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Report of the

Integrated Environmental Management

Subcommittee

Review of the

Office of Policy, Planning

and Evaluation's

Integrated Environmental

Management Program

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SAB-EC-87-034

July 24, 1987

Honorable Lee M. Thomas
Administrator
U. S. Environmental Protection Agency
401 M Street, S. W.
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Dear Mr. Thomas:

The Science Advisory Board's Integrated Environmental Management Subcommittee has completed its review of the Office of Policy, Planning and Evaluation's Integrated Environmental Management Program (IEMP) and is pleased to submit its final report to you.

The Subcommittee's review focused largely on the geographic studies initiated by the program and the development of a health scoring methodology for non-carcinogens. The Subcommittee concludes that the conceptual approaches employed in the geographic studies represent an important component of EPA's overall effort to develop and/or apply methodologies to establish environmental priorities. In particular, they provide a valuable means for developing closer working relationships with state and local governments and the general public in evaluating area-or site-specific risks and in devising effective strategies to communicate risks. These efforts constitute some of the most important achievements of the program to date.

The program's lack of clearly stated scientific assumptions and objectives, and its need for a more consistent approach to peer review, constitute its most serious technical deficiencies. The absence of consistently documented assumptions and objectives, and the ad hoc approach to peer review, has created difficulties in assessing whether the program as a whole, or specific studies, have achieved their overall goals.

The IEMP has developed a methodology to represent the dose-response relationship for non-carcinogenic agents. The Subcommittee has reviewed this methodology and, in general, concludes that the IEMP should initiate a broader Agency effort to evaluate this methodology in the context of developing risk assessment guidelines and procedures. The evaluation of this particular methodology requires an in-depth assessment of its repeated application and, until this is undertaken, the IEMP should not use it for decision making purposes.

These and other issues reviewed by the Subcommittee are included in the attached report. The Subcommittee appreciates the opportunity to review this program and requests that the Agency formally respond to its scientific advice.

Sincerely,

Ronald Wyzga, Chairman
Integrated Environmental
Management Subcommittee
Science Advisory Board

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

SAB-EC-87-034

REVIEW OF THE OFFICE OF POLICY, PLANNING AND EVALUATION'S INTEGRATED ENVIRONMENTAL MANAGEMENT PROGRAM

Integrated Environmental Management Subcommittee

Science Advisory Board

U. S. Environmental Protection Agency

July 1987

U. S. ENVIRONMENTAL PROTECTION AGENCY

NOTICE

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U. S. ENVIRONMENTAL PROTECTION AGENCY

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I. EXECUTIVE SUMMARY

The Integrated Environmental Management Subcommittee of the Science Advisory Board has completed its review of the Office of Policy, Planning and Evaluation's Integrated Environmental Management Program (IEMP). The Subcommittee's review focused largely on the geographic studies undertaken by the program and the development of a health scoring methodology for non-carcinogens. Throughout its review, the Subcommittee solicited statements from the program's managers and staff about its overall objectives and the criteria to be used for evaluating whether the program had achieved its objectives. The Subcommittee followed this effort by assessing the technical strengths and weakness of the current program and recommending needed changes.

The Subcommittee concludes that the conceptual approaches used by the Integrated Environmental Management Program represent an important component of EPA's overall effort to develop and/or apply methodologies to establish public health and environmental priorities. Studies conducted under the auspices of this program constitute large technical challenges and provide valuable experience to EPA staff, particularly those working in regional offices. And, finally, they provide a valuable means for developing closer working relationships with state and local officials and the general public in evaluating site-or area-specific risks and in devising effective strategies to communicate risks.

There is a clear need to assess environmental issues from a multi-media perspective. Conducting only medium-specific analyses can lead to ignoring more serious issues in another medium or to simply transferring a problem from one medium to another. The IEMP process offers one means of addressing these issues, taking into account transport and transfer of toxics across media and exposures from several media simultaneously. To date, however, IEMP has not exploited this capability to its potential. In part, this may reflect the nature of the areas studied, but greater efforts by IEMP to use its capability are needed.

In the course of decision making, EPA and state and local governments identify priority environmental problems in specific localities or regions. The IEMP provides a set of tools that can assist this effort. While its applications, to date, can be improved, the results of the IEMP studies (reflecting both EPA and state and local expertise) have suggested some environmental problems in specific geographic areas, and have also indicated that some issues previously perceived as very important are of lesser concern. The analytical tools used in the IEMP studies also may provide technical support for environmental management decisions that otherwise may be based upon a more subjective treatment of information.

The latter reflects the need for systematic and objective approaches to environmental decision making. Methods that try to address all facets of an issue comprehensively and to reduce them to a common metric such as risk provide significant support to decision makers by helping them to more specifically frame the problems they are seeking to resolve, and by aiding them in identifying the most important risks.

At the same time, the use of IEMP decision tools should never become the sole basis for either identifying or managing environmental problems by any level of governmental decision makers. Rather, such tools should be used in concert with the practical experience of citizens and decision makers. The Subcommittee concludes that the IEMP is most appropriately used when it stimulates decision makers to ask questions and seek data concerning the identification of the most significant public health and environmental problems.

One of the most important achievements of the IEMP has been its positive interaction with the host communities in developing the geographic studies. The IEMP has proven to be a focal point for presenting scientific concepts and information to communities and relating them to the eventual management of local environmental problems. An important benefit of this effort has been community education about environmental issues and ways to evaluate and communicate these issues.

The program's need for clearly stated scientific assumptions, documentation and objectives constitutes its most serious technical weakness. While not a research or risk assessment program per se, the IEMP greatly depends upon technical data as a basis for priority setting. Thus, clear statements regarding scientific assumptions and objectives toward which data are applied constitute a necessary aspect of the program. The frequent absence of these factors has created difficulties for peer reviewers and users of IEMP studies in developing reference points to evaluate whether the program as a whole, or its specific studies, have achieved their objectives. The frequent lack of indicators or criteria for judging program or project success or failure has made it difficult to systematically identify and institute corrective steps at earlier stages of project or program development. This latter characteristic has also resulted from staff turnover.

The Subcommittee experienced much difficulty in evaluating the IEMP. This difficulty stemmed, in large part, from the needs cited in the previous paragraph. Instances of inadequate documentation include: the de facto preference for using cancer models; inconsistent use of exposure data and pathways; delineating which assumptions were chosen because of scientific compared to administrative/political considerations; and the lack of criteria for using quantitative estimates for purposes of priority setting and screening versus risk assessment.

A second source of difficulty stemmed from the fact that, as an evolving program, the IEMP is a moving target, and until a program defines its objectives it is difficult to evaluate its performance. Finally, contrary to the Subcommittee's initial preconceptions, the IEMP is not a model or even a method, but more of a process that uses several highly variable methods, with health risk estimates providing the underlying metric of the process. This characteristic further emphasizes the program's need to adequately document its use of scientific data and models.

The program suffers from some inadequate use of scientific information and models. Two examples include the use of models for purposes other than those for which they were designed, and an over-reliance upon existing data bases for exposure assessment when such data were not collected for exposure related purposes. No clearly stated criteria for maintaining

quality control were adopted for the program as a whole or for the guidance of managers of individual projects. Similarly, no consistently designed or implemented process of peer review existed at the program or project levels. Technical advisory panels established for specific projects have not always consisted of individuals who were technically trained in the scientific disciplines required for a thorough review.

The IEMP has developed an approach both for health scoring methodologies for carcinogens and non-carcinogens, screening exercises to identify potential problems and for more detailed analyses to evaluate options for risk management. EPA has developed guidelines for quantitatively assessing cancer risks that have undergone extensive peer review. Evaluating non-carcinogens is more difficult because there exists, at present, no clear scientific consensus on the appropriate methods to quantitatively assess these agents. The IEMP has developed a method to represent the dose-response relationship for non-carcinogenic agents. The Subcommittee has reviewed the method and, in general, concludes that the IEMP should stimulate the Agency as a whole to consider such methods, among others, in the future development of risk assessment guidelines and procedures. The evaluation of a method, however, requires an in-depth assessment of its repeated application and, until this is undertaken, the IEMP should not use its method in decision making. To date, this method has not been applied to any significant degree in existing IEMP projects.

Maintaining the scientific expertise necessary to successfully address the range of issues confronting integrated environmental management is beyond the current (or, most likely, the future) capability of the IEMP, or any other individual office within EPA. It may not be necessary that any single office within EPA possess all of the needed scientific skills for IEMP projects, as long as effective means of exchanging technical information and staff exist. In the projects evaluated in this review, the IEMP has not always made effective use of other scientific talents within EPA and the scientific community concerning multi-media analyses. At the same time, scientific talent in ORD, EPA research centers and program offices, other Federal agencies and the scientific community should participate in the activities of the program.

The practice of scientific assessment encounters many uncertainties, and this is especially true when comparing the risks of environmental pollution across media. To reduce the possibility that multi-media assessments will be misinterpreted, it is essential to state clearly the various uncertainties that surround the risk estimation process in at least four areas: identification of the hazard (toxicity), exposure assessment, dose-response assessment and characterization of the risk. The IEMP recognizes the importance of this issue but, to date, it has not employed a conceptually unified framework for addressing risk and has not consistently presented a clear identification of the major uncertainties in its efforts to screen, rank and assess risk.

