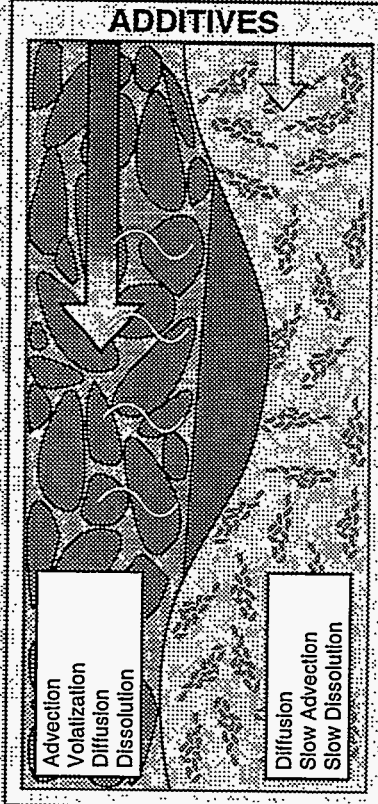
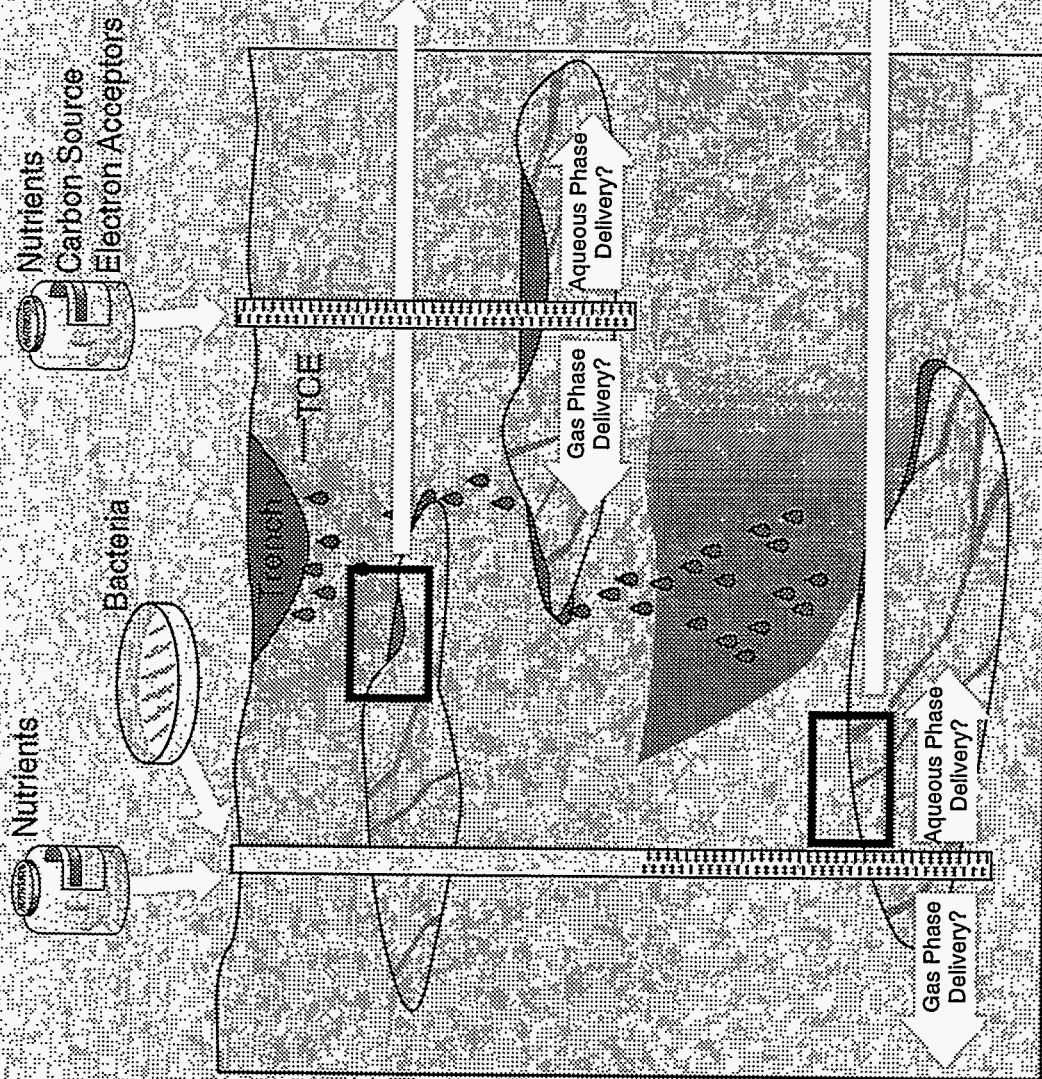
Research Topics

- Microbial and Chemical Transport Processes
- Biostimulation and Bioaugmentation Processes
- Delivery Strategies for Chemical and Biological Additives



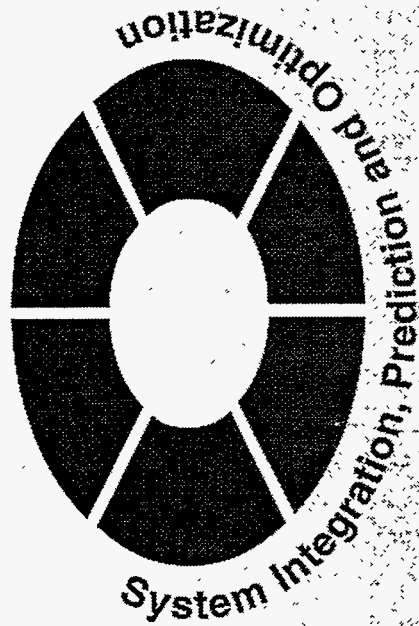
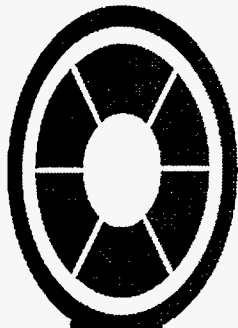
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Acceleration: Delivery Strategies for Chemical and Biological Additives



- How can the nutrients contact the microorganisms and contaminants?
- How can microorganisms be introduced without plugging the formation?
- What transport processes enhance the efficiency of delivery systems?

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Objective

To integrate scientific concepts and data from different program elements and to develop a hierarchy of improved mathematical methods for describing coupled biological, geochemical, geological and transport processes.

Research Topics

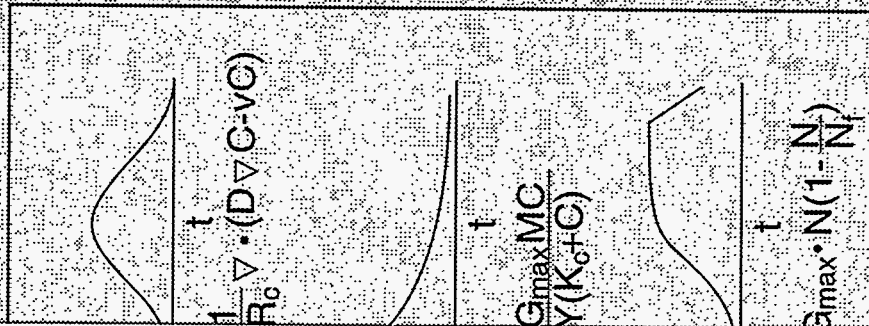
- Scientific Data Integration and Informatics
- Mathematical Representation of Community Dynamics, Biotransformation, and Biogeochemical Processes
- Integrative and Scalable Models



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UNIVERSITY OF NABIR



data?
nutrients?

Environmental Biotech: Technology Directions

Ronald Unterman
Vice President, Technology
Development

Envirogen, Inc.
Lawrenceville, New Jersey

The Advantages of Biotechnology in Environmental Restoration and Protection

- **Lower Costs**
- **Destruction of Toxics**
- **On Site Treatment**
- **Natural Solution**



Hierarchy of Remediation Approaches

I. *In Situ*



1. Intrinsic Remediation/Natural Attenuation
2. Biostimulation
3. Bioaugmentation

II. *Ex Situ: Fluids Treatment*

1. Air (SVE, Sparging): Biofiltration
2. Water: Aqueous Phase Bioreactors

III. *Ex Situ: Soil Treatment*

1. Engineered Land Treatment
2. Biopile
3. Slurry Phase Treatment (bioslurry, SoPE™)

Representative Innovative Remediation Projects

SITE / PROJECT	COSTS		
	Initial	Envirogen	Savings
Inactive Industrial Site, IL <i>TCE in groundwater and soil</i>	\$20M	\$2M	\$18M
Superfund Site, NH (Landfill) <i>Bio. treatment zones replace cap</i>	\$25M	\$5M	\$20M
Manufacturing Facility, NJ <i>Intrinsic monitoring to replace P&T</i>	\$10M	\$1M	\$9M
Superfund Site, MA <i>O₂ Sparging for As immob., VOCs</i>	\$50M	\$2M	\$48M
Inactive Industrial Site, OH <i>SVE/bioventing vrs. excavation</i>	\$10M	\$2M	\$8M
Superfund Site, ME (Landfill) <i>SVE/bioventing to reduce P&T</i>	\$20M	\$3M	\$17M



ENVIROGEN

New Solutions to Hazardous Waste Problems

Technology Directions

- I. Biocatalyst Development
(Bioadsorption, Bioconversion)**

- II. Systems Development**

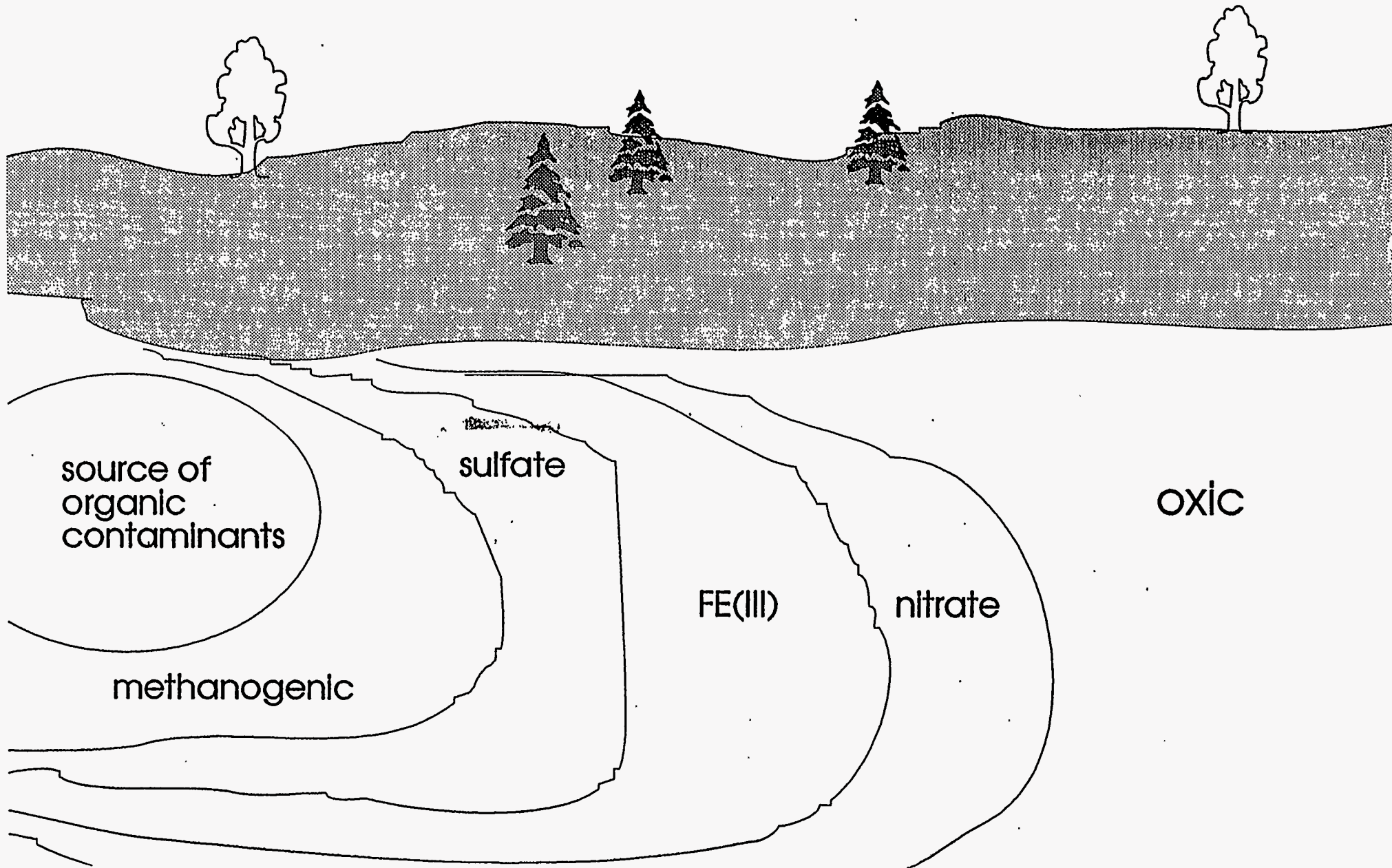
- III. Establishing Reasonable Regulatory
Targets**

- IV. Monitoring & Documentation**

Technology Directions

I. Biocatalyst Development (Bioadsorption, Bioconversion)

- Microbes
 - indigenous; exogenous; GEMs
 - aerobic; anaerobic; cometabolic
 - organics; xenobiotics; metals
- New targets chemicals
- Enzymes



Biocatalytic Activities

Aerobic Metabolic

aromatic

BTEX
phenol
styrene
chlorobenzene
dichlorobenzene(s)
aniline
nitrobenzene
naphthalene
PAHs

solvents

ethanol
methanol
acetone

chlorinated solvents

methylene chloride
methylchloride

hydrocarbons (fuels)

MTBE

pesticides

sulfur compounds

H₂S
CS₂

ammonia, nitrate

Aerobic Co-Metabolic

chlorinated solvents

trichloroethylene
dichloroethylene(s)
vinylchloride
chloroform

bromoform

MTBE

HCFCs

high MW PAHs

PCBs

Anaerobic

chlorinated solvents

perchloroethylene
dichloroethane
trichloroethane

aromatics

munitions (TNT)
pesticides

high BOD

PCBs

"Engineering" Solutions for Cometabolic Systems

▸ Process engineering

- reactor configuration
- cosubstrate feed rate
- microorganism recharge

▸ Genetic engineering

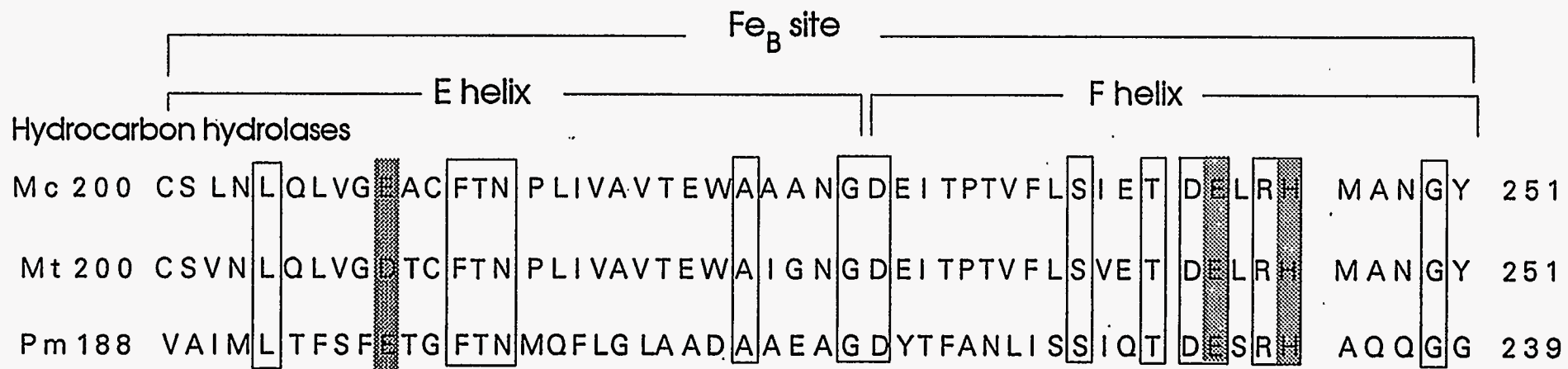
- isolate/clone structural genes only
- uncouple growth from target degradation
- uncouple induction from target degradation

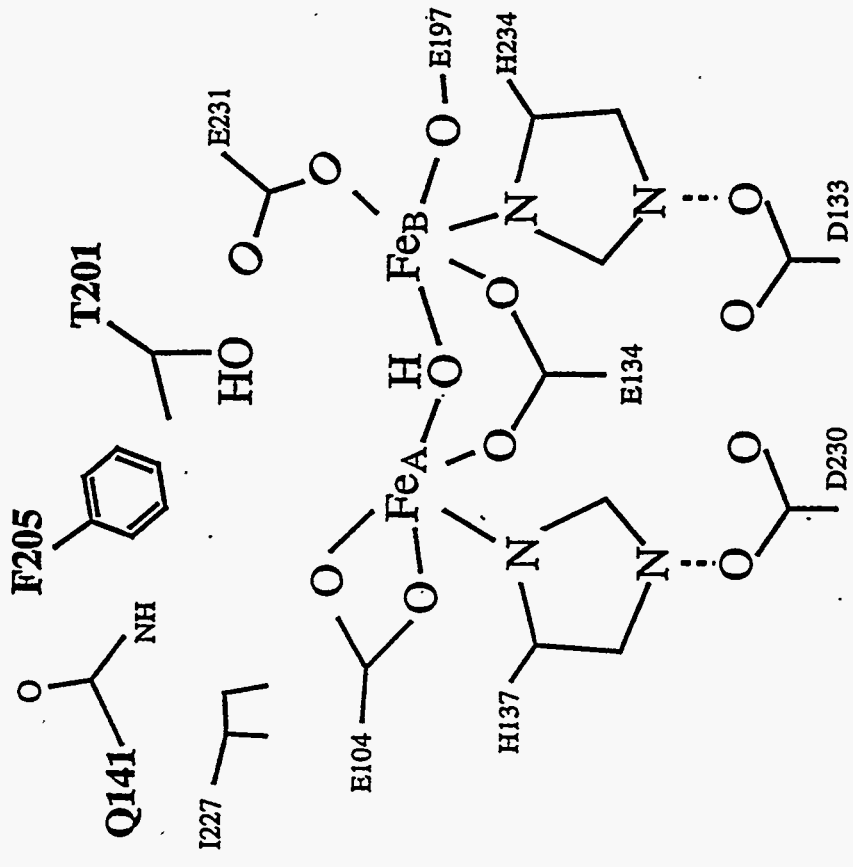


Substrates for TMO and sMMO-Containing Organisms

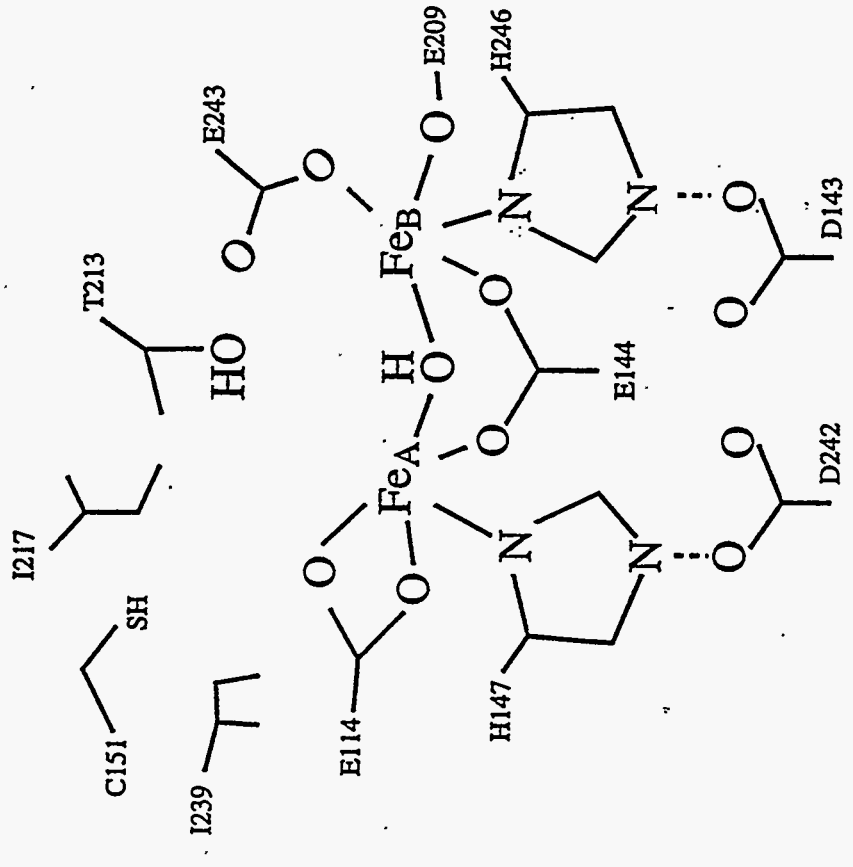
Substrate	<i>P. mendocina</i> (TMO)	<i>M. trichosporium</i> (sMMO)
Trichloroethylene (TCE)	+++	+++
cis-1,2-Dichloroethylene (c-DCE)	+++	+++
trans-1,2-Dichloroethylene (t-DCE)	+++	+++
1,1-Dichloroethylene (1,1-DCE)	---	+++
Vinyl Chloride (VC)	+++	+++
Trichloroethane (TCA)	---	+++
Dichloroethane (DCA)	---	+++
Chloroform (CF)	---	+++
Bromomethane	---	+++
Hydrohalocarbons (HCFC, HFC)	---	+++
Toluene	+++	---
p-Cresol	+++	---
Sugars etc.	+++	---

Molecular Comparison of TMO and sMMO





B. T4MO



A. MMO

I. Biocatalyst Development **(Bioadsorption, Bioconversion)**

- New/Better Activities
 - Xenobiotics
 - Chlorinated Cpds (CCl₄, CHCl₃)
 - MTBE
 - HCFCs
 - CS₂
 - Higher PAHs
- Aerobes/Anaerobes
- Fungi
- Induction of Indigenous Microbes
- Activation
- Consortia vs. Pure Cultures
- GEMs/GMOs
- Cost of Organisms/Fermentation Development
- Enzymes
- Metals (Microbes, Plants)
- Biosurfactants
- Chemotaxis

Technology Directions

II. Systems Development

- In Situ
 - Soil & Groundwater
- Ex Situ (bioreactors)
 - Soil
 - Water
 - Air
- Cometabolism
- Anaerobic

II. Systems Development:

- In Situ


- Intrinsic Bioremediation (Natural Attenuation)
- Biostimulation:
 - Nutrients, Substrates
 - Bioventing
 - Biosparging
- Bioaugmentation:
 - Constitutive Expression
 - Adhesion
 - Energy Storage
- Modeling Subsurface Flow
- NAPLs
- Fracturing
- Electroosmosis (Lasagna Process)
- Bioavailability

BIOCHEMICAL INDICATORS OF INTRINSIC BIOREMEDIATION

- * **DECREASE IN CONTAMINANT CONCENTRATION
NOT ACCOUNTED FOR IN TRANSPORT MODELS
(Adsorption, Desorption, Dilution)**
- * **PRESENCE OF CONTAMINANT-DEGRADING
BACTERIA (higher than in non-impacted wells)**
- * **PERSISTENCE OF NON-BIODEGRADABLE
CO-CONTAMINANTS**
- * **LOW O₂ HIGH CO₂ FOR AREAS IMPACTED BY
THE PLUME**
- * **DEPLETION OF OTHER ELECTRON ACCEPTORS
IN ANAEROBIC PORTIONS OF THE PLUME**
- * **DAUGHTER PRODUCTS NOT RESULTING FROM
CONTAMINATION**
- * **STABLE CARBON ISOTOPES THAT INDICATE
THE CONTAMINANTS AS THE SOURCE OF CO₂**

Hierarchy of Remediation Approaches

I. *In Situ*

1. Intrinsic Remediation/Natural Attenuation
2. Biostimulation
-  3. Bioaugmentation

II. *Ex Situ: Fluids Treatment*

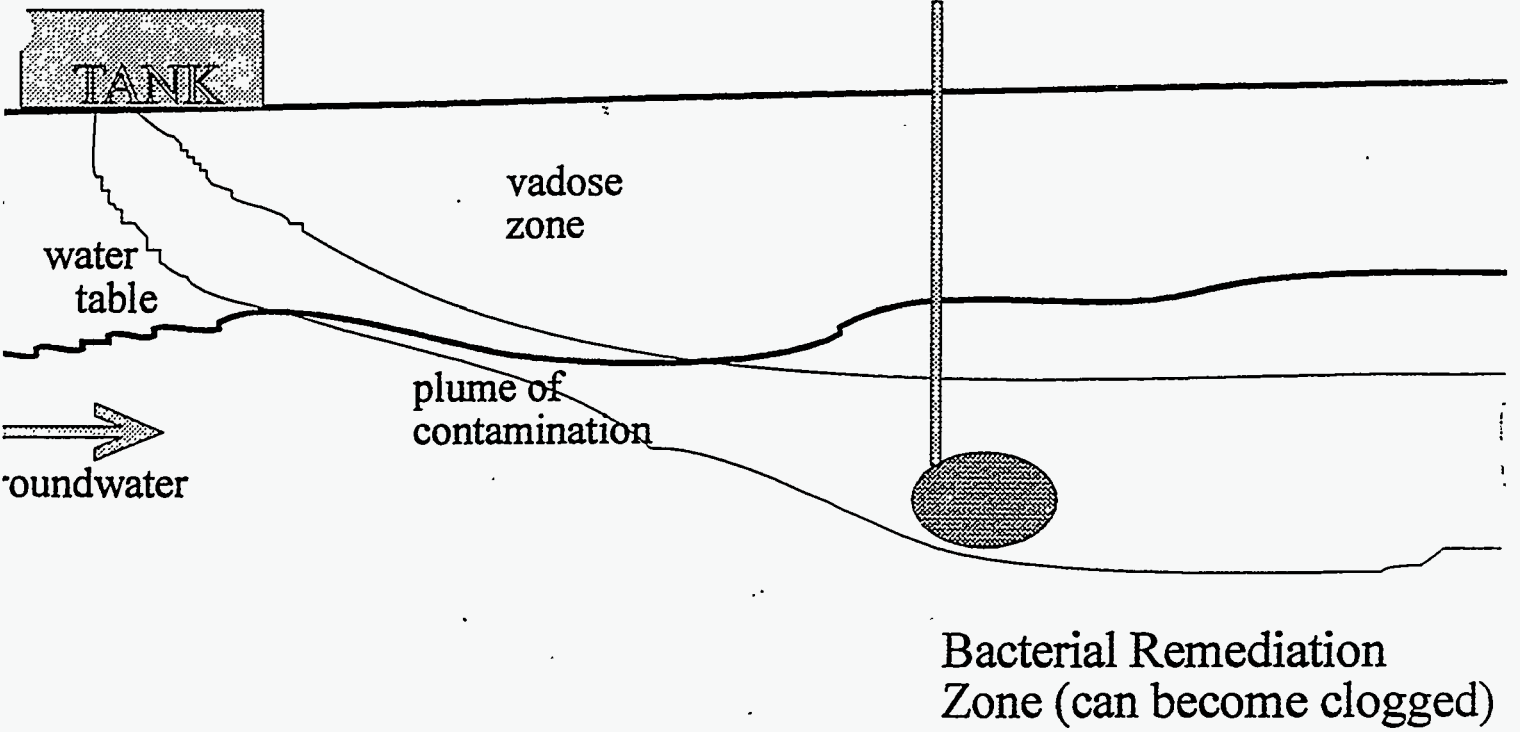
1. Air (SVE, Sparging): Biofiltration
2. Water: Aqueous Phase Bioreactors

III. *Ex Situ: Soil Treatment*

1. Engineered Land Treatment
2. Biopile
3. Slurry Phase Treatment (bioslurry, SoPE™)

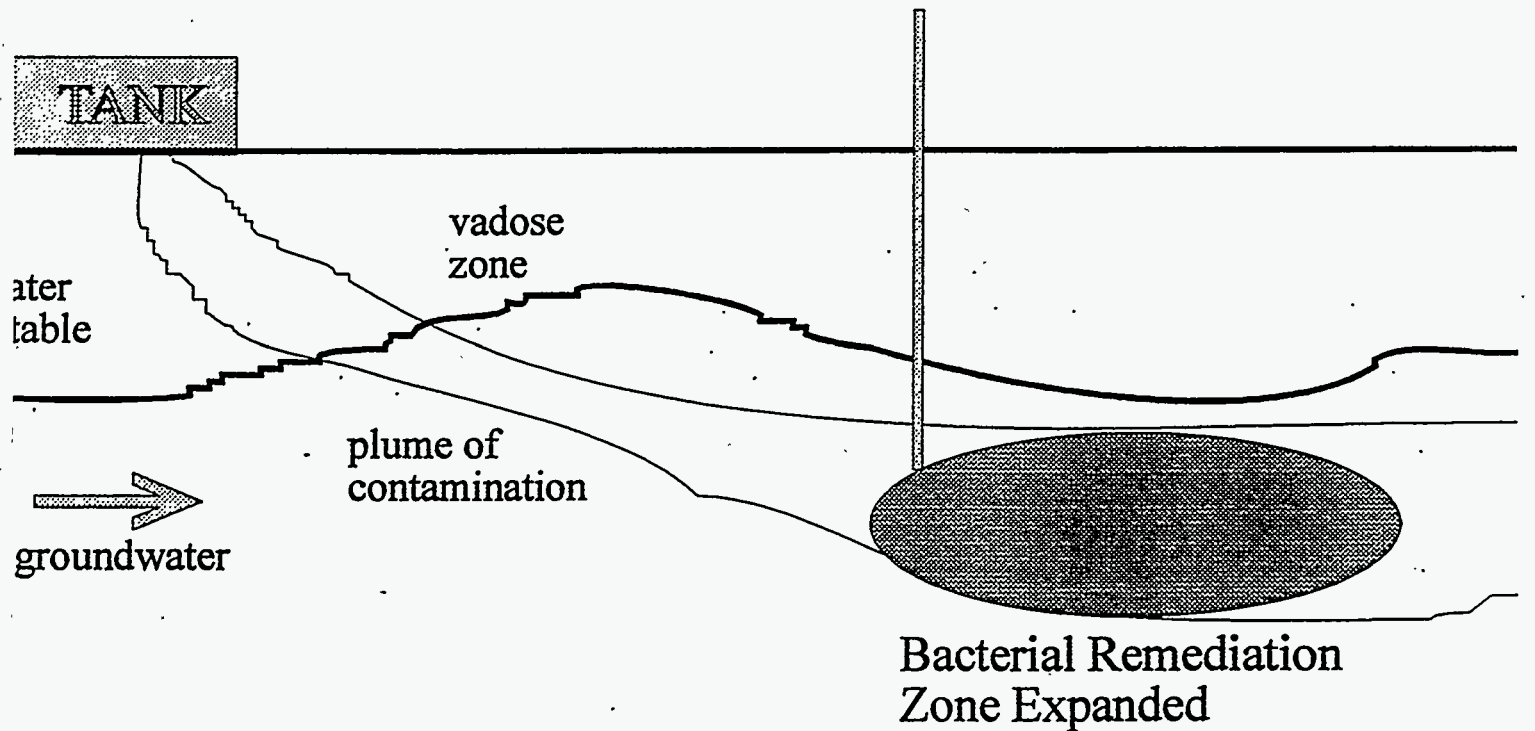
NORMAL INJECTION

INJECTION



ENHANCED TRANSPORT

INJECTION



Enhanced biocatalyst subsurface transport
using non-adherent bacteria

I. Systems Development (cont.):

- **Ex Situ (Bioreactors)**

- Solids:

- Biopile

- Bioslurry

- Engineered Land Treatment ("Land Farming")

- Bioavailability

- Liquids:

- FBR

- MBR

- Anaerobic (UASB, FBR)

- Air:

VI. Systems Development (cont.):

- Ex Situ (Bioreactors)

- Solids:

- Liquids:

- Air:

 - Biofilters

 - Biotrickling Filters

 - Bioscrubbers

 - Membrane Bioreactors

 - Process Parameters:

 - Packings, Bed Life

 - Process Control

 - Chlorinated Targets (pH, Cost)

 - Biomass Control

 - Cometabolic Targets

 - Uneven Distribution

 - Gaseous Nutrients (NH₃, N₂O,
TEP)

 - Mixtures (Sol. w/Insol.)

 - Mass Transfer/Contact Time
Limit

Technology Directions

III. Establishing Reasonable Regulatory Targets

- Why 99.9999% Degradation?

What is Zero ?

There are a lot of molecules in a mole !

- "nano pure"
- "pico pure"
- "femto pure"
- "atto pure"

Technology Directions

III. Establishing Reasonable Regulatory Targets

- Risk Assessment Tools & Models
- Technical Foundation for Risk-Based Decisions
- Cost-Benefit Analysis
- Bioavailability Issues (friend or foe !)
- Clean-Up Goals
 - Mineralization or not
 - Biostabilization
 - Humification/Bioimmobilization (TNT, PAH)
 - Intrinsic Bioremediation
 - Environmentally Acceptable Endpoints (E.A.E)

IV. Monitoring & Documentation

- Monitoring Tools:
 - Reporter Genes
 - Biosensors
 - DNA Probes (rDNA, structural genes)
 - DNA Fingerprints
 - mAb
 - Fatty Acid Analysis
 - Subsurface Respiration
 - $^{12}\text{C}/^{13}\text{C}$ Isotope Ratios ($^{35}\text{Cl}/^{37}\text{Cl}$)
- Treatability Protocols
- Analytical Protocols
 - TCLP ? AMES ? Microtox ?
- Goals
 - Cost-Effectiveness
 - Reliability
- Corporate, Govt., Public Acceptances
 - Generally Accepted Technology
 - No Resistance (eg., Incin., Landfilling)

Technology Directions

- I. Biocatalyst Development
(Bioadsorption, Bioconversion)**

- II. Systems Development**

- III. Establishing Reasonable Regulatory
Targets**

- IV. Monitoring & Documentation**

ENVIROGEN'S BUSINESS DIVISIONS

Pollution
Control

Remediation

1) Remediation Services

- subsurface
- soil, sediment

2) Water Treatment Systems

- groundwater
- industrial wastewater

3) Air Treatment Systems

- industrial VOCs,
- soil vent gas

EVOLUTION OF THE ENVIRONMENTAL BUSINESS

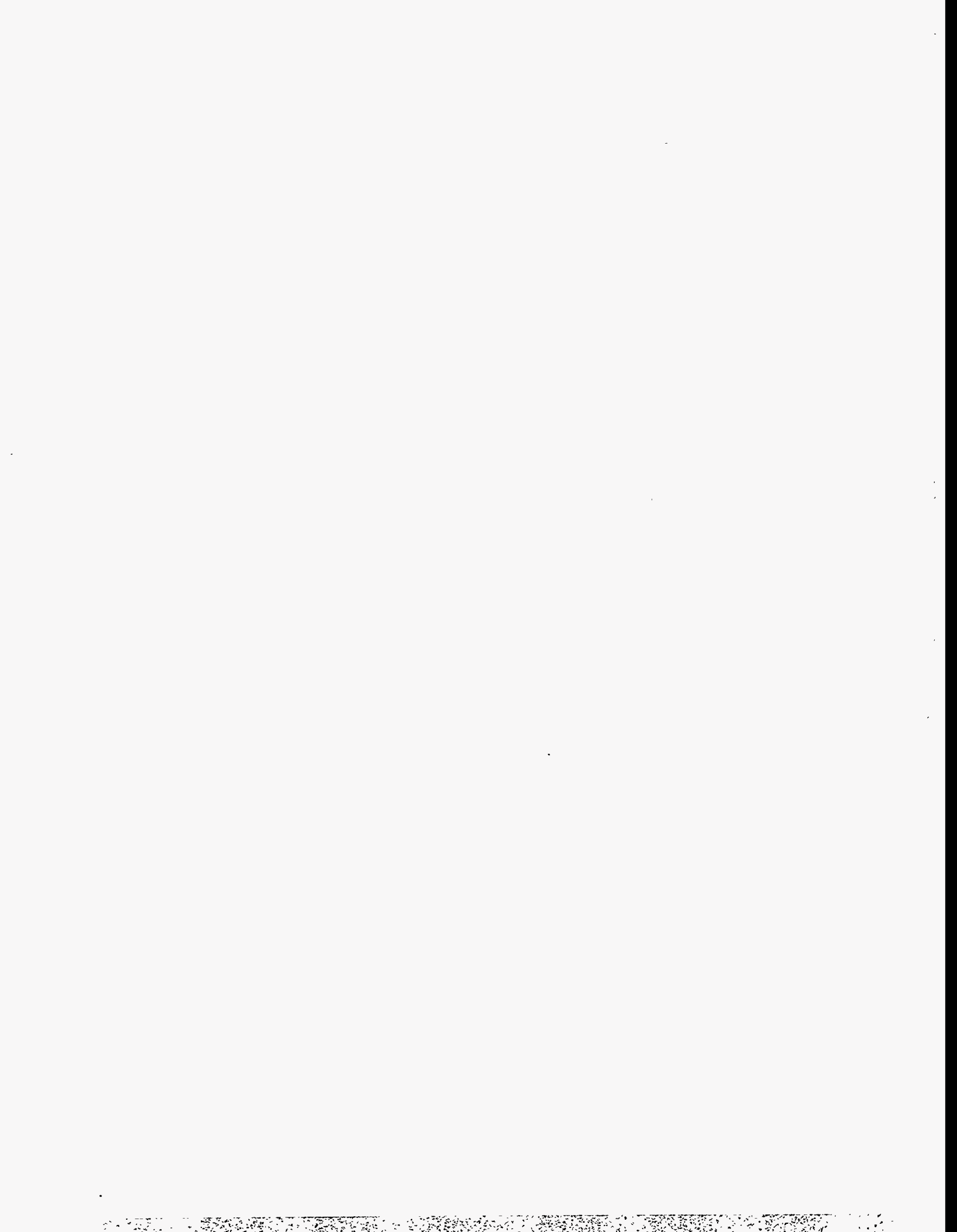
80's — HOW I CAN SAVE YOUR NECK

90's — HOW I CAN SAVE YOU MONEY

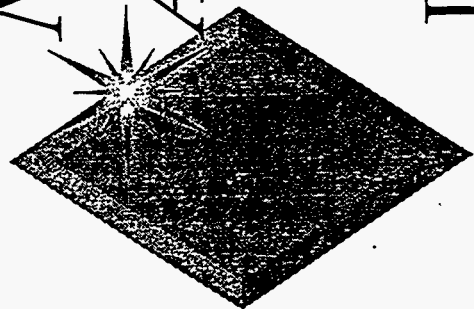
- BIOREMEDIATION
- BIOTREATMENT PROCESSES FOR WATER/AIR

2000⁺ — HOW I CAN MAKE YOU MONEY !