RECOMMENDATIONS

1. The IEMP needs to adopt clearly articulated, measurable objectives for the program as a whole and for individual projects at the time of their initiation. Development of such objectives will assist staff and management in judging the success of the program, or identify areas for subsequent modification. Vaguely stated objectives can result in misdirected efforts and unrealistic expectations. Measurable objectives also can help identify the broader role that IEMP may play within EPA.

2. The program should more clearly document the scientific assumptions it uses and communicate the limitations and uncertainties associated with the results of its various studies. This is especially important in aiding EPA and state and local management apply IEMP concepts and results to define risk management priorities. It is equally important that this effort be pursued in helping the public better understand the role and limitations of scientific assessment, an area where the IEMP has already achieved some preliminary successes. The Subcommittee recognizes that the presentation of scientific uncertainties is also a large challenge for other programs within EPA and for the scientific community.

3. The IEMP should identify the range of scientific disciplines needed to maintain competency for the variety of scientific issues addressed in the program. It should compare the current in-house expertise with the expertise available in other EPA programs, research laboratories and centers. The IEMP should develop a plan to develop cooperative working relationships with these groups in the beginning and subsequent phases of studies to gain access to scientific talent, data, methodologies and other resources, thereby maximizing its own capabilities.

4. The Subcommittee recommends that the IEMP more aggressively seek technical input from experts in the environmental and scientific community who are knowledgeable about the design and implementation of integrated environmental analyses. The participation of such experts will infuse the program with additional scientific skills and will add to its refinement and ultimate acceptance by the scientific community. The IEMP should develop explicit quality control criteria at both the program and project levels for EPA staff and contractors as well as state and local officials to ensure consistent adherence to acceptable scientific standards. It should adopt a practice of rigorous peer review for both the design and implementation of its studies. Insofar as the program addresses scientific issues, it should aggressively encourage the technical staff to participate in and present their work at scientific conferences and to submit scientific papers that address study results or methodology development to refereed journals.

5. The IEMP should submit its method to assess dose-response relationships for non-carcinogenic agents to EPA's Risk Assessment Forum. The Forum should evaluate the method, present its analyses for peer review and publish its results. Such an effort should assist EPA and the scientific community in developing a consensus approach for quantitatively evaluating non-carcinogenic agents.

II. INTRODUCTION

At the request of the Deputy Administrator of the U. S. Environmental Protection Agency (EPA) and the Assistant Administrator for Policy, Planning and Evaluation, the Science Advisory Board (SAB) agreed to conduct a scientific review of the Agency's Integrated Environmental Management Program (IEMP). This request paralleled a December 3, 1985 recommendation by Dr. Ellen Silbergeld, a member of the SAB Executive Committee, in a letter to SAB Chairman Dr. Norton Nelson. Dr. Silbergeld recommended that the Board undertake a special review of this program because of its implications for the Agency's research program and its role in EPA's scientific assessment and policy analysis activities.

The SAB Executive Committee discussed these issues and recommendations at its January 28-29, 1986 meeting and unanimously voted to form an Integrated Environmental Management Subcommittee to carry out the review. The Subcommittee was instructed to evaluate the scientific assumptions, methodologies and conclusions developed or used by the IEMP program and to make recommendations pertaining to their application or improvement. In addition, the Executive Committee directed the Subcommittee to separately review the technical adequacy of a specific project directed by the IEMP and EPA Region III for the Kanawha Valley, West Virginia. The Subcommittee issued a separate report on EPA's Draft Kanawha Valley Toxics Screening Study on May 27, 1987.

The Subcommittee recruited a number of scientific experts to conduct its review. Among the scientific areas represented were biostatistics, decision analysis, civil engineering, chemical engineering, epidemiology, exposure assessment, model development and validation, pulmonary medicine, social science and toxicology.

A. Charge to the Subcommittee

The specific charge to the IEMP Subcommittee includes the following issues:

o Evaluating the appropriateness of the overall scientific approach used in the Integrated Environmental Management Program. Is the approach adequate to address the kinds of questions for which it had been designed?

o Assessing the adequacy of models used and the clarity and reasonableness of the assumptions built into the models. Were appropriate scientific conclusions drawn from the application of the models? The Subcommittee should also review the adequacy of data integration, the conclusions drawn from using data and models and the integration of data and models across IEMP studies.

o Reviewing the health scoring methodology and the treatment of non-cancer health effects.

o Assessing the expression of the outputs of the methodology and the quality of the uncertainty analyses.

o Commenting on the existing and potential uses of the Integrated Environmental Management Program within EPA.

o Conducting a specific scientific review of the data, methods and conclusions for the Kanawha Valley, West Virginia project.

B. Evolution of the Integrated Environmental Management Program

The development of EPA's Integrated Environmental Management Program represents an Agency response to a concern by its managers and technical staff, as well as other environmental professionals outside the EPA, that the traditional approach to environmental protection is incomplete. This approach was characterized by the enactment of laws and the development of programs and regulations that sought to control pollutants as if they remained in the same medium into which they were initially released. The traditional approach insufficiently recognized that pollutants cross and recross medium boundaries, undergo chemical changes, and produce adverse effects into media other than the one(s) to which they were initially discharged. EPA staff have further identified five negative consequences resulting from the traditional framework of pollution control. These include:

o The solution to a single-pollutant, single-medium problem might simply transfer the problem to another medium (e.g., from water to air), perhaps incurring greater risks and costs of control.

o Problems involving several environmental media may not be addressed sufficiently by an environmental agency that generally examines each medium independently.

o Policy makers have no systematic way of setting priorities across sources, pollutants, and exposure pathways in different media. Consequently, environmental policies and regulations may not be cost-efficient, spending too little on some problems and too much on others.

o One-dimensional studies of pollutants and individual media may not consider total or cumulative environmental exposure either within a medium or across all media.

o Laws and regulations may use different and sometimes inconsistent objectives, methods, and standards.

Development of EPA's current concept of integrated environmental management began in 1981. To institutionalize this work, the Agency created a new Integrated Environmental Management Division in its Office of Policy Analysis. The Division, and the evolving concept, focused on public health risks relating to toxic pollutant exposures (in contrast to conventional pollutants) because of growing public concern over potential health effects from toxics and the fact that, as a class, toxic pollutants were less controlled. As defined by the Division, integrated environmental management referred to the evaluation of control of overall public health risks from various pollutants, pathways, and sources from a multi-media perspective. In the view of its managers, the goal of the program was to use existing data (and not to generate new scientific data) to compare the costs of a proposed pollution control strategy with the risk reduction achieved by it. They believe that the IEMP was designed principally as a policy analysis tool that could aid senior EPA officials to set pollution control priorities based upon relative risk across all media.

Three key assumptions guided Division managers and staff. These included:

o Some public health risks are worse than others.

o Some pollution controls are more efficient than others at reducing risks.

o Pollution control involves trade-offs among risks, economics, technology and other factors considered in risk management.

The program methodology is essentially divided into two phases. The first phase primarily focuses on assimilation and aggregation of available data to reach priority-setting conclusions, and the second phase analyzes the relationship between the costs of a proposed control strategy and the risk reduction achieved by it. As a practical matter, roughly 90% of the IEMP's work focuses on the first phase.

Initially, the IEMP conducted essentially two kinds of studies: analyses of specific industries or issues, and area specific or geographic studies. The Subcommittee notes that, since mid-1984, the emphasis within the IEMP has shifted away from industry-wide studies and toward issue-or problem-specific studies (sludge, hazardous wastes) that are thought to be of interest to policy makers, and specific area studies (Baltimore, Denver, Philadelphia and the Santa Clara Valley). Also, during this period, the IEMP has been developing methodologies to consider the health effects of conventional pollutants and the effects of pollution on non-health endpoints such as crops, materials, fisheries and aquatic life. A more detailed statement of the IEMP's evolution and its current structure can be found in Appendix A, a letter from Mr. Daniel Beardsley, Director, Regulatory Integration Division (which includes the IEMP), to Dr. Ronald E. Wyzga, Chairman of the Subcommittee.

Presently, the major focus of IEMP is on geographic studies, two of which--Baltimore and the Santa Clara Valley--have advanced to completion of a Phase I report. The Philadelphia IEMP study has been released as a final report. A fourth study, Denver, is in its initial stage of preparation. These geographic studies provided the major input for the Subcommittee's review of IEMP. Because the Santa Clara Valley study is the most recent IEMP project and, thus, the study most likely to benefit from previous experience in developing IEMP concepts and analyses, the Subcommittee places greater emphasis upon the performance of this study in its review. Also, the Philadelphia study was completed at the time of this review, and no written reports were available for the Baltimore and Denver studies. An additional study of the Kanahwa Valley is nearing completion. Although the latter study makes partial use of the experience and approach of the IEMP, it is not an IEMP study. Appendix B contains the Subcommittee's separate review of this latter study.

The Subcommittee also notes that various IEMP staff participated in other projects within EPA during 1981-1987. These include: developing EPA conceptual papers and primers on risk assessment and risk management; serving as a principal source of ideas for former Administrator Ruckelshaus' speeches; preparation of new training courses on risk assessment and risk

management for EPA employees, Congressional representatives, members of the scientific community and the media; and assisting in the preparation of an EPA study addressing the magnitude of the air toxics problem. None of these activities were reviewed by the Subcommittee.