- BIOCONVERSIONS
- VALUE ADDED CLEAN-UPS

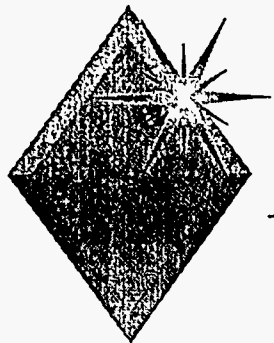


*NABIR: Potential Industrial
Applications*



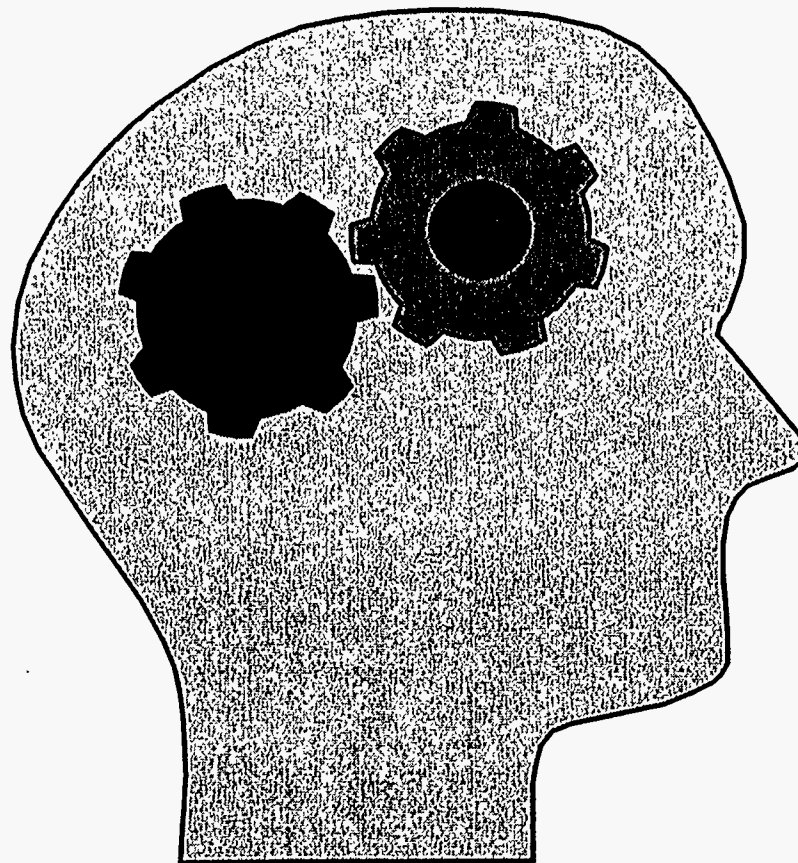
Jennie C. Hunter-Cevera

*
...to provide the scientific understanding
needed to harness natural processes and to
develop methods to accelerate these
processes for the bioremediation of
contaminated soils, sediments and
groundwater at DOE facilities.



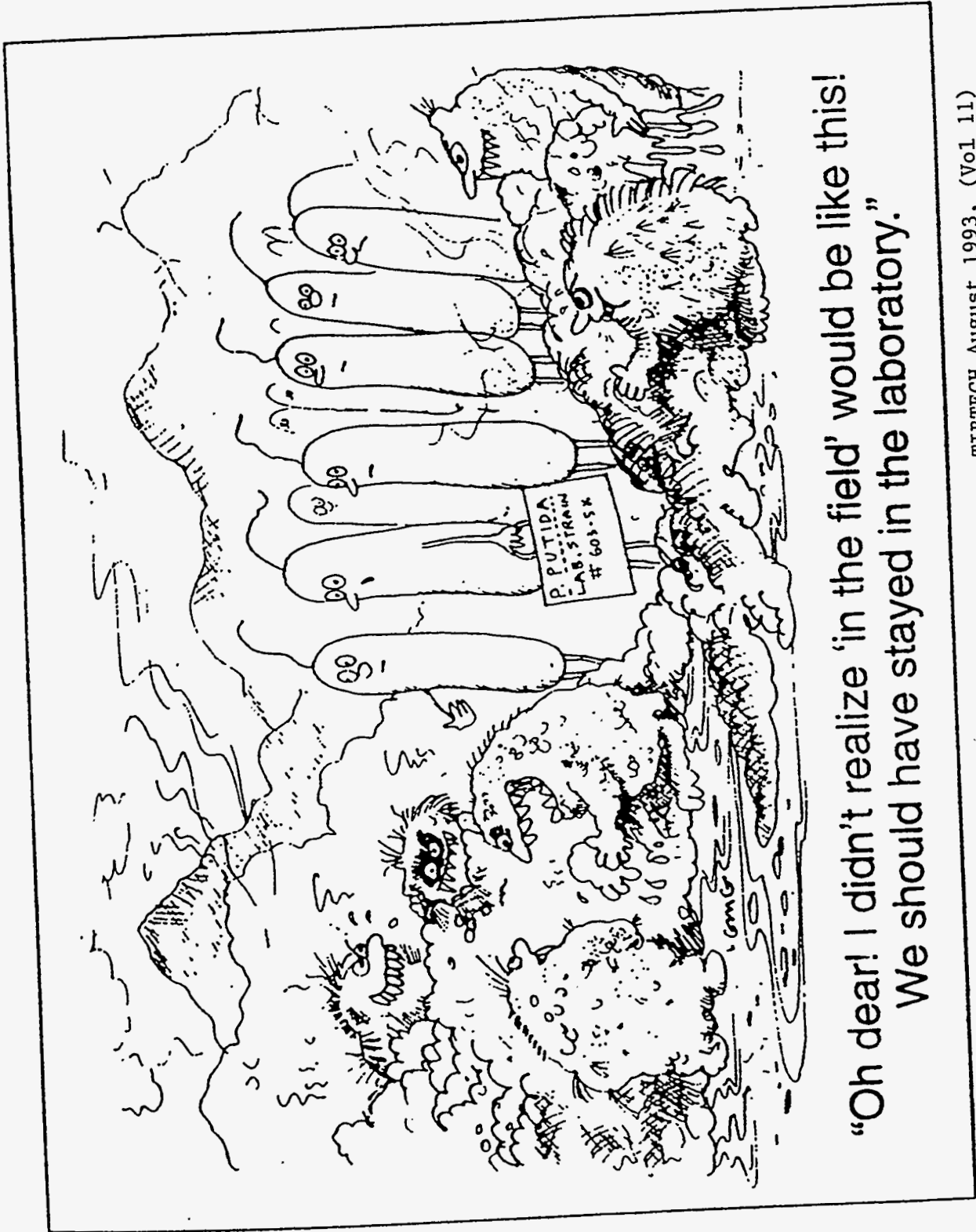
NABIR

- ◆ Providing new solutions to old problems
- ◆ Providing new technology for industry and biotechnology



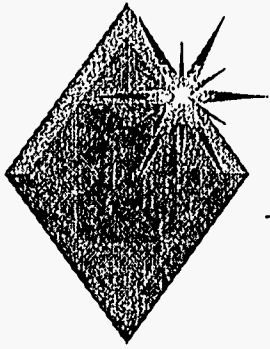


From:
"Biotechnology: Microbes & the
Environment", Center for Science Information,
1990



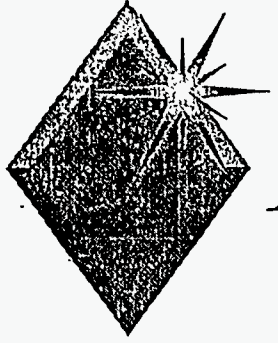
“Oh dear! I didn’t realize ‘in the field’ would be like this!
We should have stayed in the laboratory.”

TIBTECH August 1993, (Vol 11)
Lui and Sufliya



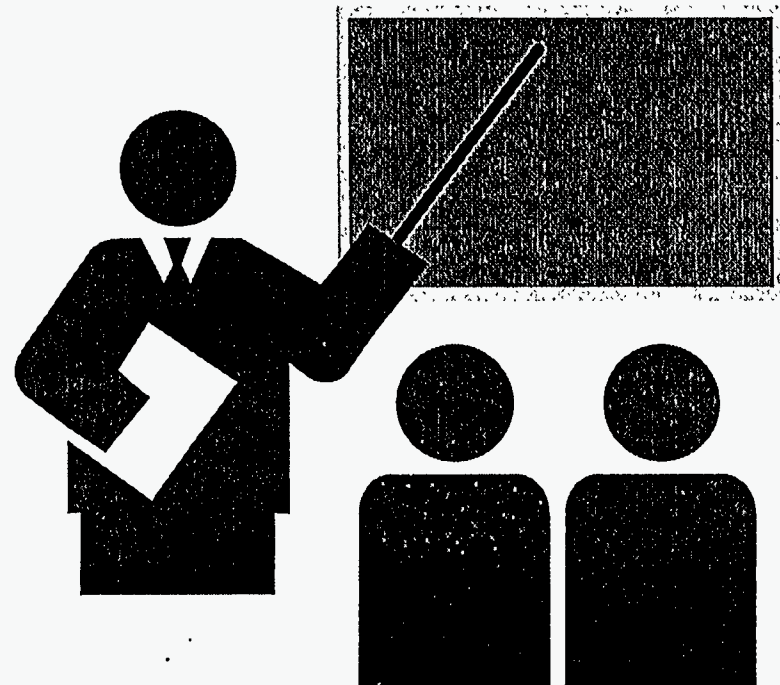
NABIR Strengths

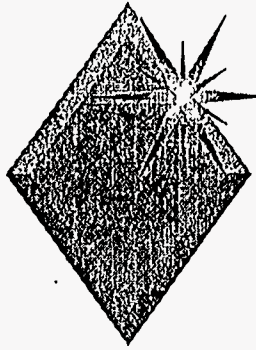
Scientific Leadership	Scientific Team	“Real World Problems”
Experience of previous DOE research programs	Integration of scientific disciplines	Experienced Program Managers
Field Research Centers	Network in Place	Partnerships for Enablement



NABIR AND SCIENCE

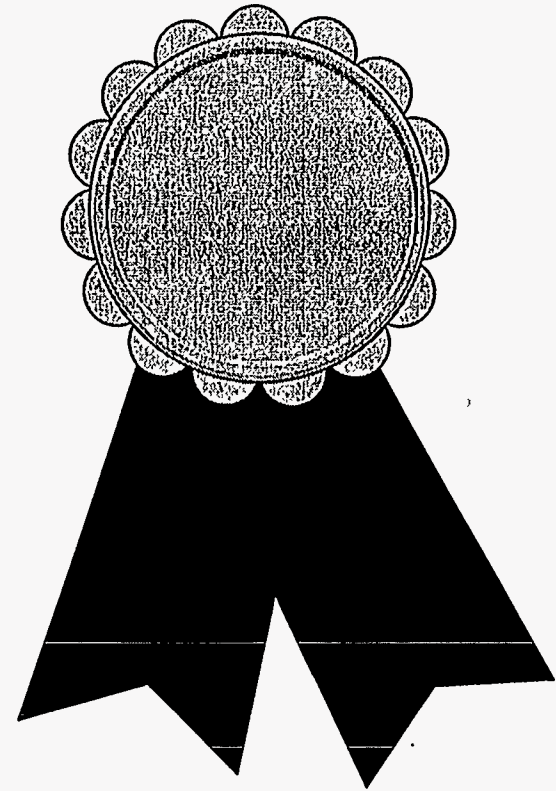
- ◆ Education
- ◆ Science
- ◆ Outreach
- ◆ Public Perception
- ◆ Stakeholders

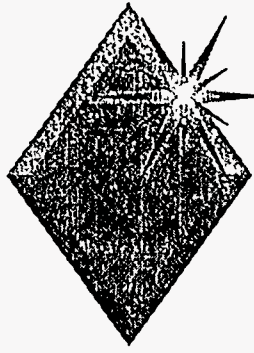




NABIR Customer Requirements

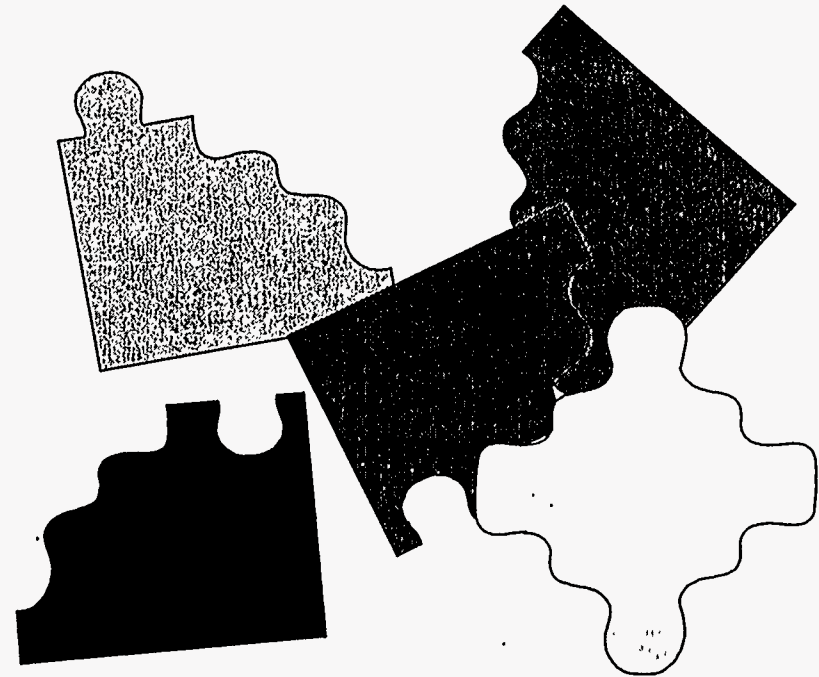
- ◆ Cheaper
- ◆ Faster
- ◆ Better
- ◆ Reproducible
- ◆ Validation
- ◆ Certification

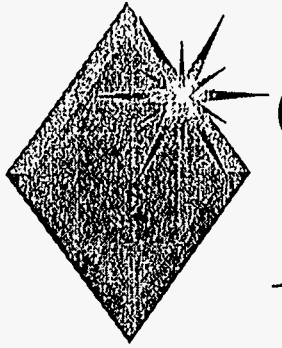




Biodegradation and Biotransformation

- ◆ Biocatalysis
- ◆ Novel pathways
- ◆ Novel molecules
- ◆ Improved bioreactor process design
- ◆ New down-stream processing techniques

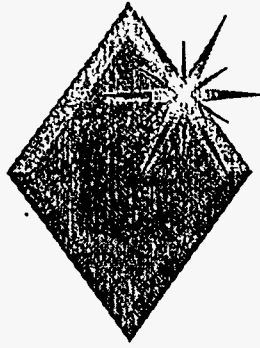




Community Dynamics and Microbial Ecology

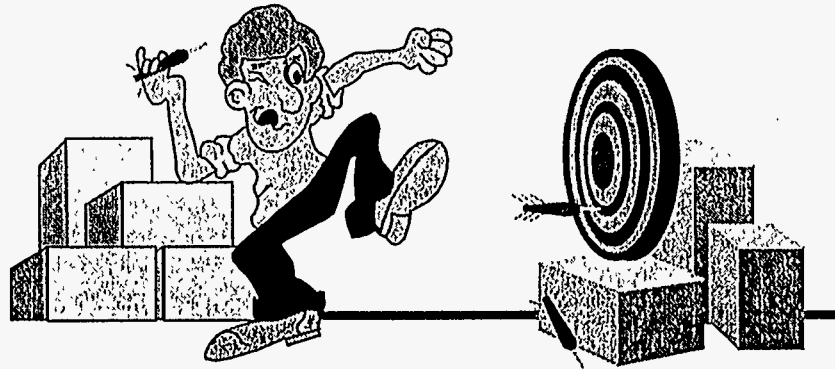
- ◆ Novel isolation methods
- ◆ Novel microorganisms
- ◆ Resistant microorganisms
- ◆ Stress recognition and response
- ◆ Regulatory functions

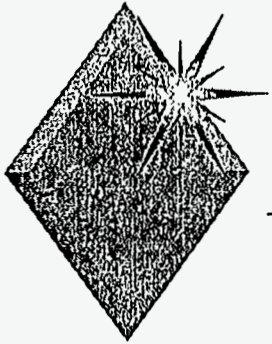




Biomolecular Science and Engineering

- ◆ Molecular structure/function
- ◆ Pathway engineering
- ◆ Cell-free systems
- ◆ Activity enhancement
- ◆ Improved large scale recombinant processes

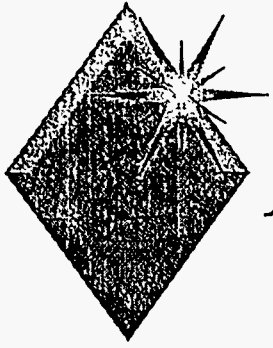




Biochemical Dynamics

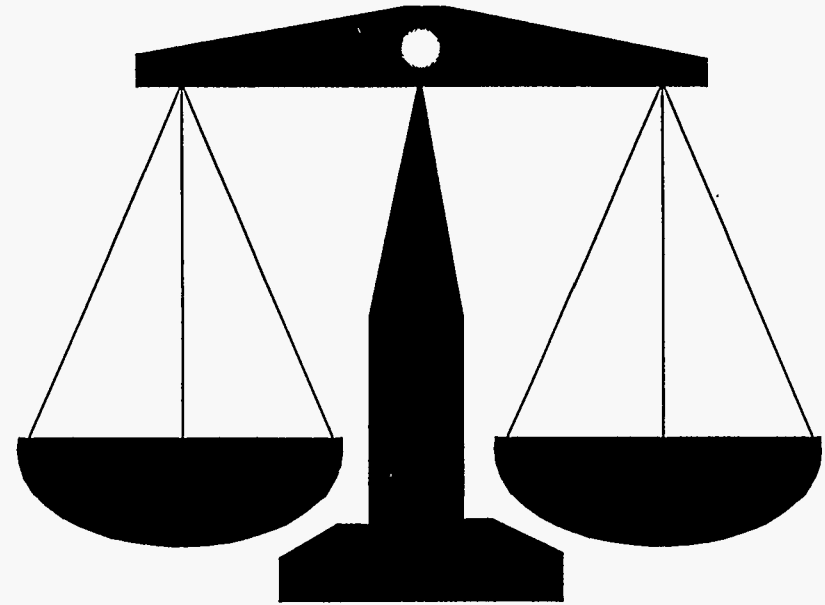
- ◆ Factors affecting nutrient uptake
- ◆ Cell surface chemistry
- ◆ Biodiversity
- ◆ Metal-cell interactions
- ◆ Sequestration phenomena

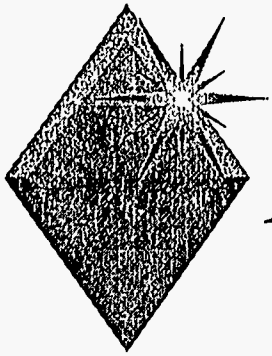




Assessment

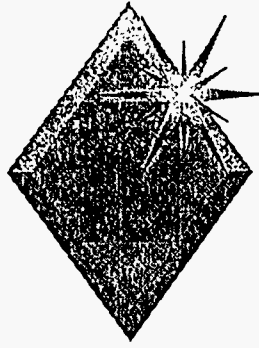
- ◆ Diagnostics
- ◆ Novel monitoring methods
- ◆ Improved characterization tools
- ◆ Validation of existing and new technology
- ◆ Improve health risk assessment





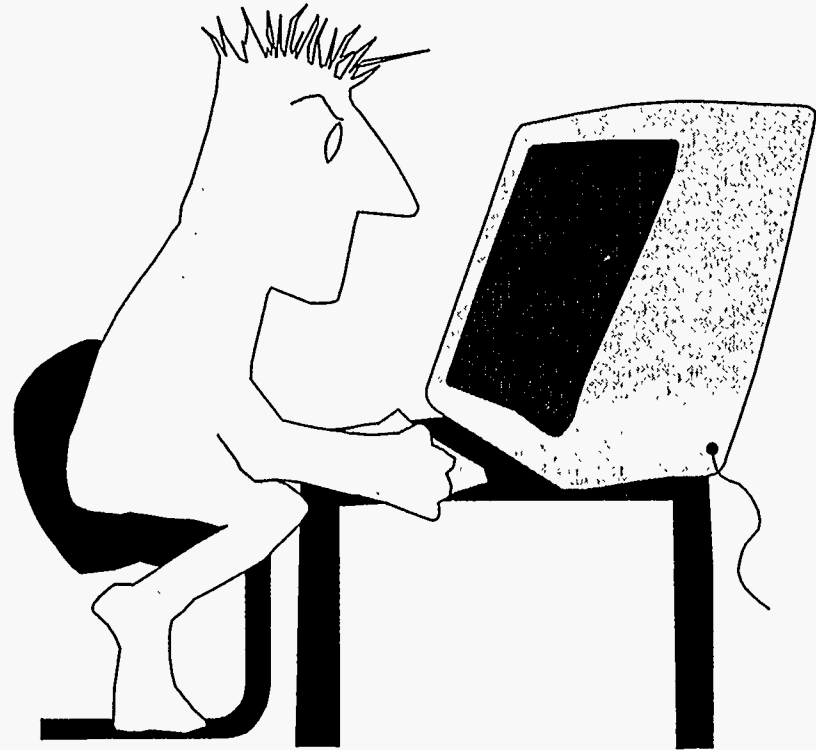
Acceleration

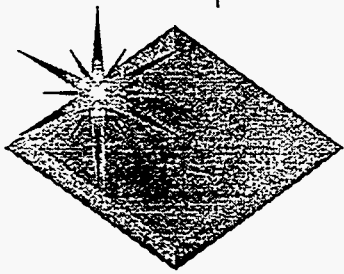
- ◆ Improved microbial processes
- ◆ Improved delivery systems
- ◆ Improved biostimulation and bioaugmentation



System Integration, Prediction and Optimization

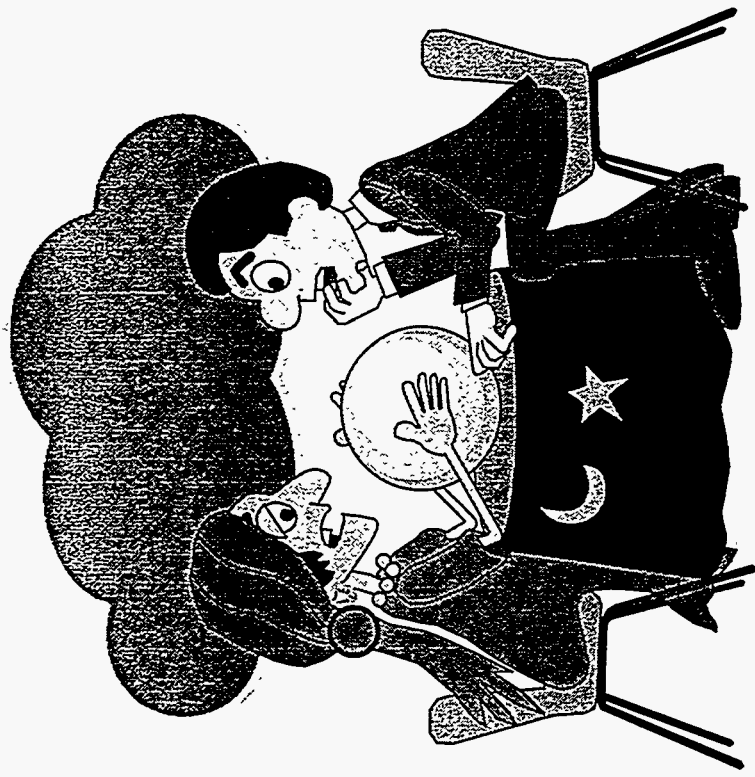
- ◆ Improved mathematical models
- ◆ Improved data bases
- ◆ Improved statistical models for integration
- ◆ Validation of scale-up models

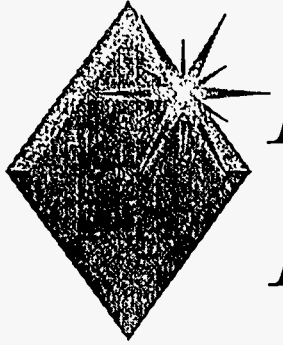




Beyond NABIR

- ◆ Agriculture
- ◆ Pharmaceuticals
- ◆ Diagnostics
- ◆ Chemical Commodities
- ◆ Mining
- ◆ Environmental Restoration

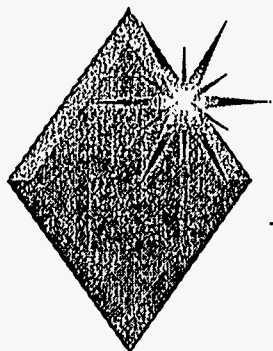




Demand and Need for Enzymes

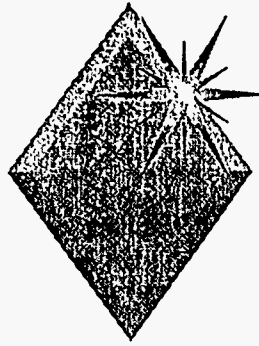
- ◆ “Annual world sales of enzymes exceed \$1.0 billion (US); and the market is growing at a rate greater than 10% per year with specialty enzymes increasing two fold faster than industrial enzymes.”

◆ J. G. Zeikus, 1966



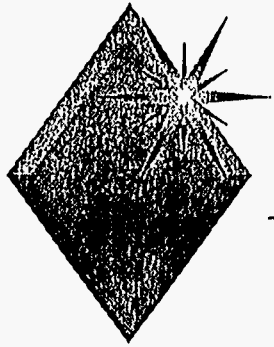
Enzyme Categories

Food Processing	Therapeutics and Diagnostics	Fine and Speciality Chemicals
Textiles	Wood Pulp and Paper	Detergents



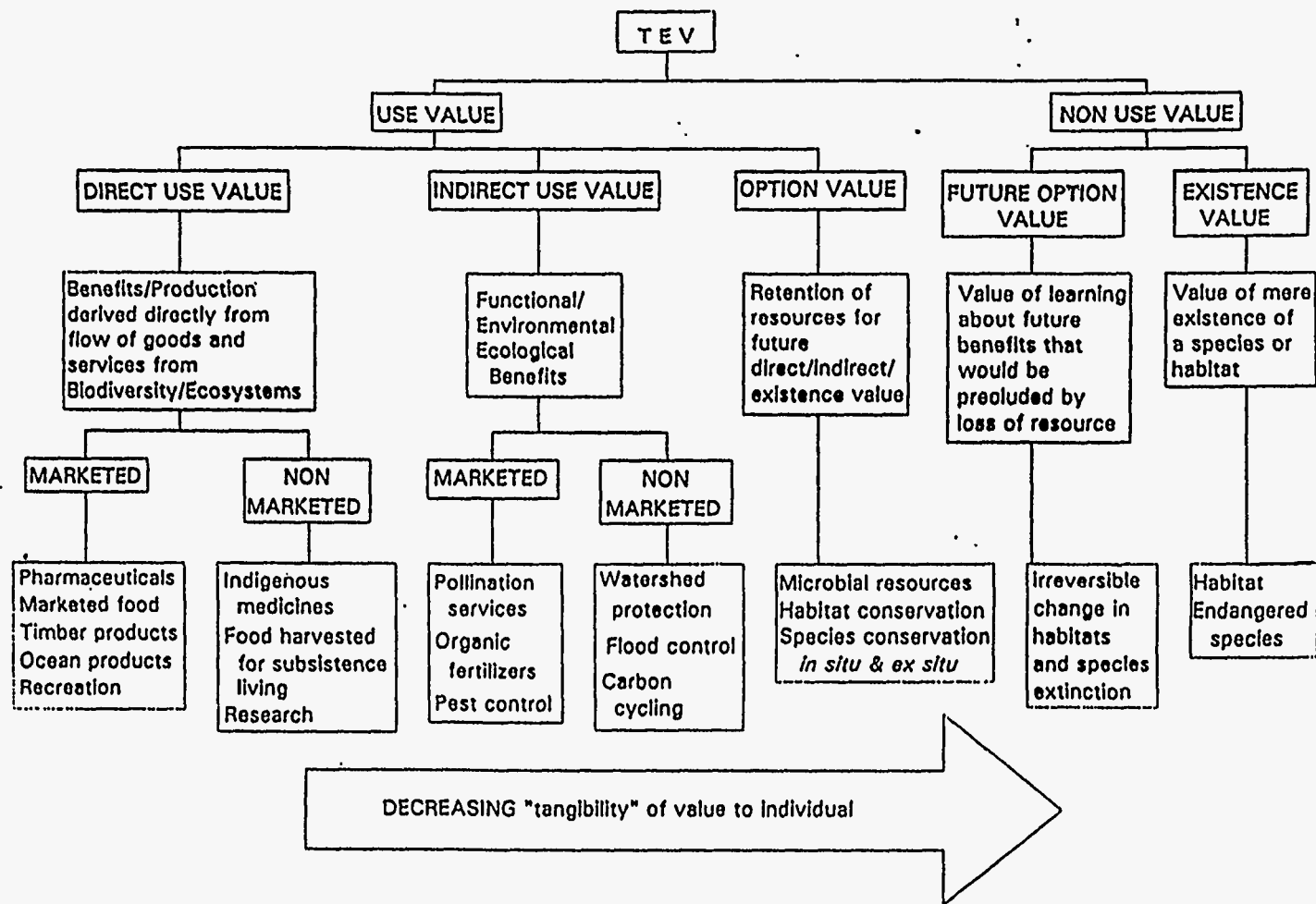
Numbers of enzymes identified and commercially available

Enzyme Type	Identified	Com. Avail.
Oxido - reductase	650	90
Transferase	720	90
Hydrolase	636	125
Lyase	255	35
Isomerase	120	6
Ligase	80	5



Potential of Biotechnology

- ◆ The success and potential of biotechnology relies on the diversity of microorganisms and the diversity of the molecules they produce as a result of primary and secondary metabolism and on the conservation of the genetic resource they provide.



DIRECT USE VALUE

Benefits/Production derived directly from flow of goods and services from Biodiversity/Ecosystems

MARKETED

Pharmaceuticals
Marketed food
Timber products
Ocean products
Recreation

NON MARKETED

Indigenous medicines
Food harvested for subsistence living
Research

INDIRECT USE VALUE

Functional/ Environmental Ecological Benefits

MARKETED

Pollination services
Organic fertilizers
Pest control

NON MARKETED

Watershed protection
Flood control
Carbon cycling

OPTION VALUE

Retention of resources for future direct/indirect/ existence value

Microbial resources
Habitat conservation
Species conservation
in situ & ex situ

FUTURE OPTION VALUE

Value of learning about future benefits that would be precluded by loss of resource

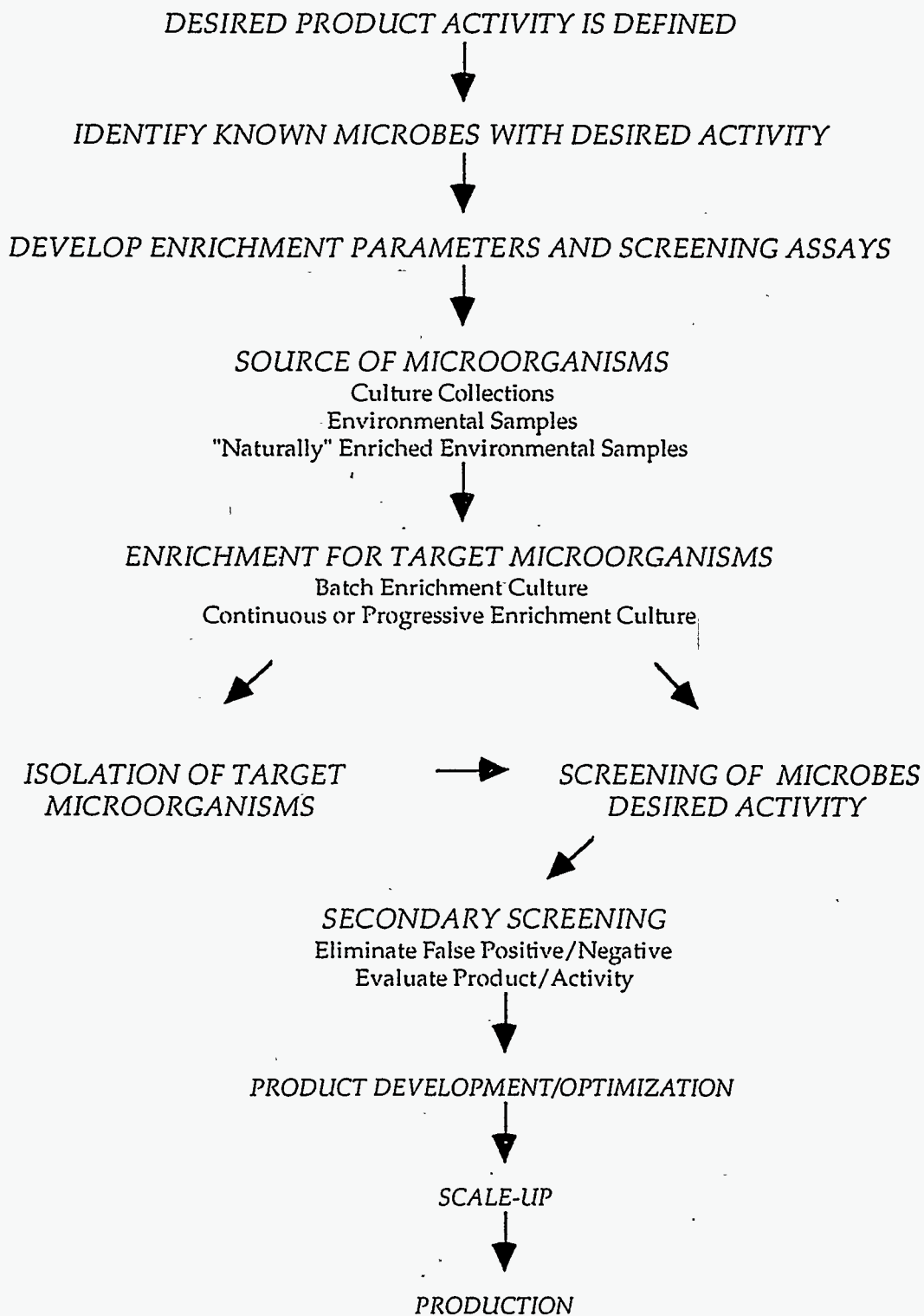
Irreversible change in habitats and species extinction

EXISTENCE VALUE

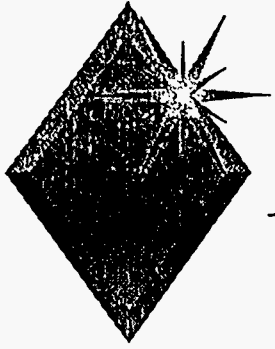
Value of mere existence of a species or habitat

Habitat
Endangered species

DECREASING "tangibility" of value to individual



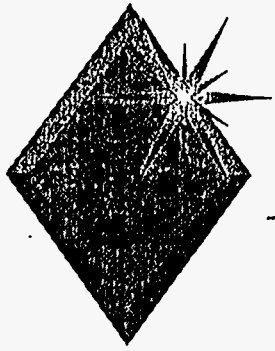
General schematic of an industrial screening program.