C. Subcommittee Review Procedures

In conducting this review, the Subcommittee met five times. In 1986, it met on April 24-25 in Washington, D. C.; July 1-2 in Philadelphia, Pa.; September 18-19 and December 4-5 in Washington, D. C.; and in Philadelphia, Pa. on March 16-17, 1987. Agendas for each of the meetings are included as Appendix C. The first two meetings consisted of introductory briefings conducted by the program staff. During these initial sessions, Subcommittee members had the opportunity to develop an understanding of the origins and expectations of the program and its subsequent development, and review and ask questions regarding technical documents prepared in support of the program or as program outputs. In addition, members of the public that requested time made brief statements to the Subcommittee of their view of the program's direction and needs. Subsequent meetings were devoted largely to discussion and review of technical support documents relevant to addressing the Subcommittee's charge and the development of draft sections of a report. The Subcommittee formed three work groups to examine in more detail the Philadelphia, Baltimore and Santa Clara Valley area projects and conducted site visits for the latter two projects, on November 14 and November 21, 1986, respectively. The entire Subcommittee participated in the review of the Draft Kanawha Valley Toxics Screening Study.

The review is organized into two parts. The first part examines the evolving objectives of the program, and the design, implementation and results of the geographic studies reviewed. Special attention is given to the health scoring methodology used in most of the projects. Part II presents the Subcommittee's evaluation of the specific geographic studies.

The Subcommittee received the cooperation of the Agency staff, both at headquarters and in its regional offices in Philadelphia and San Francisco, as well as access to program contractors. The Subcommittee also wishes to thank state and local officials in Philadelphia, Baltimore, the Santa Clara Valley, and West Virginia for making available both information and their valuable insights on this program.

PART ONE:

OBJECTIVES, DESIGN, IMPLEMENTATION AND

RESULTS OF PROJECTS IN THE IEMP PROCESS

III. THE IEMP OBJECTIVES

The general goal of IEMP, as presented in Appendix A (page 10), is to "develop a model for local environmental management that 1) is integrated, to the extent that it has an analytically defensible basis (quantitative, if possible) for establishing pollution risk reduction priorities across media; 2) takes into account both cost-effectiveness and potential for pollution transfer in selecting pollution control remedies; 3) can be practically used by local officials; and 4) contains an implementation process which maximizes the potential for broad public understanding and acceptance of management decisions." The Subcommittee concludes that this general goal is laudable.

Limitations in the quantitative data base available to the IEMP and the necessity of integrating data of questionable to excellent quality, collected for various purposes and analyzed by technical methods of varying degrees of sensitivity and specificity, make the development of quantitative risk analyses extremely difficult. As demonstrated in the geographic projects, this problem of obtaining a quantitatively reliable data base across all areas of environmental concern is a problem basic to multi-media risk assessment. In coping with this problem in the case of the geographic studies (see part two of this report), EPA made certain compromises with the result that, in many instances, the studies focused on individual pollutants in only one medium rather than conducting a multi-media analysis. Neither have all areas of significant environmental concern been investigated. These limitations, which may be appropriate given the resources and intent of the IEMP, are not always explicitly stated.

An evolution has occurred in the general goal and specific objectives of IEMP as it has addressed differing environmental problems and the varied quality of the data base in the areas studied to date. For example:

o In the Philadelphia study, initial goals, not all specifically delineated in the technical support documents for this study, included: 1) developing and/or applying new methodologies including quantitative risk assessment, multi-media analysis, and cost-effectiveness analysis to analyze the effects of environmental pollutants on human health; 2) improving EPA decision making and priority setting through the use of these methodologies; and 3) enhancing state and local decision making through the use of these methodologies. Hence, the initial emphasis of the IEMP appeared to be on the development and application of decision making tools in an integrated multi-media framework.

o As demonstrated by the Baltimore study, which was directly primarily by local officials, the development of a process for defining environmental priorities, rather than scientific assessment per se, appeared to play the major role in the apparently successful results of the Phase I study. A deliberate decision was made to limit general public participation in this phase of the study. The interaction among local agencies and the evolution of state and local cooperation in building a plausible agenda for solving environmental problems appears to represent a major advantage for this study, although not necessarily an initial major goal.

o The mobilization of community interaction was an important facet of the Phase I Santa Clara Valley study, although the predominant objective appears to be the identification of potential environmental problems.

o The objectives of the recently proposed Denver IEMP study have further evolved from the objectives of previous studies. The first objective of this study is to "educate governments and the public on the potential of risk-based decision making". The second is to "encourage local environmental professionals to gather, share, and analyze information before considering strategies to resolve their environmental problems". The third listed objective relates to the analysis of selected issues. Thus, there has been a greater emphasis on process and less emphasis on the development of analytical data, at least in the initial phases of the proposed Denver study.

Ideally, the ability of the IEMP to develop and achieve reasonable objectives is based on its prior experience and is consistent with the development of a successful multi-media assessment methodology and an environmental management program in a specific area. In other instances, secondary goals (whose achievement often yielded beneficial impacts) emerged that were not part of the original project design. In addition, some individual projects have achieved some of their stated goals without actually achieving the ultimate program goal of developing an integrated environmental risk management process or methodology. Care needs to be taken that the integrative process does not become the major goal and the solution of environmental problems secondary. Continual peer review of some type may help to forestall inconsistencies between stated or implied objectives and development of a methodology that can support such objectives.

IV. PROJECT DESIGN

In general, multi-media approaches to risk assessment can introduce more of a "systems" approach to environmental decision making. This approach is more likely to enable policy makers to examine the transfer of pollutants across media as particular control strategies are adopted. This contrasts with the single pollutant-single medium methodology which is more likely to transfer the problem from one medium to another, perhaps leading to greater risks and higher abatement costs.

A strength of the IEMP project designs is the attempt to develop a multi-media approach to environmental decision making. Clearly, the difficulties of multi-media studies are compounded by the fact that data quality may vary with media; hence, the so-called "risk-based" decision may indeed become a "best guess" decision based on an interpretation of the available data. Nevertheless, if appropriately executed, the IEMP approach can represent a considerable improvement over decisions made subjectively or on the basis of data from only a single medium.

Since the program is not limited to using specific models, it has the flexibility to assess a variety of issues of particular concern to local communities and to target data gaps and research needs. Thus, the Santa Clara Valley study initially targeted ground water problems and the Denver study plans to emphasize the brown cloud.

An additional element of the program is the capability it offers to local policy makers for detecting gaps in the data base that may become more apparent when the total data, across media, are carefully examined. With responsibility for data collection on environmental chemical hazards related to air, water, soil, homes, and occupational exposures usually divided among local groups, there are bound to be areas of environmental concern that fall between the cracks. To the extent that individual projects have designs that integrate the collection and analysis of data across media, they can also serve a research planning or data identification function.

There has been some use of locally developed clinical data (for example, the Baltimore study includes data on hospital treatment of children from lead poisoning) but, in general, clinical and epidemiological data are not considered in most studies and, where available, should receive greater emphasis. Although carrying out an epidemiological program is not, and should not be, the responsibility of the IEMP, the program should consider initiating a mechanism to enable local clinicians to identify unusual or area-wide health problems in the community of study. If such information is sought, the IEMP should ensure that appropriate expertise is available to oversee the collection and interpretation of such data.

Each project needs to build quality control mechanisms as an integral part of its design. At present, the IEMP studies have made only fragmented attempts to incorporate quality control measures. These control mechanisms can take several forms, such as the validation of

input data using several sources, the validation of modeled outputs through use of monitored data or even some validation of estimated health risks through the collection of clinical data.

Peer review is also one mechanism of quality control. To date, the IEMP has developed no systematic definition or approach to peer review. Peer review has occurred at various times in various projects for differing issues.

V. PROJECT IMPLEMENTATION

The implementation of the various IEMP projects varies in each geographic area, resulting in both strengths and weaknesses for the program as a whole. On the positive side, the program can target area-or site-specific problems and involve community leaders, whose participation is critical to successful implementation in developing follow-up efforts. EPA is inevitably involved in sharing its considerable technical resources and information with communities attempting to control serious environmental problems. Without direct access to these scientific and technical resources, the communities' potential to address issues raised by the IEMP would be more limited. At the same time, the Agency is too removed geographically from many local technical and public issues to be able to act effectively by itself.

A noteworthy feature of implementing the program is the reliance placed on quantitative analysis as a prerequisite to decision making and risk management. This feature is also imparted to the constituencies directly involved in the studies. Risk assessments peformed by the Cancer Assessment Group are adapted to local circumstances to set management priorities.