Key Benefits

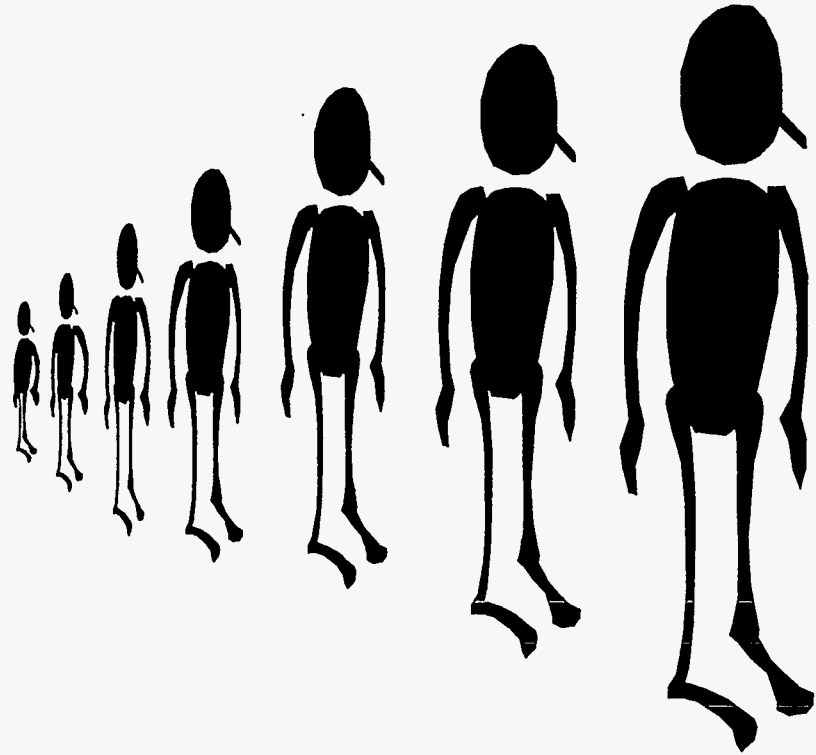


- ◆ Integrates a variety of scientific disciplines that will lead to advances in understanding the how, when, what, who and why of bioremediation.
- ◆ From these data, many applications can be transferred to other research fields.
- ◆ Overall quality of life improves with respect to health, environment and lifestyle.



NABIR: Next Steps

- ◆ Marketing of NABIR
- ◆ Academic,
government and
industry involvement
- ◆ Intra and extra federal
agency collaboration
- ◆ Publication of research
results
- ◆ Technology Transfer



**PARTNERSHIP WITH THE PUBLIC: A
KEY TO ACCEPTANCE OF
INNOVATION**

Eve Bach
Staff Economist/Planner
July 18, 1996

Arc Ecology

833 Market Street, Suite 1107, San Francisco, CA 94103
Tel: (415) 495-1786 Fax: (415) 495-1787 E-mail arc@jgc.apc.org

WHO IS THE PUBLIC?

- **All of us in some sense**
- **A role that everyone gets to play, depending on the issue**

ON ISSUES OF ENVIRONMENTAL REMEDIATION

- **Spatially concentrated (high exposure to potential problems)**
- **temporally diffuse (spread over future generations)**

**THE PUBLIC IS INTERESTED AND EXCITED
ABOUT THE PROMISE OF BIO-REMEDIATION
INNOVATIONS**

- **To solve intractable problems**
- **To restore a healthy environment**
- **Hoping that technological innovation can restore as well as degrade the environment**
- **understanding that savings are likely to be capitalized in the land values**

WHAT ARE WE CONCERNED ABOUT?

1. Risk of failure

- **ineffectiveness**
- **wastefulness and foregone opportunities**
- **creation of new problems**

2. Unknowns

- **scientific**
- **economic**

3. Skepticism Based on Past Experiences

- **communities used as laboratories without their consent**
- **unfulfilled promises**

4. Anger about the contamination

LOSS OF CONFIDENCE IN INSTITUTIONS RESPONSIBLE FOR ENSURING SAFETY

- **Sobering experience of former Soviet Union (toxics outlasted the institutions responsible for the public's safety)**
- **Defunding of government enforcement agencies (USEPA)**
- **Weakening of local government (usually responsible for overseeing restrictions on future use such as deed restrictions)**

**1. ENVIRONMENTAL BIO-REMEDIATION
INNOVATIONS ARE TESTED IN COMMUNITIES.**

2. IMPLEMENTATION TAKES A LONG TIME;

**3. SAFETY OVER THE LONG HAUL ASSUMES A
DURABLE AND STRONG INSTITUTIONAL
INFRASTRUCTURE**

- **to ensure that implementation over time is consistent with design**
- **to monitor over time to detect and correct unexpected problems**
- **to ensure that the original pollution problem is solved on sites where innovative technologies and techniques do not work the first time around**

**SCIENTISTS MUST ADDRESS THE SOCIAL
INSTITUTIONS NEEDED FOR SAFE
IMPLEMENTATION**

- **Suggests the need to build partnerships with communities to enable them to “co-own” the projects**
- **Necessitates reconceptualizing the role of the public**

CURRENT MODELS OF PUBLIC PARTICIPATION

- **Models from the past do not go far enough**

**traditional reliance on the rubric of national defense
to muster public support**

**SuperFund Technical Assistance Grants: good idea,
inadequate funding**

**Restoration Advisory Boards: usually limited to
after-the-fact review**
- **NABIR Model**

**early identification of ethical, legal and social
issues at beginning of the process**
- **EPA Guidelines**

1-way communication

**equates public outreach with information
dissemination**

THE ROLE OF THE PUBLIC PARTNER IN BIO-REMEDIATION INNOVATION

- **Focus on values and judgment issues (e.g., tradeoffs between time, money, and certainty)**
- **Develop comfortable fit between a project and the culture of the host community**
- **Determine acceptable levels and incidence of risk**

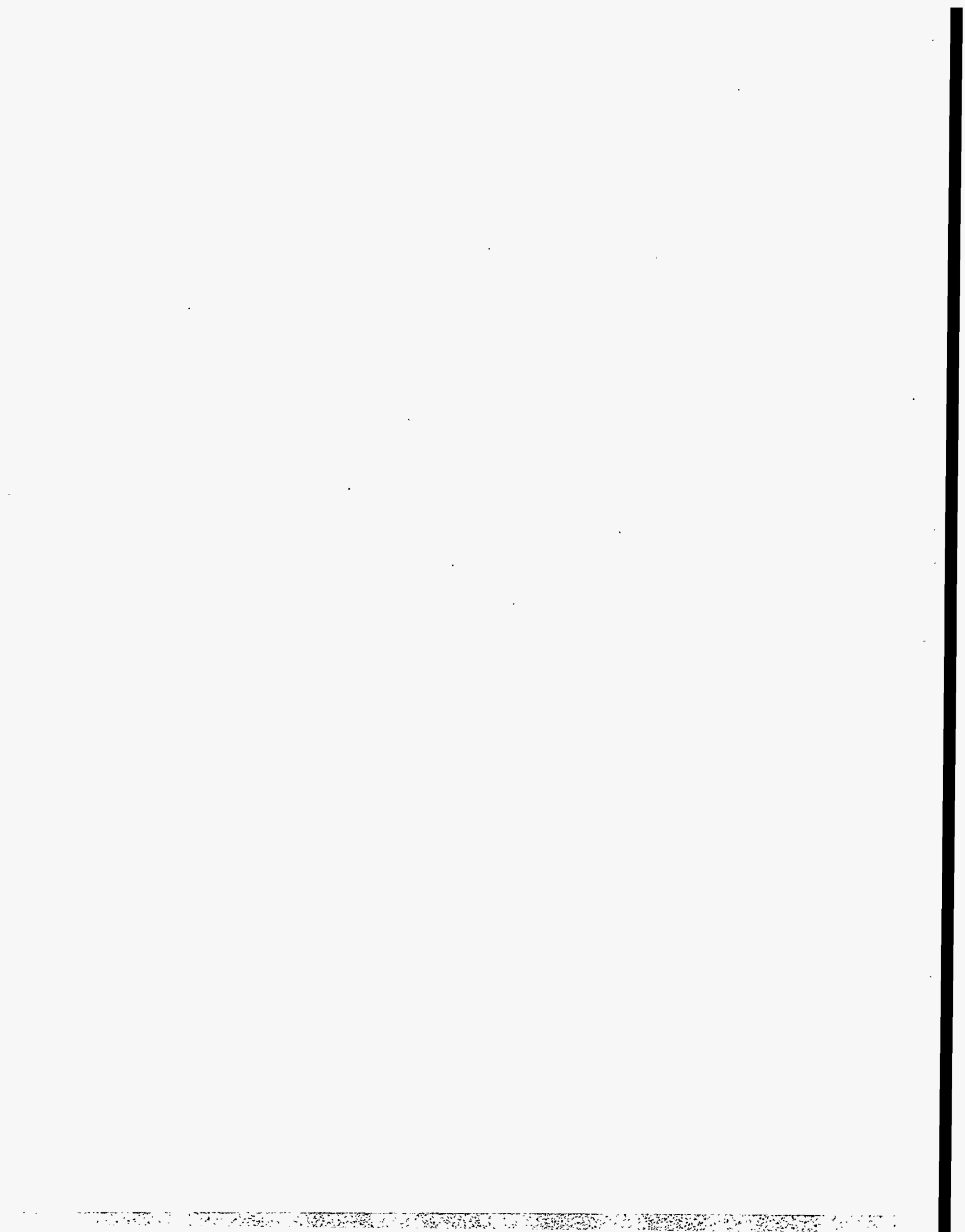
**REQUIRES SCIENTISTS TO OPEN UP PROJECT
DECISIONMAKING TO THE PUBLIC, ENGAGE IN
JOINT PROBLEM SOLVING**

PRELIMINARY SUGGESTIONS FOR BASIC

- 1. Embed public participation into the problem identification phase.**
- 2. Require prospective field research center sites to team with community partners in order to be considered in the competitive selection process.**
- 3. Enable communities to have their own technical consultants participate in peer review and development of performance measures.**
- 4. Fully develop a “failure scenario” (persuading communities that the scientist is their friend requires innovators to stay with the contamination problem until it is solved, not just long enough to learn whether their ideas work).**
- 5. Provide contingency funding to recover from failures.**
- 6. Require projects to spell out and monitor long term institutional infrastructure needs as part of project design.**
- 7. Identify and strengthen community institutions, including public interest. organization that have a track record of commitment to long term community needs.**

CONCLUSIONS

- **Responsibility is fragmented for ensuring the long term safety of biotech environmental remediation; scientists do not control the social infrastructure that implement their projects over the long term.**
- **Communities can only give their informed consent to the risks inherent in innovation if they understand their long term responsibilities to monitor and enforce safety measures.**
- **Partnerships between scientists and the public in which they “co-own” projects are key to integrating the social and research systems needed to support environmental remediation innovations.**
- **The alternatives are blanket rejection of innovation or uncritical acceptance (usually followed by a profound sense of betrayal when problems emerge).**



**Field-Scale R&D at DOE Sites:
Ten Years of Lessons Learned**

**Gary K. Jacobs
Environmental Sciences Division
Oak Ridge National Laboratory**

**NABIR *BASIC* Workshop
July 1996**

In Situ Technology R&D

- **In Situ Vitrification**

- ⇒ 1986 through present at ORNL

- **Deep Soil Mixing**

- ⇒ 1991 through present (Portsmouth & Kansas City Plant)

- **Reactive Barriers**

- ⇒ 1996 through present at Elizabeth City, NC & Oak Ridge Y-12

- **Groundwater Tracer Research**

- ⇒ 1986 through present at contaminated and uncontaminated ORNL sites

In Situ Vitrification

- **1987 “Cold” Test**

- ⇒ **Pre-CERCLA**
- ⇒ **Environmental restoration funded R&D for development of technology based on needs**
- ⇒ **Science-directed R&D schedule**
- ⇒ **“Cold” test, no radioactive material**
- ⇒ **Scientists “controlled” the site**
- ⇒ **Little public interest**
- ⇒ **ESH oversight minimal**

- **Project objectives met on schedule**

- ⇒ **Common goals & schedule**
- ⇒ **PI lead responsibility & authority**

In Situ Vitrification

● **1991 “Luke-Warm” Test**

- ⇒ **CERCLA Treatability Study**
- ⇒ **EM40 + EM50 + ER/OBES Funding (basic research)**
- ⇒ **Science-directed R&D schedule with some constraints from future ROD’s; OBES: “We will not impact the schedule.”**
- ⇒ **Small amount of radioactive material placed into ground for test**
- ⇒ **Scientists worked *with* compliance staff**
- ⇒ **Significant public interest (largely positive)**
- ⇒ **ESH oversight substantial**

● **Project objectives met on schedule**

- ⇒ **EM PI and OBES PI worked closely together**
- ⇒ **Science philosophy, not construction management**
- ⇒ **Nurtured existing relationships**

In Situ Vitrification

- **1996 “Hot” Test**

- ⇒ **CERCLA Treatability Study!!!**
- ⇒ **Cleanup-driven schedule**
- ⇒ **Actual waste site with large amount of radioactive material**
- ⇒ **Compliance staff “controlled” the site with scientists working issues**
- ⇒ **Major public interest (largely negative)**
- ⇒ **Substantial regulatory oversight (state & EPA)**

- **Project objectives not met on schedule (combination of ESH and technical difficulties)**

- ⇒ **Construction management approach**
- ⇒ **ESH success from “staged” approach to approvals**

Deep Soil Mixing

- **1992 full-scale field demonstration at Portsmouth, OH**
 - ⇒ Actual contaminated site (VOC primary target)
 - ⇒ Major interest from EM40 to collaborate with EM50 (co-funded)
 - ⇒ Significant ESH issues, but resolved on schedule
- **1996 Kansas City Plant Demonstrations (on-going)**
 - ⇒ EM40 stakeholder co-funding with EM50 TCE degradation
 - ⇒ KMnO_4 , CaO , and bioremediation
 - ⇒ Significant ESH issues from state and EPA
- **Project objectives met on schedule**
 - ⇒ Nurtured existing relationships
 - ⇒ Stakeholders directly involved
 - ⇒ Effective communication with regulators

Reactive Barriers

- **Elizabeth City, NC (1996)**
 - ⇒ EPA-DOE-Industry (RTDF) site
 - ⇒ Cr primary target
- **Y-12 Plant**
 - ⇒ Acetone, PCE, NO₃, uranium
 - ⇒ EM40 site with major regulatory drivers
 - ⇒ EM50 collaboration initiated 1996 to benefit Y-12 and technology development
 - ⇒ EM40 and compliance control of project
- **Schedules shall be met, R&D objectives ???**
 - ⇒ Negotiations on control of project directions (EM40 control versus collaboration with EM50)

Groundwater Tracer Research

- **Bear Creek Valley Site (Uncontaminated)**

- ⇒ Test area for fractured porous media transport research
- ⇒ Installation of wells and monitoring equipment
- ⇒ Injection of tracers (dyes, INA bacteria, fluorescent microspheres, and DNA-tagged microspheres)
- ⇒ ESH and compliance not a big issue

- **Success**

- ⇒ Researchers also “stakeholder” of site
- ⇒ Early communication with ESH staff and regulators

Groundwater Tracers

- **Melton Valley Tracer Site (contaminated)**


- ⇒ ^3H , ^{90}Sr , TRU, VOC contaminants
- ⇒ EM40 site (lower priority)
- ⇒ EM40-funded R&D to resolve specific needs
- ⇒ Installation of wells and monitoring equipment
- ⇒ Injection of tracers (noble gases, Br^-)
- ⇒ ESH and compliance significant, but not major hurdle

- **Success**

- ⇒ Stakeholder directly involved
- ⇒ Nurtured ongoing relationships

Lessons Learned

- **Many changes over 10 years!**
- **NABIR planning has already addressed many issues**
- **Early contact and continued communication with site stakeholders**
 - ⇒ **Identify stakeholders' measure of success**
 - ⇒ **State and EPA buy-in critical**
- **EM40 less interested in applied R&D**
 - ⇒ **Even less interest in basic R&D**
 - ⇒ **Resources diminishing except for highest priority sites**
- **Staged approach for introducing complexities**
 - ⇒ **Success at one step prior to next approval request**
- **Show added value to current or future priorities**
- **Nurture and involve existing contacts**



Genetically engineered bioluminescent
reporter bacteria for PAH bioremediation
in subsurface soil

Robert S. Burlage

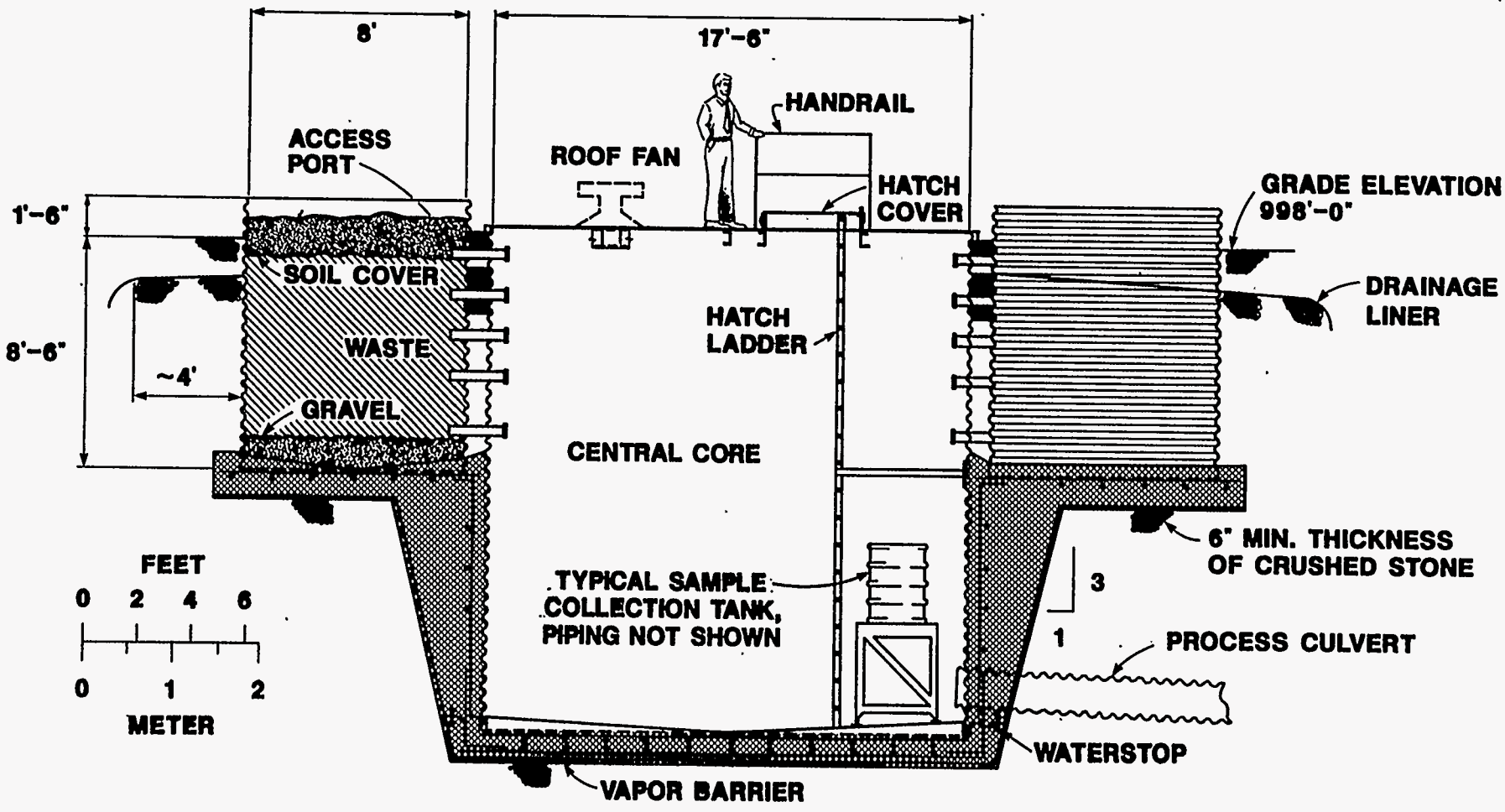
Environmental Sciences Division

Oak Ridge National Laboratory

Project objectives



- develop a model ecological framework for risk assessment and process optimization using GEMs
- develop a multi-user intermediate-scale test facility
- acquire data on in situ bioremediation of representative PAH compounds



Lessons Learned

- ◆ Sometimes rules collide, and you get squashed.
- ◆ Sometimes rules are inappropriately applied to your project.
- ◆ Rules are usually well-intentioned.
- ◆ Regulators are powerless to change the rules.
- ◆ Pioneers must adapt to these problems

Recommendations

- ◆ Anticipate problems when you can
 - e.g. MOU with EPA
- ◆ Change things when you can
 - find out who has regulatory authority
- ◆ Accept setbacks as learning experiences
- ◆ Be flexible in your research goals
- ◆ PM: select the right PI

A PI's Duties are:

- ◆ Task-based

Researcher, Writer, Accountant, Mentor

- ◆ People-based

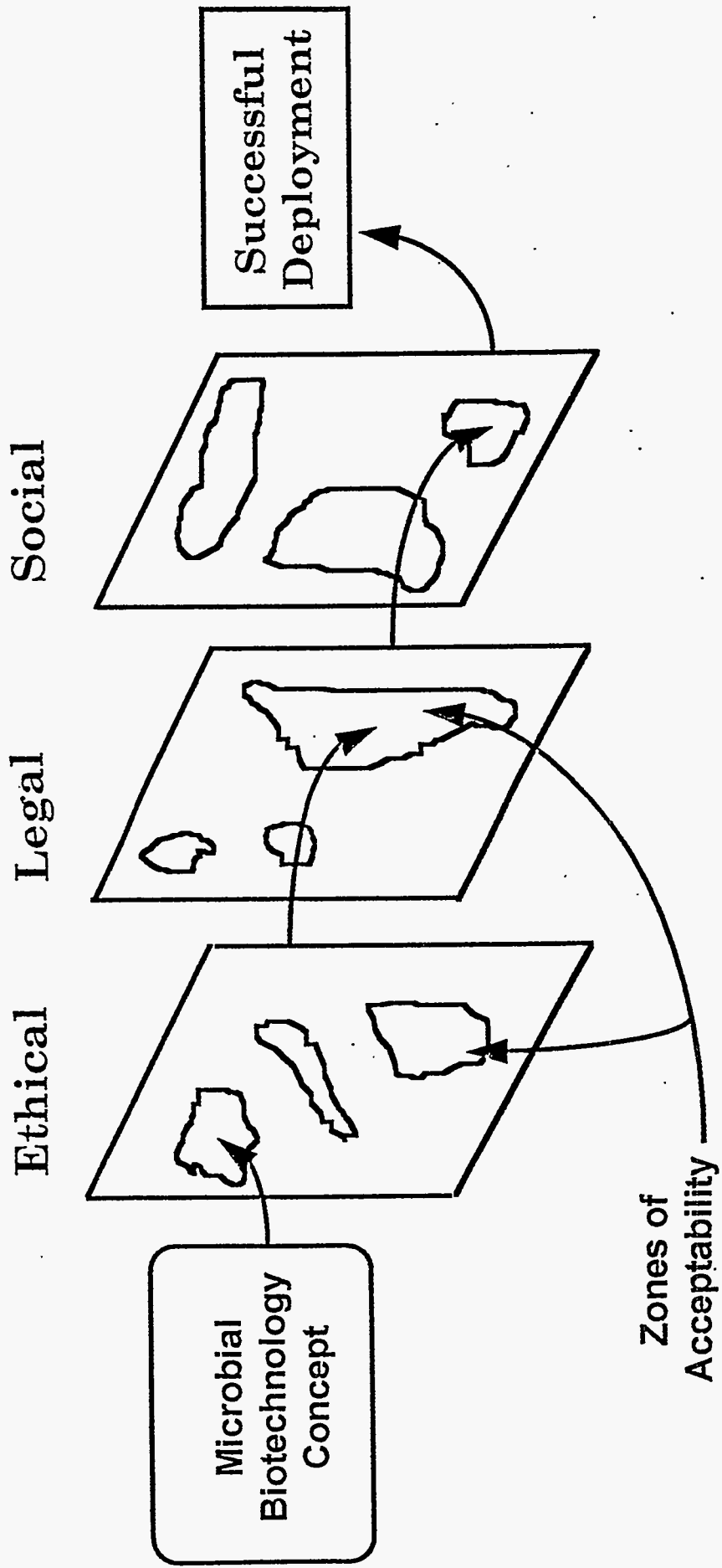
Manager, Lawyer, Diplomat, Mediator

- ◆ Supernatural

Magician, Psychic

Stakeholder Issues and Engagement Processes

**Gordon Bilyard
Pacific Northwest National Laboratory**



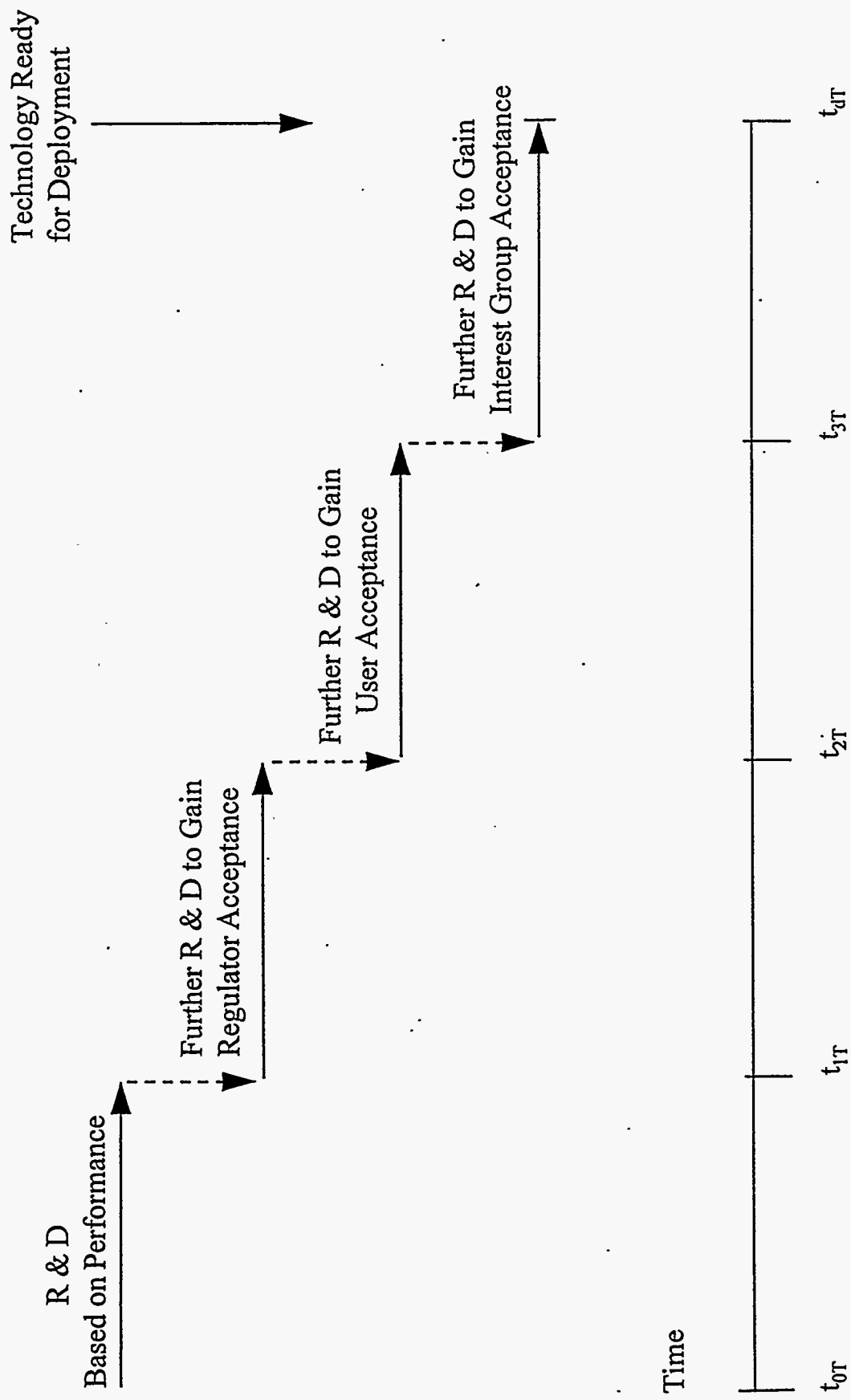
Stakeholder Perceptions and Issues

- Lower costs of bioremediation are attractive, but environmental and human health are more important
- Concern for environmental and human health increases from native to non-native to genetically engineered organisms
- Environmental and human health issues include:
 - Non-native organisms may “outcompete” native organisms
 - Uncontrolled exchange of genetic material could occur
 - Bioremediation breakdown products could be more hazardous and persistent than starting compounds
 - Bioremediation technologies may not be able to achieve regulatory compliance
 - Bioremediation technologies may have greater propensity for damage claims resulting from unintended impacts
- Patenting life forms may not be moral or ethical

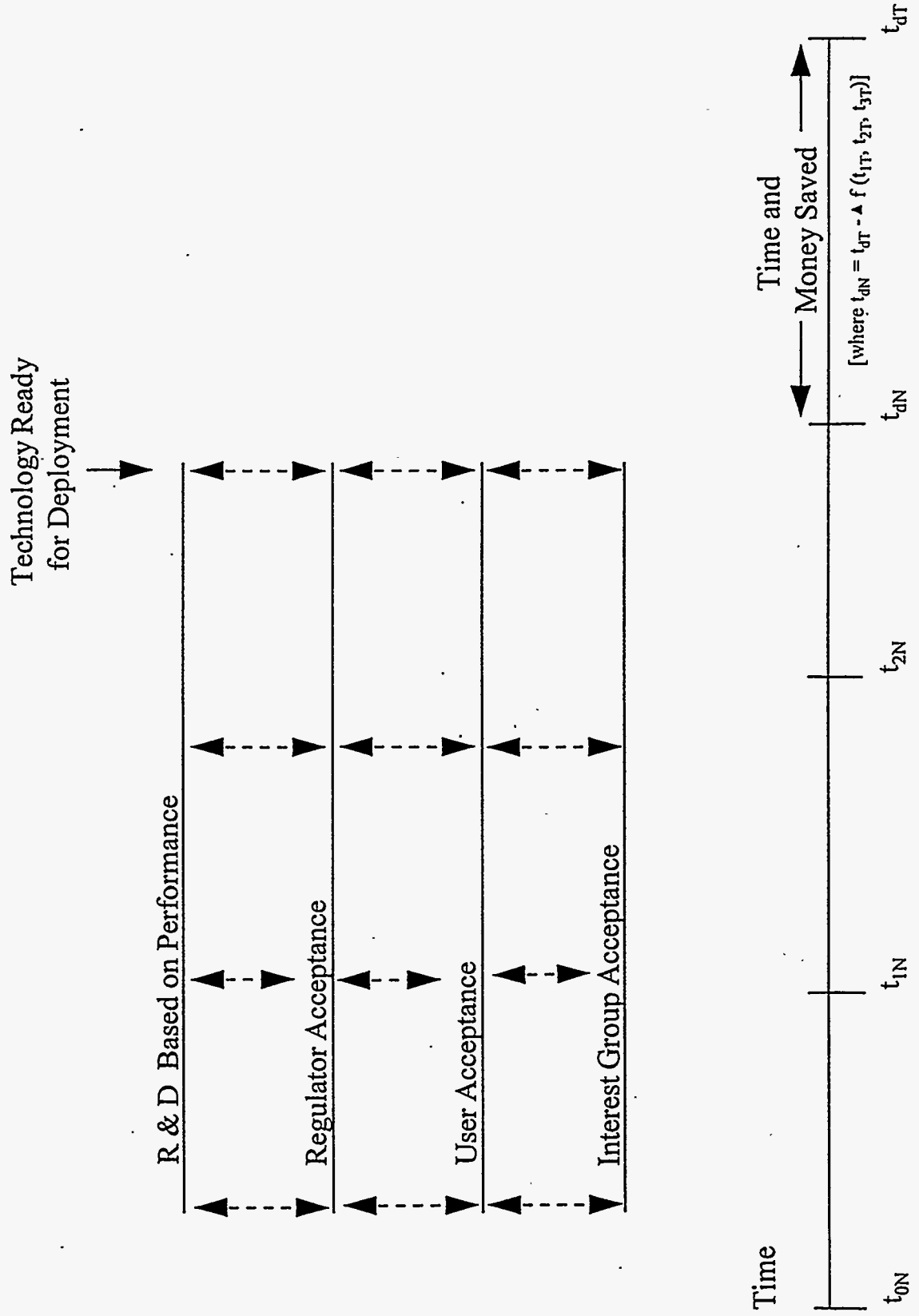
Information Needs Identified by Stakeholders

- Effectiveness of the technology under different geological conditions with a broad range of contaminants and contaminant mixtures (to test robustness)
- Assumptions and expectations about the intermediate products, by-products, and residual contamination from the biotechnology
- The elements of risk and the risk management strategy for the biotechnology
- The liability implications and insurance requirements for the biotechnology
- The assumptions, control mechanisms, and methods for responding to technology failures
- The methods and equipment necessary to monitor the effectiveness of the technology as an operating unit and with respect to environmental effects
- A demonstration that further cleanup actions are not foreclosed by use of the biotechnology

Traditional, Sequential Approach to R & D:



New, Parallel Technology Acceptance Approach to R & D:



POTENTIAL REGULATORY ISSUES ASSOCIATED WITH BIOREMEDIATION

Susan E. Arnold, J.D.
Oak Ridge National Laboratory

Workshop on Bioremediation and its Social Implications and Concerns
July 18, 1996

I. INTRODUCTION

A. Coordinated Framework for Regulation of Biotechnology

B. Role of Federal Agencies

- EPA, USDA, DOE, DOD, USAID, DOC, DHHS, DOI, DOJ, DOS, DVA, NASA, and NSF

II. FEDERAL REGULATION OF BIOREMEDIATION

A. Toxic Substances Control Act

B. Federal Insecticide, Fungicide and Rodenticide Act

C. Resource Conservation and Recovery Act

40 CFR Part 264 - Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

1. Land Treatment - Subpart M
2. Tank Systems - Subpart J
3. Miscellaneous Units - Subpart X

FEDERAL REGULATION OF BIOREMEDIATION (cont.)

D. National Environmental Policy Act

- Requires the preparation of an Environmental Impact Statement (EIS) when a federal agency proposes “major Federal actions significantly affecting the quality of the human environment.” 42 U.S.C. § 4332(2)(C)
- The term “major” has been construed several ways by the courts.

FEDERAL REGULATION OF BIOREMEDIATION (cont.)

- 40 C.F.R. § 1508.18(b)(4) includes as a Federal action the approval of specific projects, such as construction or management activities located in a defined geographic area.
- An action “affects” the physical environment for purposes of NEPA only if it changes the environment and if the causal relationship between the action and the environmental effects is reasonably close.

FEDERAL REGULATION OF BIOREMEDIATION (cont.)