The weaknesses revealed in the implementation of the program may be viewed as mirror images of the strengths cited above. The lack of a common approach to implementing various studies creates difficulties in utilizing past experience or correcting technical oversights. The IEMP program has taken several different approaches to risk assessment that, at times, has led to insufficiently rigorous or inconsistent applications. Specific concerns of the Subcommittee include the following:

o The definition of risk assessment varies across projects. The most widely accepted definition of risk assessment, within EPA and the scientific community, is based on the four part construct developed by the National Academy of Sciences. This construct includes: hazard identification, dose-response assessment, exposure assessment and risk characterization. Various IEMP projects make selective use of these four components, but do not explain the scientific reasoning for omitting particular components in specific projects.

o In practice, risk assessment can be used as a vehicle for making choices for prediction or protection. The IEMP needs to clarify this distinction. Risk assessment for the purpose of prediction is an effort to estimate the public health and environmental effects that may result from anthropogenic or natural exposures to selected populations. As such, risk prediction attempts to place the magnitude of the risks in perspective with the total exposures encountered. Assessment for the purpose of protection aims at deliberately choosing conservative assumptions and models to protect against the probability of certain effects occurring. While both risk prediction and protection represent statements of probability, they rest on differing assumptions and ultimately serve different objectives. The IEMP program should clarify its definition and use of such concepts.

o The estimation of exposures is limited in several ways. Considering only incremental or limited sources of exposure can result in the failure to identify potential health problems. Methods might be considered to examine the effects of integrated exposure through several routes. For the analysis of health data, the IEMP has generally depended upon peer reviewed material generated by other parts of the Agency. When this has not been the case, however, specific acknowledgment of this fact has often been lacking.

o As previously noted, quality control measures have been uneven with respect to field data. Dispersion models have been applied without adequate explanation or justification.

o The IEMP should distinguish between the value of its efforts as a screening tool to identify and assess potential health risks and its reliability as a technical basis for managing risk. The level of analysis and the requirements for expertise are very different for these two objectives. The current IEMP process is better oriented to the first effort, where simpler methods and limited expertise are needed to help define potential problems. The information, expertise, and tools required to help refine risk estimates that serve as a technical basis for regulatory decisions at either the Federal, state or local level of government are considerably greater and, to date, IEMP has not been able to assemble and direct the financial and personnel resources required to address the latter effort.

o In general, uncertainties regarding the analysis of exposure, particularly across media, have not been delineated and given sufficient emphasis, which invites the danger that the public will place unwarranted confidence on the analytical conclusions. This issue could easily be addressed by initiating sensitivity analyses reflecting different analytical assumptions and developing different scenarios of risk. Where confidence intervals can be derived from the use of models they, too, should be emphasized. Results might more appropriately be presented as ranges of risk estimates.

o There is a need for the IEMP to more closely integrate its work with risk assessment activities in other EPA offices. To date, the program's relations with other units of the Agency have been inconsistent. The IEMP has made wide use of risk assessments developed by the Cancer Assessment Group. Except for limited inquiries of an ad hoc nature on selected technical issues, it has not effectively exploited the scientific talent and resources that exist in other units of the Office of Research and Development (especially the laboratories or research centers) or the technical staff within the regulatory offices. The Subcommittee also urges ORD and the program offices to more aggressively participate in IEMP activities. The Subcommittee has identified within EPA a number of ongoing efforts at multi-media risk assessment that have undergone review by the public and the scientific community and that are accessible to the IEMP. These include:

1. Assessing the risks of various sludge management options--ORD Environmental Criteria and Assessment Office (ECAO)/Office of Water.

2. Evaluating public health and environmental impacts of municipal waste combustion--ECAO/Office of Air Quality Planning and Standards (OAQPS).

3. ORD's Total Human Exposure (THE) program.

4. ORD's Ecological Risk Assessment research program.

5. OAQPS's multi-media evalution of lead.

Building effective working relationships with these and other programs within EPA can achieve several important benefits for the IEMP. These include: 1) access to and participation of scientitic talent that does not exist within the program; 2) awareness of, and access to, data bases relevant to problems the IEMP is investigating; 3) enhanced scientific credibility resulting from the use of data and methods that have undergone extensive peer review.

VI. PROJECT RESULTS

Several very different types of results have emerged from the IEMP projects. These roughly correspond to the varying objectives that were stated at the beginning of the differing IEMP projects conducted thus far. Phase II efforts envisage considerably more detailed analyses. To date, however, most have not been conducted; hence, their results cannot be evaluated. For this discussion, the Subcommittee broadly categorizes the project results as follows:

o Interaction and communication among government officials, industry and the public.

The Baltimore and Santa Clara Valley studies demonstrate that the IEMP methodology can be a very strong catalyst for communication between EPA and state and local officials (as in Baltimore) or among EPA, state and local officials and the public (as in the Santa Clara Valley). It can provide a natural forum for the routine interchange of similar information and concerns. There is also the potential for improved governmental and public response to emergencies and pollutant problems that previously have not been discussed and analyzed in such a forum. Another positive result of the IEMP is that it can provide a vehicle for scientific experts to discuss and improve ongoing research and monitoring programs.

The idea of having a non-adversarial forum for the exchange of information among local governing bodies and interests is a very useful idea. As yet untested, however, is the question of whether incentives or institutional mechanisms are strong enough to ensure the continuation of this interaction among officials, industries, and the public once EPA funding ends.

o Information generated and disseminated about the relative magnitudes of pollutant problems.

A strong feature of the IEMP is that it provides a common metric of risk for better understanding the magnitude of health effects associated with widely differing sources. The importance of this feature should not be underestimated; it facilitates communication of complex issues and provides for a more systematic and objective basis for environmental decisions.

However, the results presented may not be as comprehensive as perceived, and they are subject to considerable uncertainty. The resultant "risk meter" numbers will appear to be too authoritative and should be qualified by uncertainty measures. For the most part, the IEMP methodology produces conservative upper bounds on the risks that are analyzed. Such numbers, if they are not qualified, can be very misleading both to decision makers and to the public. The Subcommittee strongly urges that the use of the IEMP methodology not exclude other sources of information about environmental problems. For example, local data on the frequency of lead poisioning may be more authoritative and reliable than results obtained

exclusively through the use of the IEMP assessments. The Subcommittee concludes that the IEMP is most appropriately used when it stimulates decision makers at all levels of government to ask questions and seek data concerning the identification of the most significant public health and environmental problems. For various reasons, including limitations in data, time, funds, and the current state of knowledge, previous IEMP studies have not been as comprehensive as desirable. This has resulted in the analysis of restricted subsets of pollutants, exposure pathways, and types of effects. The use of a broader and perhaps cruder, but more systematic, risk screening would be one way to overcome these problems.

o Systematic framework for use in decision making.

The IEMP methodology addresses two current shortcomings of contemporary environmental decision making at various levels of government: 1) the need for policy makers to become more aware of the relative magnitude of various environmental problems and the availability of alternative regulatory and non-regulatory control strategies; and 2) the need for the public to perceive environmental problems with a more comprehensive and balanced understanding and to recognize that all major activities resulting from the use of technologies impose some degree of risk. Also, risk assessment methodologies, once learned for one type of application, have many other potential areas of application in decision making by government or industry.

o Priorities for future research.

In the process of identifying environmental priorities, the IEMP is readily adaptable as a means of identifying research needs. Initially, the methodology designed to err only on the side of false positives; further efforts must address the possibilities of "false alarm" errors. "False negatives", that is, real problems that have not been identified by the IEMP, can result if the application of the risk assessment approach does not address this possibility.

In using the IEMP as a vehicle for setting priorities for future research, special attention to these "unknowns" must be given. IEMP managers and the Office of Research and Development should develop specific mechanisms to ensure the specific data needs identified by the IEMP, or results obtained from specific projects, are integrated on a continuing basis with research planning efforts carried out by ORD.

VII. HEALTH SCORING METHODOLOGIES

There are two overall levels of analysis in the IEMP work for developing health scoring methodologies. These include: 1) a screening exercise under which potential problems are identified; and 2) more detailed analyses for evaluating risk management options. To date, efforts have been limited to screening exercises.

A. Screening Efforts

Achieving the objective of these efforts requires a comprehensive identification of potential concerns that are within the bounds of the study; hence, errors of omission are of greatest concern. Nevertheless, the approach must be scientifically credible and as consistent as possible with the knowledge and understanding of experts, including those in other parts of EPA. The approach should also provide some rough indication of the magnitude of potential problems so that more important issues can receive prompt attention.

Health assessment methods can be classified as those suitable for carcinogens and those suitable for non-carcinogens.

1) Carcinogens

Risk assessment guidelines exist for carcinogens. EPA's Carcinogen Assessment Group and other groups within EPA have generally applied the guidelines to estimate risks of exposures to carcinogens as a technical basis for regulation. The assessment methodology used is generally a conservative one, providing an upper bound estimate of risk. The use of upper bounds can lead to misinterpretation and can complicate the comparison of risks of two different compounds. The risk number estimated for a less potent carcinogen with considerable uncertainty associated with the risk assessment method can be much larger than the comparable number estimated for a more potent carcinogen with less uncertainty inherent in the assessment. The Subcommittee is concerned with these issues, but it notes that other scientific review panels, including those within the SAB that reviewed the cancer guidelines, have concluded that, at present, we can only have confidence in the plausible upper limit calculated using the methods described in the EPA's Guidelines for Carcinogen Risk Assessment. Procedures for making "most likely" or "best" estimates with the range of uncertainty defined by the plausible upper limit estimate and the lower limit estimate (which may be as low as zero) should be important goals for risk assessment research at EPA.

The preparation of specific risk assessments requires significant judgment about the choice and interpretation of input data and the specific analyses of these data. This is evidenced by the considerable discussion supporting the analyses undertaken in most of the Health Assessment Documents developed by the Office of Research and Development. Those risk assessments developed within the Carcinogen Assessment Group (CAG) generally receive extensive review by many experts within and outside the

agency, including the SAB. Hence, the risk estimates produced by the CAG have the credibility that derives from a widely reviewed and consensus-based methodology and an application of the methodology that receives additional review. CAG estimates should, therefore, be used to estimate carcinogen risks when such estimates are available. In some cases, it may be appropriate for the IEMP to review the basis for the CAG estimates and examine the sensitivity to specific assumptions in determining the numerical results. When this is undertaken, it should be explicitly stated to avoid confounding results based on different levels of review.