E. Animal and Plant Health Inspection Service, U.S.
Department of Agriculture Regulations

- 7 C.F.R. Part 340 Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests

FEDERAL REGULATION OF BIOREMEDIATION (cont.)

- 7 C.F.R. Part 335 Introduction of Nonindigenous Organisms (proposed rule withdrawn)
- F. Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms - Guidelines recommended to USDA by the Agricultural Biotechnology Research Advisory Committee (ABRAC)

III. STATE REGULATION OF BIOREMEDIATION

A. Genetically Engineered Plants

B. Hazardous Waste Regulations

IV. CONCLUSION

A. Currently, federal and state legislation pertaining to bioremediation is limited.

B. With EPA's increased focus on the use of innovative technologies, specifically bioremediation, federal and state legislation governing bioremediation will follow.

Public Policy

**What is current public policy
and its implications for NABIR?**

Janice Longstreth, Ph.D.
Waste Policy Institute

Public Policy

Public Policy

What is it and how is it formed?

Who “bakes” it—who are the cooks?

Who provides the ingredients?

Why should you care?

What you can do.

Public Policy

What Is Public Policy?

Definition according to JL:

Instructions given by government to government to provide for and protect the “life, liberty, and pursuit of happiness” and guarantees of the Constitution.

Public Policy

What Is Public Policy and How Is It Made?

If our society is a melting pot, then public policy is the stew that comes out of it.

The quality and attractiveness/appeal of that stew is dependent not only on the components but also their proportions and the skill of the cook(s).

One person's stew may be another person's poison.

Public Policy

Who Provides the Ingredients?

“The public”

“The governments”

Other interested and affected parties

- Lobbyists
- Industry
- Small businesses
- Environmental groups
- Scientific groups

Public Policy

Who Are the Cooks?

Congress, the President, Agencies, and
the courts

State and local equivalents

Public Policy

Why Should You Care?

The regulatory situation is relatively benign.

That can change with the first widely publicized "screw-up."

Ask hospitals how they liked the Medical Waste Tracking Act.

Public Policy

Why Should You (Scientists) Care?

Complex process—which can provide unexpected results.

Arise in response to “problems.”

Science and scientists are more often perceived as components of these problems—not parts of the solution.

Public Policy

Society Has Lost Its Faith in Science/Scientists

We have been resting on our laurels

- Conquest of infectious diseases
- Increases in quality of life
("Better living through chemistry")

The public is saying, "What have you brought me lately?"

- Three-Mile Island
- Chernobyl
- AIDS(?)
- Drug-resistant organisms

Public Policy

What Can You Do?

Consider this:

You as scientists have a problem. You want to be able to design, build, and implement a research program—presumably “for the benefit of society.”

But society isn't sure it believes you're competent to make the judgment of what benefits them.

Solutions you have come up with—“You can trust us”—aren't working.

Robustness of solution is directly related to the diversity of input.

"ENVIRONMENTAL APPLICATIONS OF BIOTECHNOLOGY: FOCUS GROUPS"

UNPUBLISHED REPORT

MARCH 1996

ENVIRONMENT CANADA AND INDUSTRY CANADA

**KATE DEVINE
BIOTREATMENT NEWS**

OBJECTIVES

TO PROVIDE INFORMATION THAT WOULD BE USEFUL IN HELPING TO INCREASE PUBLIC UNDERSTANDING OF BIOTECHNOLOGY.

ENVIRONMENT CANADA WANTS TO EXPLORE:

- THE PUBLIC'S UNDERSTANDING OF THE CONCEPT OF BIOTECHNOLOGY AND AWARENESS OF SPECIFIC APPLICATIONS
- AWARENESS OF POTENTIAL BENEFITS AND RISK OF BIOTECHNOLOGY
- PERCEPTIONS OF CURRENT USE OF THESE APPLICATIONS
- ACCEPTABILITY OF SPECIFIC APPLICATIONS IN THEIR COMMUNITY
- PERCEPTIONS OF TRADE-OFFS AND WILLINGNESS TO MAKE THEM
- CREDIBILITY OF ALTERNATIVE MESSAGES AND INFORMATION SOURCES TO CALM FEARS
- THE ROLE OF GOVERNMENT AGENCIES - ENCOURAGING, REGULATING AND UNDERTAKING BIOTECHNOLOGY APPLICATIONS

METHODOLOGY

EIGHT FOCUS GROUPS:

- NINE OR TEN INDIVIDUALS PER GROUP
- GROUPS DIFFERENTIATED BY EDUCATION (HIGH SCHOOL OR LESS VS. UNIVERSITY)
- EVEN DIVISION BASED ON GENDER
- MIX OF SOCIO-ECONOMIC
- AGES OF 25 TO 55
- EXCLUDED: ENVIRONMENTAL ACTIVISTS, THOSE IN MARKET RESEARCH, THE MEDIA, THE ADVERTISING AND THE FEDERAL GOVERNMENT

* * * * *

FOUR CANADIAN COMMUNITIES

**MONTREAL
TORONTO
SASKATOON
VANCOUVER**

FINDINGS

PUBLIC'S UNDERSTANDING OF BIOTECH AND APPLICATIONS AWARENESS

- "BIOTECHNOLOGY" ASSOCIATED PRIMARILY WITH HEALTH AND FOOD
- ENVIRONMENT AND HEALTH MORE IMPORTANT THAN FOOD PRODUCTION
- MIXED FEELINGS ABOUT "SCIENCE AND TECHNOLOGY" - ADVANCES IN PRODUCTIVITY BALANCED BY COMPLEX AND STRESSFUL EXISTENCE
- IDENTIFIED APPLICATIONS: NON-CHEMICAL PESTICIDES AND OIL SLICK-EATING BACTERIA

CURRENT USE PERCEPTIONS

- NOT AWARE OF APPLICATIONS FROM A LIST OF ENVIRONMENTAL BIOTECHNOLOGIES OTHER THAN COMPOSTING AND BIOLOGICALLY-PRODUCED FUELS
- ASSUMED THAT BIOTECHNOLOGIES WERE BEING USED IN CANADA BUT OTHER THAN COMPOSTING AND BIOLOGICALLY-PRODUCED FUELS, FEW WERE SURE

FINDINGS (CONT'D)

AWARENESS OF BENEFITS AND RISK & TRADE-OFFS

- CAUTIOUS OF BIOTECHNOLOGY - RESIGNED TO INEVITABILITY OF ITS INTRODUCTION
- PERCEIVED BENEFITS - CLEAN UP POSSIBLE
- NEGATIVE LONG TERM RAMIFICATIONS - AVAILABILITY OF CLEANUP TECHNOLOGY WOULD NEGATE ADDRESSING REAL PROBLEM
- UNCOMFORTABLE WITH GENETIC ALTERATION
- UNLIKELY TO PROTEST AN APPLICATION OF BIOTECHNOLOGY IN THEIR COMMUNITY IF KEPT INFORMED OF BENEFITS AND RISKS
- WANTED TO KNOW OF CONTROLS AND LONG TERM CONSEQUENCES OF USE

GOVERNMENT & INFORMATION SOURCES

- ASSUMED FUNDING, RESEARCH, STANDARDS AND MONITORING TAKING PLACE IN GOVERNMENT
- IMPORTANT FOR GOVERNMENT TO GIVE PUBLIC A VOICE
- MORE CONFIDENCE IN INDEPENDENT BODY OVERSEEING BIOTECHNOLOGY

IMPLICATIONS OF SURVEY

KNOWLEDGE IS MINIMAL; SUSPICIONS ARE HIGH - WILL REQUIRE BETTER INFORMED POPULATION FOR BETTER PUBLIC SUPPORT.

KNOWLEDGE LEVELS CONSISTENT (LITTLE KNOWN) BUT COMFORT LEVELS NOT - HIGHER EDUCATED ARE LESS SUSPICIOUS.

COMFORT LEVEL UP WHEN NEW TECHNOLOGIES ASSOCIATED WITH FAMILIAR TECHNOLOGIES.

SEMANTICS IMPORTANT - USE OF TERMS WITH IDENTIFIABLE WORDS WITHIN (E.G., BIORESTORATION) RAISES COMFORT LEVEL.

PUBLIC PRIORITIES FOCUSED ON BENEFITS, WHICH WILL ENCOURAGE ENVIRONMENTAL (FOOD BIOTECH SEEN AS PROFIT-MAKING).

SUSPICIONS HIGHER THAN WITH FOOD (CAN AVOID ENGINEERED FOOD) BUT NO CONTROL OVER ENVIRONMENTAL EFFECTS.

IMPLICATIONS (CONT'D)

CONCERN TO TRUST WORK BEING DONE BY PEOPLE THEY DON'T KNOW OR THEY FEEL DON'T KNOW THE CONSEQUENCES.

IF PUBLIC EDUCATION UNDERTAKEN - PROS AND CONS BOTH MUST BE INCLUDED.

PUBLIC EXPECTS TO BE CONSULTED IN ESTABLISHING GUIDELINES OR CODE OF ETHICS FOR BIOTECHNOLOGY.

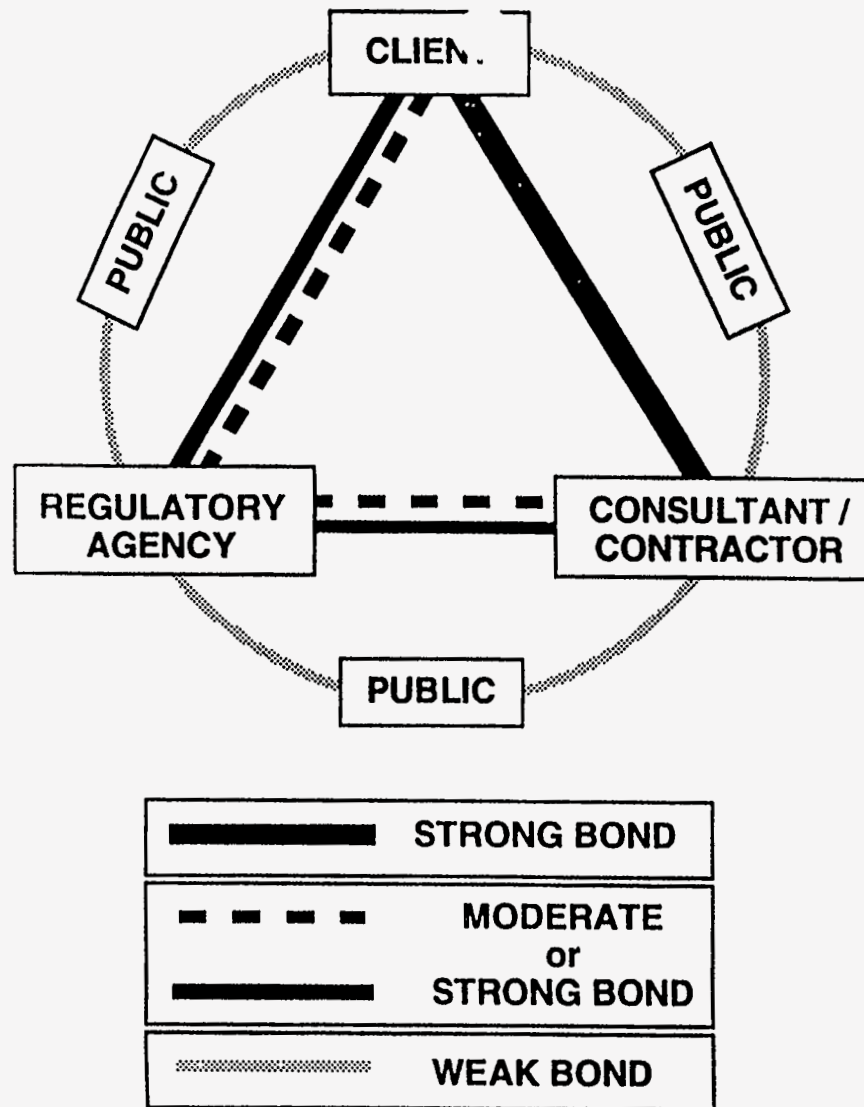


Figure 2.1 Interaction diagram of remediation project players.

NABIR Public Outreach Considerations

Perspectives from the DOE
Human Genome Management
Information System

Betty Mansfield, Oak Ridge National Laboratory



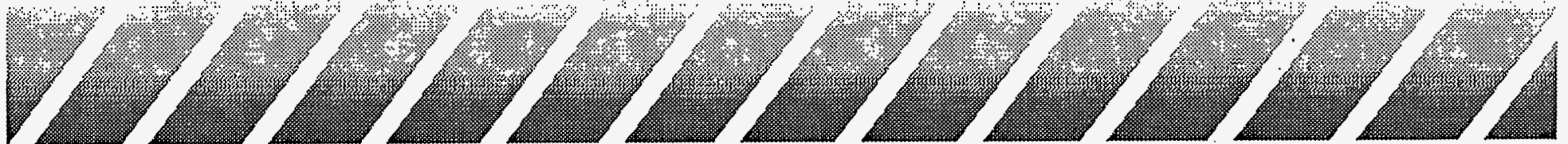
Communication is critical for the HGP

- ◆ Research is multidisciplinary and distributed
 - biologists, computer scientists, engineers
physicists, social scientists, bioethicists, etc.
 - approx. 1000 groups world-wide are involved
- ◆ Groups using and affected by HGP resources:
 - broader biomedical research community
 - medical, legal, and education professionals
 - biotechnology, pharmaceutical and venture capital
industries; science writers/publishers
 - genetic disease groups, students, public at large



Communications goals and services

- ◆ Help facilitate and reduce duplication of research effort by informing scientists of
 - ❖ goals, research in progress, resources generated, progress and providing a general forum for information exchange. Help foster collaborations and sense of connectedness among researchers and between researchers and funders.
- ◆ Aid public genetics education and serve as clearinghouse to promote more informed public discussions and decisions
- ◆ Produce *Human Genome News*, *DOE Primer on Molecular Genetics*, progress reports, and four WWW sites; aid ELSI grantees
 - ❖ HGN subscribers number nearly 13,000; mostly scientists, other allied professionals. Primer popular to professionals and public.
 - ❖ >8,000 visits to our websites each month; largely public.



NABIR::HGP some comparisons

◆ Similarities

- Have clearly identified goals, duration, and cost estimates
- Multidisciplinary/distributed
- Public education needs
- Studies in societal, ethical issues needs
- Potential policy needs
- Broad applications of results for positive benefits to civilization
- Potential for project termination if public understanding is poor, technologies misused or unintentionally/inappropriately deployed to the detriment of civilization

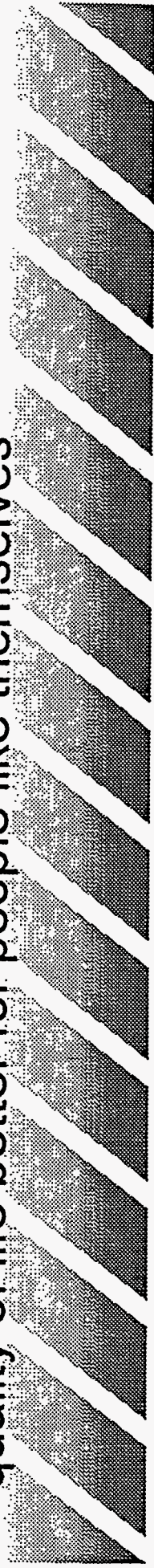
◆ Differences

- Greater environmental concerns in NABIR
 - ❖ microbial evolution is faster, alterations are to “germ line” unlike in humans where changes are made to somatic cells, possible distribution of genetically altered microbes to inappropriate niches: the Kudzu factor, loss of organismic diversity. Possible exchange of genetic information with unintended organisms.
- NABIR BASIC includes intellectual property issues
- Absolute requirement for regulatory framework in HGP because of issues of informed consent, privacy, discrimination; potential for misuse and individual whims

Survey of public perception of biotechnology

William K. Hallman, Bio/Technology Vol. 14, January 1996

- ◆ Survey done in New Jersey when consumers were still in the initial stages of making up their minds about biotechnology
- ◆ Many thinking about biotechnology issues/products for first time
- ◆ More than half had not heard of “genetic engineering”
- ◆ When asked to indicate first thought after hearing the phrase, “genetic engineering,” about half of those who could respond had negative descriptors like “escaping virus,” “frightened,” “Nazi/Hitler,” or “mad scientist”
- ◆ Most respondents said they approved of genetically engineered products that would improve human health and welfare, save money or time, or help the environment
- ◆ More than two-thirds believe genetic engineering will make the quality of life better for people like themselves



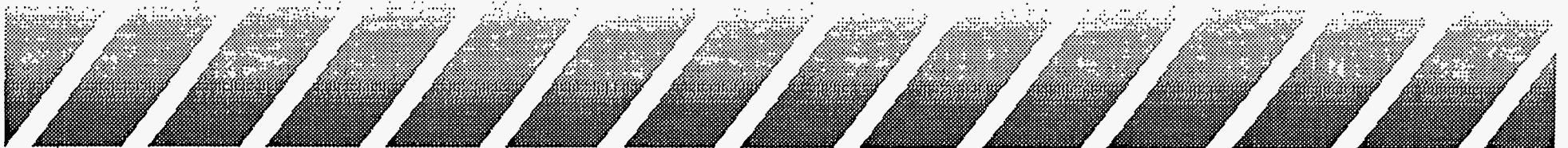
Public perceptions, continued

- ◆ About 40% of the group surveyed believes that new genetically engineered organisms could pose a threat to the environment if they could reproduce
- ◆ Scientists were seen as the most credible group and the industry making genetically engineered products was seen as the least credible source of information about biotechnology; farmers and environmental groups were seen as more credible than state or federal government agencies
- ◆ Despite this lack of governmental credibility, the majority surveyed favored close government control over biotechnology. Nearly two-thirds of those surveyed agreed with the statement: “the potential danger from genetic engineering is so great that strict regulations are necessary.” Both scientists and non-scientists alike agreed equally to this statement



Public perceptions, continued

- ◆ However, four-fifths of the respondents said research into genetic engineering should be continued at the same level of support
- ◆ Perceptions of agricultural biotechnology will continue to change as genetically engineered products continue to enter the market
- ◆ Conclusion: “The lack of trust in the two institutions with the greatest resources and responsibilities for ensuring the safety of agricultural biotechnology must be seen as an important obstacle to honest discussions about the merits of this new technology...both government agencies and commercial concerns need to take a more proactive role in community discussions and debates about genetic engineering, especially as they relate to consumer fears and preferences.”



Guiding principles for science communication

- ◆ Be honest, knowledgeable, and discuss negative project potential; let public know they are important
- ◆ Learn public concerns, address them when opportunity arises
- ◆ Be sensitive to public concerns and misconceptions
- ◆ Do not be defensive in discussions, refer requestors to an array of balanced information---including that which presents responsibly-argued negative viewpoints
- ◆ Refer public to BASIC research portfolio so they can see how ethical and social issues are being addressed
- ◆ Avoid language that inflames or confuses and be aware that the same words can have different meanings to different people/groups

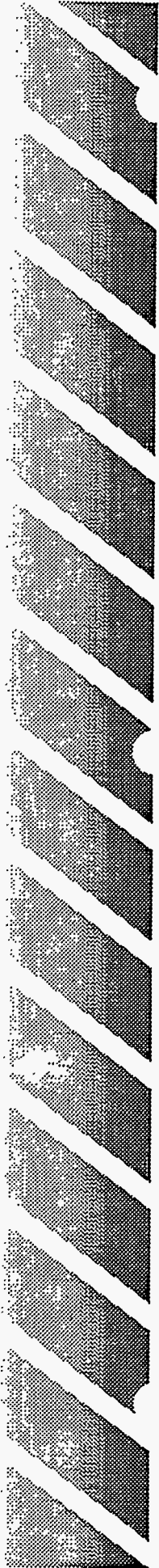


Considerations for BASIC

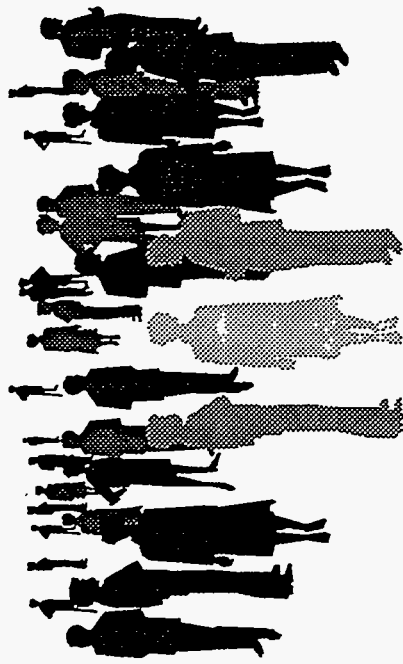
- ◆ What local, state, and federal laws apply to NABIR research?
- ◆ Is there a need to consider the concerns of other countries in releasing genetically modified organisms in this country? Are there international guidelines (WHO), laws?
 - ❖ Some people, especially in third-world countries will object
- ◆ Should “environmental impact”-type studies be done before each modified organism is released?
- ◆ Convene BASIC and environmental research grantees together at the same meetings to foster open discussions and better understanding



Considerations for BASIC



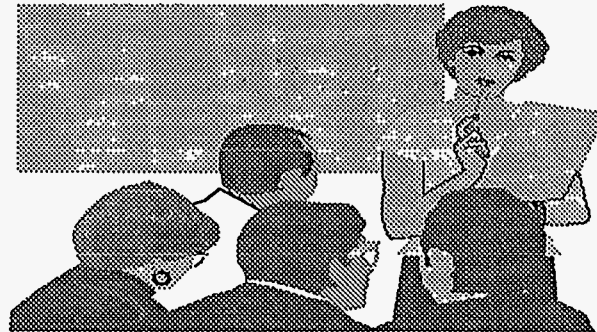
THE PUBLIC: DEFINITION AND STRATEGIES



DR. MANUEL PERRY

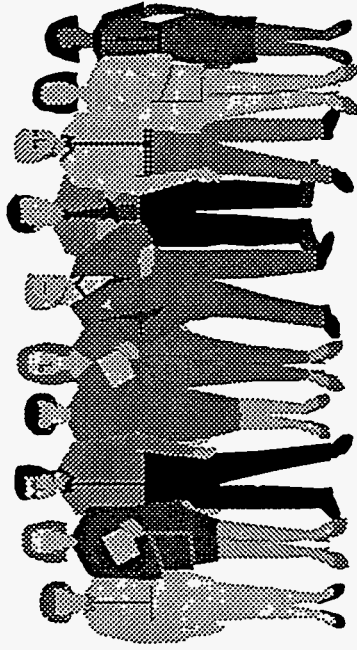
TYPICAL DEFINITION OF PUBLIC IS LIMITED

- POLICY MAKERS
- DECISION MAKERS
- ADVOCACY GROUPS
- OPPOSITION GROUPS
- NEWS MEDIA



A BROADER DEFINITION IS DEMANDED

**THE VIEWS, OPINIONS, AND NEEDS
OF ALL CITIZENS MUST BE ADDRESSED!!**



THE TOPIC OF WASTE DEMANDS NEW THINKING

- **THE NEEDS OF IMPORTANT GROUPS MUST BE ADDRESSED:**
 - **ECONOMICALLY DISADVANTAGED (POOR)**
 - **PEOPLE OF COLOR (MINORITIES)**
 - **EDUCATORS (TEACHERS)**

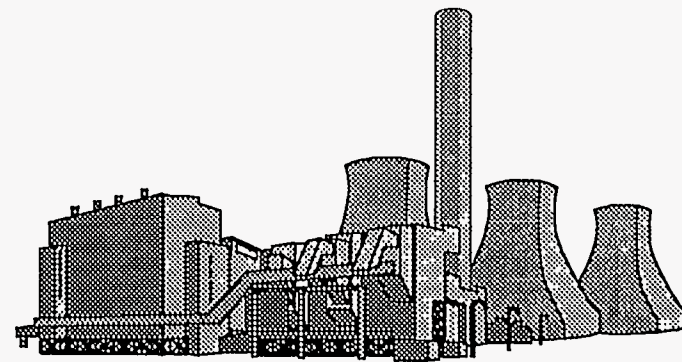


WHY THESE GROUPS

- **ECONOMICALLY DISADVANTAGED**
- **PEOPLE OF COLOR**
- **EDUCATORS**

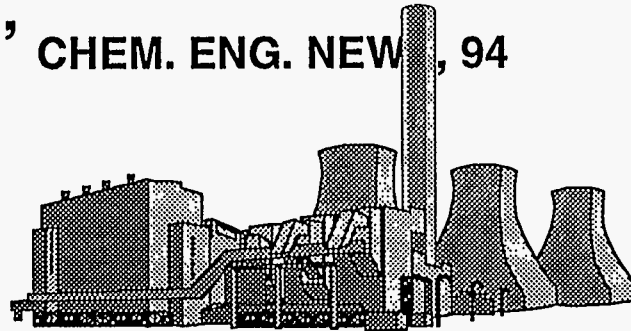
HISTORY HAS TAUGHT US A LESSON

- **NEW WASTE SITES ARE OFTEN LOCATED IN
ECONOMICALLY DISADVANTAGED
NEIGHBORHOODS**
 - **LANDFILLS NEW YORK**
 - **WASTE SITES CALIFORNIA**
 - **DUMP SITES MISSISSIPPI**



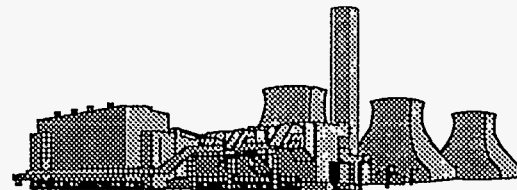
HISTORY HAS TAUGHT US A LESSON

- **NEW WASTE SITES OFTEN ARE LOCATED IN NEIGHBORHOODS OF PEOPLE OF COLOR:**
 - URBAN CHICAGO ILLINOIS
 - MOJAVE TRIBE CALIFORNIA
 - APACHE TRIBE NEW MEXICO
 - NATIVE TRIBES WASHINGTON
 - EAST ST. LOUIS ILLINOIS
- **“MINORITIES ARE 47% MORE LIKELY TO LIVE NEAR WASTE SITE..”** CHEM. ENG. NEWS, 94



HISTORY HAS TAUGHT US A LESSON

- **LITTLE IS DONE TO INVOLVE EDUCATORS -
KINDERGARTEN TO COLLEGE - WHY, HOW,
SO WHAT OF “WASTE”**
- **WE SAY:**
 - “TRUST US”
 - “WE ARE SCIENTISTS”
 - “WE ARE FROM THE GOVERNMENT”
- **WHO WILL TEACH FUTURE CITIZENS ABOUT
WASTE**

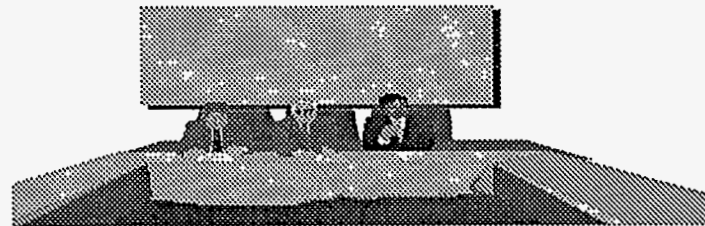


MORE PEOPLE AND GROUPS MUST BE INCLUDED IN "THE PUBLIC"

- **POLICY MAKERS**
- **DECISION MAKERS**
- **ADVOCATES**
- **OPPONENTS**
- **NEWS MEDIA**
- **ECONOMICALLY DISADVANTAGED - YES**
- **PEOPLE OF COLOR - YES**
- **EDUCATORS - YES**

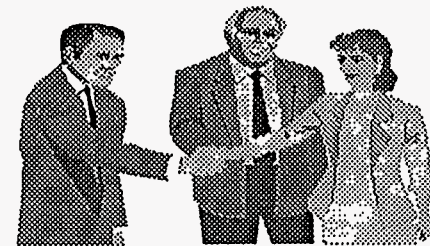
ACTIVE INCLUSION STRATEGIES MUST BE ESTABLISHED

- **FOR THE ECONOMICALLY DISADVANTAGED**
 - HOLD PUBLIC FORUMS IN POOR NEIGHBORHOODS
 - MAKE INFORMATIONAL MATERIALS AVAILABLE IN ALL NEIGHBORHOODS
 - HAVE INFORMATION PROVIDERS GO TO POOR NEIGHBORHOODS AND TOWNS; DON'T EXPECT PEOPLE TO COME TO YOU
 - DON'T BELIEVE BECAUSE PEOPLE ARE POOR THEY DON'T KNOW, CAN'T LEARN, OR ARE NOT INTERESTED



ACTIVE INCLUSION STRATEGIES MUST BE ESTABLISHED

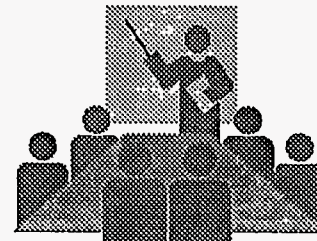
- **FOR PEOPLE OF COLOR:**
 - INCLUDE THEM IN POLICY/DECISION MAKING POSITIONS EARLY IN THE PROCESS
 - ESTABLISH INFORMATIONAL PROGRAMS TO MEET THEIR NEEDS AND CONCERNS
 - SOLICIT THEIR INPUT EARLY IN THE PROCESS
 - UTILIZE THE NEWS MEDIA NETWORKS THAT THEY READ, WATCH, AND LISTEN
 - HOLD MEETINGS IN THEIR NEIGHBORHOODS
 - DON'T ASSUME THEY CAN'T LEARN



ACTIVE INCLUSION STRATEGIES MUST BE ESTABLISHED

- **FOR EDUCATORS:**

- INVOLVE EDUCATORS “NOW” IN THE DELIBERATION PROCESS
- CHARGE EDUCATORS WITH THE ROLE OF DEVELOPING EDUCATIONAL CURRICULUM MATERIAL FOR SCHOOLS
- PROVIDE FUNDING TO ASSIST IN DEVELOPING AND IMPLEMENTING EDUCATION PROGRAMS - PILOT AND NATIONWIDE
- ASSESS THE EFFECTIVENESS OF EDUCATION PROGRAMS ON STUDENT LEARNING - WHAT, HOW, AND SO WHAT OF BIOREMEDIATION



IN CONCLUSION

- **FOR A SMOOTH, EFFECTIVE BIOREMEDIATION PROGRAM TO BE APPROVED AND IMPLEMENTED A NEW DEFINITION OF “PUBLIC” AND DIFFERENT STRATEGIES MUST AGREED TO - NOW!!**





Laboratory Technology Research

Office of Energy Research, Laboratory Technology Research Division

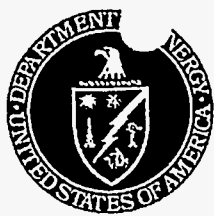
Program Overview

Pete T. Pesenti

Office of Energy Research

**Workshop on Bioremediation and Its
Social Implications and Concerns
DOE NABIR**

**July 18-19, 1996
Airlie House, Virginia**



Laboratory Technology Research

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- **U.S. industry's basic research is declining.**
- **DOE comprises an important part of the National R&D network. ER Laboratories have strong research competencies necessary to carry out their missions that are also very relevant to U.S. industry**
- **The ER Laboratory Technology Research Program (ER-LTR) was initiated in FY 1992 to make industrially relevant scientific expertise available to industry through cost-shared collaborations**
- **The program helps bridge the gap between basic science and cost effective commercial development**



Laboratory Technology Research

Office of Energy Research, Laboratory Technology Research Division

Mission

To link the science at Energy Research Laboratories to applied technologies through high risk technology research, emphasizing collaborations with industry



Laboratory Technology Research

Office of Energy Research, Laboratory Technology Research Division

Project Characteristics

- Multidisciplinary
- Technical risk too great for industry to initiate alone
- Emerges from basic science expertise at laboratory
- Merit selection based on peer review
- Benefit to laboratory competency & DOE public missions
- Large potential benefit to subsequent industry or applied program development if successful

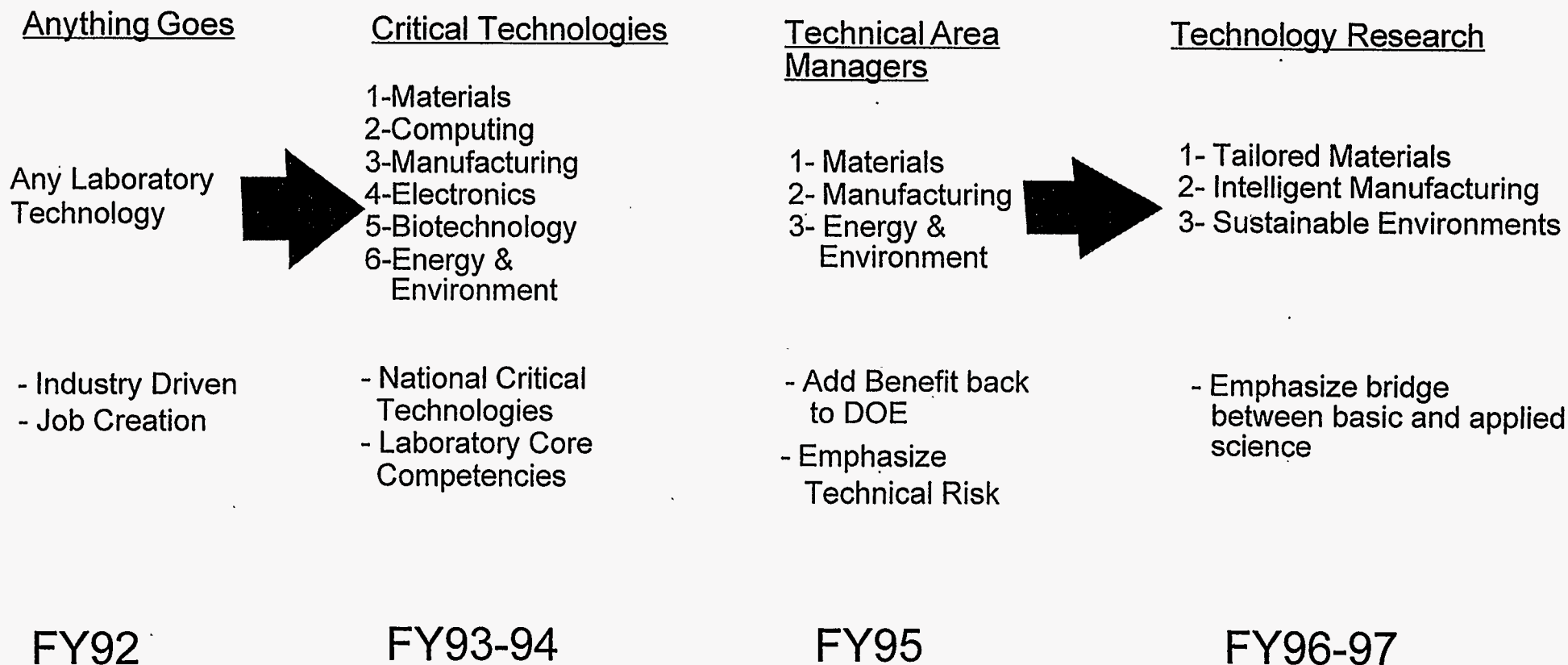


Laboratory Technology Research



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Strategic Focusing of Laboratory Technology Research





Laboratory Technology Research

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Program Elements

- **Quick Response Projects**
 - <\$100K, one year or less
 - small business
 - regional strategy
- **Laboratory Collaborations**
 - \$250K/year for three years
 - 50/50 cost share
 - focused by technology research area
- **Major Partnerships**
 - >\$10M/year for five to ten years
 - multiple industry and DOE partners
 - technology roadmap from industry sector
 - » AMTEX: American Textiles Partnership
 - » PNGV: Partnership for a New Generation of Vehicles



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CRADA Characteristics

- No DOE funds Flow to Nonfederal Party(s)
- Intellectual Property and Invention Rights negotiated
- 5 year Public Disclosure of Data Protection
- DOE-Approved Joint Work Statement required
- DOE Review and Approval Required



Laboratory Technology Research



Office of Energy Research, Laboratory Technology Research Division

Sustainable Environment

- **Biotechnology** - emphasis on understanding the microbial and biochemical mechanisms that may contribute to solving complex bioprocessing problems. Topics include molecular biology, biochemistry, microbiology, and biomedicine.
- **Chemical Processes** - development, at the structural level, of new classes of catalysts and large-scale industrial processes.
- **Novel Energy Devices** - investigation of new developments in mechanical engineering and materials science to accelerate work in the miniaturization of motors, pumps, and compressors to a microscale size. Potential applications to heating and cooling industry could be significant.