Occasionally, there may be some evidence that a substance is a carcinogen, yet its risk has not been estimated by CAG. In such cases, the presence of this substance could be noted by the IEMP as a sort of "yellow flag" warning. When bioassay results are available, it may be appropriate to calculate a quantitative risk estimate using a methodology consistent with EPA's Guidelines for Carcinogen Risk Assessment. In the absence of internal review by EPA staff and external peer review, such estimates should be clearly identified as speculative, and their use should be restricted to "what-if" investigations to assess the potential magnitude of the health risk posed by the substance in question. Careful qualifying language should be used to discourage readers from misinterpretating these estimates as having the same level of credibility as the peer reviewed estimates from CAG, and to discourage the use of these estimates by EPA or other regulatory agencies at the Federal, state, or local level for regulatory decision making. The extensive caveats used with the risk estimates for TCA in the Santa Clara Valley IEMP Phase I report represent the type of careful description needed when such speculative estimates are used. Nevertheless, some peer review of such independently derived risk estimates would be desirable.

2) Non-Carcinogens

Evaluating non-carcinogen issues is more difficult because there are, at present, no guidelines for quantitative risk assessment for non-carcinogens, although such guidelines are currently under development by several groups. There also does not appear to be a clear consensus on the appropriate role of quantitative risk assessment for these agents.

Recently, the Agency has introduced the concept of a Reference Dose (RfD). This is an implicity safe level below which effects are not expected, although its definition appears to be largely in terms of the procedure used to calculate it. Reference doses, or an equivalent such as an Acceptable Daily Intake (ADI), have been calculated by several Agency offices as a scientific prelude to regulation and/or policy development. These calculations have followed the traditional practice of using a no-observed-adverse-effects-level (NOAEL) from animal studies and dividing by a safety factor of 10, 100, or 1,000 in order to estimate a level at which human exposure becomes a concern. ADI and RfD levels have generally received extensive peer review. The methods involved to calculate the RfD are well delineated, but substantial interpretation of the underlying data is usually required. The IEMP uses the RfD in its screening efforts; when estimated exposures exceed the RfD, the estimated number of individuals exceeding the RfD is identified. Often potential or even identified toxics are encountered for which no RfD exists. In these cases, the IEMP has applied the methods used to calculate the RfD to the underlying toxicity data to estimate the "lowest presumed human

threshold." This value is used in the analysis as the RfD would be used. The calculation of this value may depend quite critically on judgment, in addition to the toxicity data. Given the different levels of peer review associated with RfDs, it is important that those derived within an IEMP project be clearly identified and caveated.

The use of the RfD alone, without an estimate of response above this level, does not address some potentially important issues such as the severity of impact and the number of people likely to respond to the environmental level of the agent. Individual or population response depends upon both the environmental level of the agent and upon the shape of the dose-response curve. The IEMP has developed a method to represent the dose-response relationship and has asked the Subcommittee to review it. The IEMP has noted some examples when application of the method would change the relative priority given to various issues.

The Subcommittee has reviewed the method, and in general, concludes that the IEMP should stimulate the Agency as a whole to consider such methods, among others, in the further development of risk assessment guidelines and procedures. The evaluation of a method, however, requires an in-depth assessment of its repeated application. The Subcommittee recommends, therefore, that EPA's Risk Assessment Forum undertake this effort, present its analysis for peer review and publish its results.

At this time, the Subcommittee believes IEMP's main emphasis should be on the RfD. In its screening effort, the IEMP should identify the number of individuals exposed to levels at or above the RfD. Where significant numbers of individuals may be exposed above the RfD, further analysis of the severity of the impact and the dose-response relationship will be appropriate.

B. More Detailed Studies

These studies require considerably more detailed information and greater precision in risk estimates to help guide risk management policies. Accordingly, some modification of the IEMP methods is warranted. One advantage of these studies is that they are more narrowly focused, and attention may be concentrated on a small number of toxic substances to aid risk management decisions. Because considerably more detailed scientific input is required in these studies, peer review mechanisms need to be an integral part of these efforts.

1) Carcinogens

The EPA Guidelines for Carcinogen Risk Assessment provide for the flexibile use of available scientific information for quantitative risk assessment, and the Subcommittee encourages development of procedures for making "most likely" or "best" estimates, as opposed to the plausible upper bound estimates calculated using EPA's standard methodology. Innovation in carrying out detailed quantitative risk estimates for specific carcinogens should receive peer review, and such estimates should be accompanied by

extensive sensitivity analysis. The sources of uncertainty in the risk estimate should be clearly identified and discussed. The methods used for the risk estimates should be fully documented and summarized in non-technical language so that the basis for the calculation is readily accessible to all interested parties.

2) Non-Carcinogens

The state of the art of quantitative risk assessment is not as far advanced for other health endpoints as it is for carcinogens. When it is clear that a significant number of people are exposed in the ambient environment above the RfD level for a toxic substance, further analysis may be needed as a technical basis for risk management. The Subcommittee supports the development of appropriate methods to carry out such an analysis, drawing upon the scientific and analytical resources available in the Office of Policy, Planning and Evaluation, the Office of Research and Development, and other parts of EPA. Such an analysis should receive careful scientific peer review, especially where innovative methods are used. For many substances, the severity of the impacts may be a major issue as, for example, distinguishing between clinically measurable effects that are rapidly and completely reversible at low levels of exposure, versus irreversible impacts representing clearly significant adverse changes in health status that may occur with higher or repeated exposures. It will be appropriate to document fully the methods used to carry out extensive sensitivity analysis showing how conclusions depend on specific data and assumptions, and to describe the extent and sources of uncertainty in the quantitative risk estimates.

PART TWO:

THE PHILADELPHIA, BALTIMORE, SANTA CLARA VALLEY AND DENVER GEOGRAPHIC PROJECTS

VIII. PHILADELPHIA INTEGRATED ENVIRONMENTAL MANAGEMENT PROJECT*

A. Overview of the Project

The Philadelphia IEMP was a large-scale study of the effect of toxic pollutants on human health in the Philadelphia metropolitan area. Although the study had a number of goals, not all of them clearly delineated, the three most important goals included: 1) developing and applying new methodologies or applying existing methodologies to new situations--particularly quantitative risk assessment, multi-media analysis, and cost-effectiveness analysis; 2) improving EPA decision making and priority setting through the use of these methodologies; and 3) improving state and local decision making through the use of these methodologies.

Phase I of the Philadelphia IEMP identified eleven issues to pursue in Phase II. These related to chlorinated solvents, benzene, chloroform, formaldehyde and volatile organic compounds in general. Phase II involved risk and control-option analyses of seven of these issues and also proposed to collect monitoring data on four issues: benzene emissions, formaldehyde releases to ambient air, combustion of used oil and air emissions from landfills.

B. Comparison with Other IEMP Studies

Philadelphia was the first of the geographic IEMP Studies. In terms of institutional arrangements, EPA, state, and local officials worked together to direct the project, although the dominant role was played by EPA. This contrasts with later studies in which EPA yielded more decision making authority to state and local officials.

C. Comments by Interested Parties

The Subcommittee heard testimony from state and local officials involved in the Philadelphia IEMP. The general tone of these comments was negative. The officials viewed the study as having made their duties more difficult by unduly alarming the public about issues that involved some greater-than-zero risk of cancer but that, in the view of these officials, did not represent a high public health priority. An industry spokesman testified that the study should have used best estimate risk assessments rather than the standard EPA worst case methodology. No views from environmentalists or other groups were heard by the Subcommittee on this study.

D. Subcommittee Comments

The Philadelphia IEMP study has only partially met its goals. The three goals included:

- o Methodology Development and Application

The underlying methodological innovation of the project was to analyze environmental priorities (and potential control actions) on the

* Subcommittee members contributing to this section of the report included Dr. Cornish, Dr. Davies, Dr. McMichael, and Dr. Frank.

basis of overall risk regardless of the medium or form of the risk. This is a significant departure from current practice (at both the Federal and local level) and, in the opinion of the Subcommittee, is a very important and useful innovation. It is, in fact, the most important methodological contribution made by the IEMP as a whole. It should also be noted that the development of such a risk-based methodology is a very difficult intellectual and scientific task.

The application of quantitative risk assessment in the Philadelphia project involved the use of a health scoring methodology that the Subcommittee closely examined. The risk assessment results showed small cancer risks from toxics in ambient air (an upper-bound estimate of about 0.2 excess annual cancers from both point and area air sources) and a larger, but still modest, risk from drinking water (2.4 cases annually). However, it should be kept in mind that these results excluded some potentially significant sources of toxics, notably motor vehicles and municipal incinerators. Given the lack of comprehensiveness in the analysis of sources, the risk assessment is primarily useful as a way of assessing the comparative importance of particular sources rather than of the importance of the toxics problem generally.

The lack of comprehensiveness was primarily due to the limits on resources available to the study and to a recognition by the staff on what could be achieved. It was aggravated by the failure of some of the IEMP's efforts to collect original data using novel or state-of-the-art techniques. Four such efforts were part of the Philadelphia project: benzene and formaldehyde in the ambient air, air emissions from landfills, and combustion of used oil. The benzene data indicated that ambient benzene levels were within ambient air guidelines, but the small number of samples and the high degree of variability of observed concentrations limit the reliability of the data. The use of models to predict ambient concentrations of formaldehyde failed because of formaldehyde formation in the atmosphere through photo-oxidation of volatile organic compounds (VOC). Ambient levels of formaldehyde derived from monitoring appeared to be below guideline levels, but doubt has been cast on the analytical method employed in the monitoring program (see page IV-14 of the Philadelphia study). A variety of difficulties with the experimental ROSE system resulted in a failure to measure the contributions of a landfill to ambient VOC levels, although data obtained on VOC levels in the general vicinity of the landfill contributed to a concern over toxic air emissions from landfills. The data on combustion of used oil were not sufficient to allow exposure or risk assessment (IV-22), although analysis of samples of used oil indicate that the lead content of used oil is a potentially significant problem (IV-25).

o Impact Upon EPA Decision Making

The impact of the Philadelphia study upon EPA is difficult to ascertain. The study set some important precedents for the later geographic studies

(e.g., the basic Phase I - Phase II framework and the idea of bringing local officials into decision making). It also can be argued that the Philadelphia study encouraged EPA to think in terms of overall comparative risk as the basis for setting priorities.

The Philadelphia project resulted in bringing two specific problems to EPA's attention--the contribution of municipal wastewater treatment plants to VOC air pollution and the problem of lead in used motor oil. EPA has taken no final action on either problem, although National Pollution Discharge Elimination System (NPDES) permits for treatment plants increasingly take the VOC problem into account. In addition, it can be argued that the relatively low risks attributed by the project to toxics concentrations in ambient air and water confirm an Agency view of the lack of urgency of the toxics problem in this area.

o Impact Upon State and Local Decision Making

As noted above, state and local officials did not think that the project has been particularly useful to them. However, the IEMP staff reported that, in private conversations with Philadelphia area officials, the latter expressed the view that the study yielded a deeper awareness of the problems posed by the inter-media transfer of pollutants, prompted a continuing informal cooperation among these officials and EPA and contributed to the effort by certain industries to pretreat their wastes in advance of impending Clean Water Act regulations requiring pretreatment. The Philadelphia study (VI-44) notes that the chemical manufacturer that was the prime source of VOC discharges to the Philadelphia treatment plant has markedly reduced its discharges, although it is not clear whether action can be traced to the IEMP study. There may be a greater knowledge of and sophistication about risk assessment and cost-effective analysis at the local level as result of the IEMP project, but it is not clear that the project has had any lasting impact on state or local decision makers.

IX. BALTIMORE INTEGRATED ENVIRONMENTAL MANAGEMENT PROJECT*

A. Overview of the Project

The Baltimore project began in pilot form in 1983 under full EPA control. In 1983, EPA delegated this control of the project to two local committees, a Management Committee and a Technical Advisory Committee.

A great deal of the effort expended in the Baltimore project from its inception seems to have revolved around issues related to the governance and control of the project, setting the scope of the project, identification of specific issues and compilation of data. Resolving issues related to project management and control required an intensive effort such that the project was actually started twice, the first time in the fall of 1983 and the second time in late 1984. In the process, there were considerable changes in personnel, and major shifts in contractors that were developing information for the project.

Plans for Phase II of the Baltimore study are to conduct more detailed evaluations of issues that have been identified as particularly critical in Phase I, and to institute pollution control measures, where needed. The Phase II process is less well defined that Phase I, largely because it focuses on site-specific issues and because of unresolved questions on the funding of implementation plans.

B. Comparison with other IEMP studies

There are many features of this study that differentiate it from the other geographic studies. The Baltimore IEMP has progressed from an EPA designed study to one that is enriched by state, county, and local inputs concerning potential and actual toxic pollution problems. A statement frequently used during a visit by a workgroup of the Subcommittee was the assumption of local control in the context of an experiment in environmental management. In contrast to the Philadelphia study, there is a high degree of local confidence in the approach being implemented in Baltimore. The level of local control in this study is atypical of IEMP studies, and it is planned that future studies will not follow this approach, but one similar to the Santa Clara Valley study.

The Baltimore Management Committee provides a vital link to ensure progress in the overall development of the project and has worked closely with the Technical Advisory Committee (consisting of scientists from local governmental agencies and universities) to develop a set of priorities in Phase I. The six identified issues are presently being finalized for examination in Phase II. In contrast to some other IEMP projects, the Phase II activities primarily will include further research rather than the implementation of management decisions based upon weak exposure and risk data. A commendable feature of the Management Committee deliberations has been its determination to develop the program at its own pace, and not be driven by externally imposed milestones. This has provided the Baltimore IEMP study with the time necessary to ensure that the priorities

* Subcommittee members contributing to this section of the report included: Dr. Brown, Dr. Hartung, Dr. Lioy, and Dr. Silbergeld.

for Phase II are the most important, and will be able to proceed with a degree of scientific and engineering rigor.

Another departure from the other IEMP studies has been the Management Committee decision to establish a standing Technical Advisory Committee to oversee the Phase II analyses. The peer reviewers' role will include assessment of the uncertainties, the methods of expressing risk, and the health significance of the risk numbers. This additional committee has the potential for making significant contributions to the study, and its role should be revisited at a future date to assess its success within the overall IEMP process.

One of the impressive aspects of the Baltimore IEMP study stems from the selection of the final six priority issues after discussions were held on over forty potential issues. Further, the final list of priority issues would be considerably different if the Management Committee had been required to make hastier decisions. Again, this points to a thoughtful approach to the decision making process, and the need to digest information available from a number of sources.

Another aspect of the Baltimore study that is different from all other IEMP studies is the manner in which local committees used the health scoring methodology. The results of the methodology did not determine the final prioritization of issues. Local experience and data on exposures, morbidity, and mortality were used in making the final selections. The result was the identification of at least two issues, indoor air pollution and lead, for inclusion in the final list that would not have necessarily been included otherwise. This approach to applying the health scoring methodology underscores the need to view Phase I as a semi-quantitative exercise, and avoid the temptation to count bodies, e.g. as in the Philadelphia and Santa Clara studies.

C. Evaluation by EPA's Program Evaluation Division

A major conclusion of an internal EPA review of the study by the Program Evaluation Division was that the integrated environmental management concept is basically a rational approach to environmental protection which deserves a fair trial and possible application in some form. However, in practice, there are many technical, institutional and managerial issues that provide some reconsideration as to whether the IEMP approach is workable in practice.

On the technical side, the limited availability of data and the limitations in the scientific underpinnings make it difficult to establish reasonable estimates of risks for exposure resulting from multiple chemicals by multiple routes arising through multiple media.

Institutional and managerial problems include jurisdictional disputes and the public debates concerning politically unappealing issues in election years. The management of the project in the face of conflicting

interests and insecure sources of funding for the investigation of environmental problems (that are often coupled to more secure sources of funding for any remedial measures that might be proposed), is an extremely difficult proposition.

In general, the Program Evaluation Division concluded that the IEMP process is still in an evolutionary stage, that the basic concepts within the IEMP approach are sound, but that the scientific and technical basis for executing the program is weak.

D. Comments by Interested Parties

As with other IEMP studies, the Subcommittee sought out opinions from persons who had directly observed or participated in the study and had formed impressions or judgments of its strengths and deficiencies. In Baltimore, most of the potentially interested parties have received some chance to participate, either through its Management Committee or the Technical Advisory Committee. The latter also provided access to the IEMP of additional consultants from government, industry, public interest organizations and universities. However, neither industry nor public interest groups influenced the Phase I efforts significantly; their inputs will be somewhat more vigorously sought in Phase II, according to the Management Committee. Finally, both committees had the benefit of further peer review by a Risk Assessment Review Panel assembled by the Johns Hopkins School of Public Health.

To solicit the views of interested parties, the Subcommittee and IEMP staff arranged for a subgroup of the Subcommittee to meet with persons especially knowledgeable about the Baltimore project. That group included all the official members of the Management Committee, the Chairman of the Technical Advisory Committee, some consultants to the project, and members of the EPA staff for the Baltimore project.

The subgroup heard a clear message to the effect that, in Phase I of the Baltimore IEMP, process was more important than science in determining its direction. The majority of the participants, if not all of them, appeared to view this situation as a great virtue of the Baltimore project in comparison with other IEMP Studies. They seemed to view the difficulties of the Philadelphia project as largely attributable to a lack of attention to process. Although the Subcommittee recognizes that the participants, by being at the core of this process, may tend to inflate its virtues, there is no doubt that at least this group believed the project to be a success because of process, not through any exclusive virtues of the IEMP itself.

The participants also believed that the issues selected for study or action in Phase II deserved attention, and that the process of arriving at those choices enabled a much greater opportunity for intergovernmental exchange of information and coordinated action on environmental problems than had previously existed. The interactions occurring through the management and technical committees, for example, made it possible for

state, county, and city officials to agree on a course of action to lessen the risks of lead by banning it in solders used in construction throughout the Baltimore area.

Less definite was whether the IEMP itself was the reason for the success or merely a convenient mechanism for intergovernmental cooperation. Local officials were skeptical about the risk assessment process and were not eager to use it as a dominant tool in selecting Phase II issues. In fact, the IEMP approach played only a support role in clarifying comparative risks, not for identifying the hazards of greatest concern. One participant said, in effect, that the project had produced no surprises, that local environmental agencies knew more about Baltimore's problems than EPA headquarters could hope to identify. Nevertheless, when asked whether any other EPA program might have had equal effect if control had been released to local officials, he stated no. The consensus of local opinion is that the discipline of attempting to adopt a multi-media perspective was useful, even though most problems turned out to be dominantly in one media; the risk analysis framework was an interesting and potentially valuable concept; and the multiple-criteria decision approach was appropriate for Baltimore's needs.

Another virtue of the IEMP process for local participants was the opportunity to benefit, scientifically and financially, from other EPA programs. Baltimore's environmental agencies were able to use the IEMP experience to work with EPA's Office of Research and Development in its decision to conduct a Total Exposure Assessment Methodology (TEAM) study in their region. This work will consider human exposure to toxic substances through several routes, including indoor air. Baltimore will thus gain a more sophisticated profile of the distribution of exposures from various sources in its environment, with Federal support. Other EPA offices will also contribute efforts to help Baltimore characterize its environmental problems.

Particularly important from these participants' vantage point was the ability of the local governments to control how the results of the IEMP were to be communicated to the public. They believed that other IEMP studies had erred in presenting body counts of predicted numbers of cancer deaths, even with many qualifying phrases (although they did emphasize the importance of careful qualification of any results). Because the Subcommittee has not seen the Phase I Baltimore project report, it is not yet clear how the results will, in fact, be presented, but it seems likely that it will not state many purely quantitative results capable of easy misinterpretation.

One final observation should be mentioned. The participants seemed to think that little truly scientific work had occurred in Phase I, even though EPA and its contractors had undertaken several data collection and processing efforts on behalf of the Baltimore project leadership. Some of the analyses seemed to have had the effect of confirming preconceptions about the most important environmental issues in Baltimore, rather than identifying new issues or discounting the preconceptions. The participants seemed confident that more influence from scientific analyses would be expressed in Phase II.

E. Subcommittee Evaluation of the Baltimore IEMP Study

1) Scope of the Project

The Baltimore IEMP study exceeds in scope other geographic projects by including indoor air pollution as a candidate issue and several issues not exclusively concerned with human health. Both of these expansions are well within the spirit and capability of the IEMP concept and are valuable additions. The Baltimore project, like other IEMP studies, avoids occupational hazards and the risks of sudden environmental events such as an upset at a chemical plant. While some would argue that such considerations are logically part of an overall strategy for environmental management, they are clearly at the fringes of the area of potential study topics.

In general, the Baltimore project meets or exceeds the requirements for an integrated management study. Viewed from one perspective the process for identifying issues used in Baltimore was less systematic than desirable from the IEMP perspective and could have missed, or assigned improper priorities to, important issues. Relying as it did on nominations from Technical Advisory Committee members and on selection procedures that were influenced by personal evaluations, the Baltimore project could have emphasized visible or scientifically interesting issues over ones with greater local importance. On the other hand, by relying upon individuals with considerable expertise and experience with local problems this process may have minimized the expenditure of time and other resources on peripheral problems. Both local committees are convinced that the process was better at selecting the truly important issues precisely because it included expert judgment rather than relying on a narrower risk assessment concept for priority setting.

2) Project Design

Without a final Phase I report, the Subcommittee cannot fully evaluate the quality of the Baltimore project design. Its information originates from EPA's Program Evaluation Division report and other documents made available by the IEMP staff, and from the meeting with representatives of the two local committees. As can be inferred from statements elsewhere in this section, the Subcommittee is not fully comfortable with the apparently high degree of reliance on informed opinion in the process of selecting high priority issues. Furthermore, although the analyses of specific classes of issues appears to be logical, the Subcommittee has no documentation to confirm this impression. Finally, the Subcommittee believes that a clear analysis may have been obscured by the tendency to make multiple classifications of issues into incommensurable and overlapping classes. For example, the three Technical Advisory Committee subcommittees were concerned with human health (an environmental hazard endpoint), ground water (an environmental medium), and ecological impact (another environmental endpoint). It is not clear from the material presented how the classification by risk and uncertainty was used in selecting issues and whether that use was logical. Presumably, issues of high risk and low uncertainty are candidates for risk management actions, while issues of high or moderate risk and high uncertainty are candidates for further study.

Offsetting the above apparent or real shortcomings in the project design is the obvious advantage of utilizing local personnel and their familiarity with Baltimore's environmental problems. Most observers in EPA, as well as in Baltimore, now appear to believe that the qualitative inputs from local environmental professionals arrived at a better final list of issues for Phase II than would have been possible by applying the method for risk assessment of human health hazards used in Philadelphia and the Santa Clara Valley. Perhaps the balance between these strengths and weaknesses will become more apparent once the Phase I report is released.

3) Degree of Integration

The discussion of multi-media integration within the Baltimore IEMP study reveals some difficulties. The medium-specific regulatory demands placed upon the states increases the difficulty of allocating resources to examine multi-media issues on a continuing basis. The degree to which the IEMP can institutionalize multi-media analysis requires more thought, since it is not readily apparent in those projects reviewed by the Subcommittee. It should also be recognized that it is EPA's plan to turn the process over to the state, and it is not clear that an integrated environmental planning process currently exists.

4) Project Execution and Achievements

The Baltimore IEMP is not close to completion and, therefore, it is impossible for the Subcommittee to assess the final results. Some observations are warranted, however, to provide some perspective on the potential for success.

The IEMP approach led to the generation of many useful hypotheses about health and environmental problems in the Baltimore area. Although anecdotal documentation exists on inter-media transfers of pollution, neither the prevalence nor the magnitude of such events had been previously investigated and documented. The IEMP approach in Baltimore is logical in that it seeks to identify environmental problems in all media simultaneously, to prioritize them, and to construct an optimal approach for the mitigation of these problems. It does this by evaluating the potential exposures and resulting risks to humans arising from all media.

The evaluation of potential exposures is largely based upon the data which are readily accessible in large data banks. A weakness in these data is that they were often collected for purposes other than exposure estimation. In the early phase of the project in 1983, while it was still fully under the control of the EPA/IEMP, there was a modest sampling program designed to identify selected volatile organic compounds in air. In spite of this effort, the previous evaluation committee still believed that the data base was relatively sparse, considering the broad range of intermedia issues which needed to be dealt with, and recommended that the data base and the guidelines for their use should be improved.

The fact that most management decisions are being delayed until after the completion of Phase II is a positive sign, and this caution should increase the likelihood of succeeding in many areas. The approaches used to address the six priority issues have different, but identifiable, endpoints that can be used to make management decisions. Each issue and approach are briefly stated below:

o Indoor air pollution--completion of a TEAM study by EPA's Office of Research and Development and the IEMP.

o Ambient air toxics--identification of sources and development of a regulatory program.

o Underground storage tanks--development of engineering solutions to leakage problems.

o Lead--abatement strategies for painting, and lead pipe replacement.

o Baltimore harbor--development of a practical design to study the harbor with eventual state funding of a study.

o Trihalomethanes--using national approaches to solving the problem.

5) Strengths and Weaknesses

How does the Baltimore IEMP study compare with the profile of strengths and deficiencies that the Subcommittee sees in the IEMP program as a whole? It may be too early to answer this question, in that no final report from Phase I is yet available. The remarks below must necessarily reflect preliminary observations on the direction of the project.

In many ways, the Baltimore project portrays almost the exact opposite profile seen in most IEMP projects. It is much more traditional in that it uses consensus building to identify the major issues rather than apply a consistent yet incomplete risk-driven assessment. Consequently, it has the virtues and flaws of that approach. These include:

o Taking into consideration a wide variety of additudinal and impressionistic as well as scientific factors. Human perceptions of risk are considered to be important and not necessarily just a misreading of "true" risks.

o Processing information of many kinds that cannot easily be placed in a quantitative framework.

o Viewing local interests as a positive influence on decision making, not as an impediment to clear quantitative thinking, and taking advantage of the political process rather than avoiding it.

o Seeming, at least through Phase I, to avoid relying on risk assessment methods that are easily challenged as unreliable and uncertain.

o Including environmental problems that have few, if any, human health hazards, yet may be important for non-human organisms or for the physical environment.

o Featuring a peer review process designed to identify scientific weaknesses.

o Suffering from lack of scientific demonstration that the issues selected for future work are, in any absolute sense, the most important ones. It is not clear that these issues would rank at the top of Baltimore's environmental problems if ranked on health risk, either collective or individual.

o The decision making process may be more vulnerable to influence by a strong individual or agency that may have a different agenda than that which is in the best environmental interests of the whole community.

X. THE SANTA CLARA VALLEY STUDY*

A. Overview of the Project

The IEMP, as demonstrated through the Santa Clara Valley study, represents an effort to create an innovative process of integrated environmental management and education. The task of Phase I of the study was to identify and compare potential human health risks attributable to various pollutants, sources, and exposure pathways. The results of Phase I are to assist Federal, state and local governmental officials, as well as firms and individuals, in setting research and regulatory priorities. Phase I was also designed to identify pollutants, sources, and exposure pathways for which limited data exist.

An important goal of the study, as viewed by the IEMP staff, has been to integrate scientific information and public policy making and to improve public comprehension of acceptable risk. The study, according to the IEMP staff, would be considered successful if it created a "legacy of an environmental management process." According to the involved parties, however, the structure of the integrated environmental management process in the Santa Clara Valley is still very fragile.

The IEMP has helped to reduce public conflict between the different organizations and increase understanding of the capabilities and limitations of each organization. Thus, the IEMP has contributed to improved communication among members of the community organizations and encouraged them to share information and resources. The IEMP also encouraged a public realization that there is a community responsibility regarding the toxic waste problem.

B. General Review Comments

The methodological aspects of the Santa Clara Valley study are relatively simple and approximate; this is commensurate with the objectives of a screening study. The study uses numerous simplifying assumptions, most of which overestimate the risks. Under this approach, most potential problems (with the exceptions noted in Section 3) could be identified. It is also possible that many less serious problems could be identified in the preliminary contaminant screening process.

The Subcommittee's greatest concern with the study occurs at the point when it goes beyond the screening efforts of Phase I. For the most part, Phase I identifies problems determined by upper bound analyses that are subject to considerable uncertainty. The uncertainties occur principally in the areas of exposure and toxicity (potency). It is important that these two factors should be neither underestimated nor grossly overestimated prior to analyzing risk management options. Therefore, the uncertainties associated with exposure and toxicity estimates should be clearly identified and, to the extent possible, quantified as soon as possible in the course of the Phase II work.

* Subcommittee members contributing to this section of the report included Dr. Cohen, Dr. North and Dr. Wyzga.

Making appropriate risk management decisions and setting research priorities (as in Phase II) can only be accomplished with foresight of the type and magnitude of uncertainties involved in the risk assessment process. These efforts require more sophisticated tools than those employed in the Phase I study.

Local authorities appear to take the study results regarding health risks literally. For example, the screening results of Phase I were misinterpreted by several members of the Public Advisory and Intergovernmental Coordinating Committees. These persons implied that potential effects (presumably upper bounds) were best estimates. Therefore, more care is needed in presenting as well as in deriving results.

C. Sources and Contaminant Selection

One of the important objectives of the project was "to evaluate and compare the health risks...from toxic pollutants in the environment." Given this objective, the consideration of sources may be too limited because the pollutants considered, and their sources, are largely based upon incomplete data bases from a single medium. A truly integrated study needs to go further and ensure that all relevant pollutants are considered. The study made a reasonable effort in its initial compilation of chemicals; some, however, were dropped from further consideration due to lack of existing monitoring data. Further monitoring efforts may be advisable in, or prior to, Phase II to ascertain whether these chemicals are present. Consideration might also be given, in or prior to Phase II, to the transformation products of some of the chemicals initially identified.

One way of testing the comprehensiveness of sources is to examine exposures predicted from source levels and to compare these with monitored concentration levels. Discrepancies could indicate poor source inventory or less than adequate modeling. The discrepancy noted for benzene, for example, may be a clue that source estimates for organics emitted to the air are low. The study also assumed that chlorinated hydrocarbons do not degrade, despite strong evidence that 1,1,-DCE and vinyl chloride were detected where no likely sources were identified. The rationale for and implications of this assumption should be clarified. This suggests that comparisons of exposure monitoring and modeling should be undertaken in, or prior, to Phase II. Finally, source-receptor modeling is a viable procedure that should be been taken to assess the significance of various sources in relation to Phase II.

D. Contaminant Transport

1) Ground water

The Phase I analysis assumes that the major clay confining layer is impermeable and that contaminants can move past this layer through conduit wells. This assumption relies on: 1) limited monitoring data indicating that contaminants have not yet reached the lower aquifer through the clay layer, and 2) on judgments of individuals consulted by the project managers. Hence, the study suggests that ground water contamination is limited to the upper aquifer. The study does state, however, that cracks or fissures

in the confining layer separating the upper and lower aquifer can lead to a significant exchange of pollutants between the two zones. Yet, an analysis that considers possible contaminant migration through cracks and fissures in the clay layer was not considered in Phase I. Consequently, quantitative estimates of the time scale for future contamination of the lower aquifer have not been provided. The above deficiency has been recognized in the Phase I report and a recommendation has been made to reexamine the effectiveness of the clay layer in protecting the lower aquifer (Phase I study, chapter 4, page 92).

The Phase I analysis assumes that the dispersion coefficient in the Santa Clara Valley is similar to aquifers elsewhere. Furthermore, retardation factors for the Palo Alto Baylands have been applied to all the hydrologic zones except the southeast recharge zone. Uncertainties in model prediction associated with the above assumptions, and their effect on the risk analysis, have not been clearly addressed. There is a need to provide better documentation of the various scientific assumptions and models utilized in reaching the conclusions regarding the degree of ground water contamination.

Ground water contaminant transport models employed by the IEMP are generic rather than site-specific. Since ground water contamination problems are site-specific and require detailed hydrological characterization in order that contaminant migration be assessed, it is unlikely that generic modeling can lead to more than a very crude assessment of the level of current or future ground water contamination.

The analysis of future risks from ground water contamination is the most uncertain part of the Phase I analysis. In fact, it is unclear whether future contamination resulting from continuing contaminant plume migration is likely to be higher or lower than the current estimates. Thus, conclusions to date may be incorrect.

2) Air Contaminants

The characterization of metals and organic particulates was based on rough estimates of emissions from a partial accounting of a variety of plausible sources. The area sources were scaled to the Santa Clara Valley based on information available in the national literature, while point sources were estimated based on preliminary source testing. The estimates of ambient concentrations for particulate organics and metals have not been confirmed by modeling of the emission estimates. Moreover, detailed source estimates specific to the region have not been carried out. Some of the above deficiencies are being addressed by Phase II of the study.

In the analysis of organic particulates, the study assumes that data on Benzo(a)Pyrene concentrations from other cities can be applied to the Santa Clara Valley. Although it may be logical to scale emission rates based on data for other regions, the assumption of equivalent

concentration levels may be a gross oversimplification. The concentration of B(a)P in the atmosphere greatly depends on the rate of atmospheric dry deposition in the region as well as the effect of rain scavenging during rainy periods. It would have been more appropriate to estimate the concentrations of organic particulates based on multi-media transport models driven by estimates of sources in the area. The second assumption employed was that the ratios of total suspended particulates to polyaromatic hydrocarbons from other cities can be applied to the Santa Clara Valley. Both of the above assumptions have not been substantiated, and the degree of uncertainty is unclear. The uncertainty in the PAH estimates is at least two orders of magnitude and, for B(a)P, presumably even greater. In order to clarify the quantitative risk estimates, the uncertainty in the estimates of B(a)P exposure and toxicity should be discussed.

Future monitoring of organic particulates should include the determination of particle size distribution, and the size distribution of the relevant organics within the aerosol phase. Such information is necessary in order to assess the rate of dry and wet deposition of particulate organics.

E. Exposure and Health Risks

Estimation of chronic health risks for many toxics derive from total exposure and, thus, the consideration of incremental exposures could be misleading. This is less of an issue for carcinogens where most commonly used dose-response curves are linear at levels where exposure occurs; hence, incremental risk is relatively independent of the baseline exposure. This is not the case, however, for systemic toxicants where the estimated exposure may be less than an assumed threshold level at which effects occur. When the estimated exposures are added to exposures from all sources (such as indoor, occupational, or other sources not considered in the study), the total exposure may exceed the threshold. This is of particular concern given several estimated concentrations that are near the reference dose (RfD). See Tables 3-26, 3-28, 4-13, 4-29, and 5-15 in the study. One way to address the above problem is to determine if significant indoor or occupational sources are present for those toxics where environmental levels may be below (by an appropriately chosen factor) the RfD level where a concern for adverse health effects can exist.

The health risk assessments originate largely from the EPA Cancer Assessment Group's plausible upper bound potency estimates, combined with exposure levels estimated from models where monitoring data are not available. The methodology for health risk assessment described in Chapter 2 of the study follows standard EPA practice for the most part. Chapter 2 presents a good non-technical introduction to this methodology. In this chapter and elsewhere, the study could be greatly strengthened as a

scientific document by including pertinent technical references. For example, references should be included for the CAG methodology and the EPA health assessment documents (or similar sources) for all the potency and reference dose numbers used in the revised Phase I report.

The limited assessment of non-cancer health effects appears to be based only on the reference dose. It also appears that pressure from some of the local participants led the authors to include the discussion of non-cancer health methodology in Appendix B of the study. This appendix is incomplete. It is unclear how potency estimates are developed from the data, and table B-1 and subsequent graphs cite unreferenced numerical information.

Given that the assessment of health risks addresses mostly carcinogens, the use of average rather than peak exposure levels is appropriate. For non-carcinogens, however, the question of the acceptable method to measure dose over time can become very important. The above approximate approach may be adequate (in a Phase I analysis) considering that the objective of the study is to identify substances and exposure routes for further scrutiny (in Phase II) rather than carry out detailed analyses to estimate the incidence of health effects.

Aside from the above concerns with the methodology, the Subcommittee has concerns with the discussion of the estimated health risks associated with exposure to treated drinking water. The study concludes that "Trihalomethanes (THM) appear to account for a substantial portion of the total health risks from surface water souces of drinking water." Moreover, "different disinfection technologies exist that result in different THM levels; thus, THM exposure is potentially controllable to a significant extent. Based on data from the SCV Water Department, we estimate that chloroamination reduces THM levels, and thus risks, by about 1/3 from THM levels generated by chlorination alone." The above conclusion is based upon an oversimplification of the water treatment issue because it ignores the efficacy and other potential impacts of the treatment alternatives. The National Research Council addressed the health effects of disinfectants and their by-products (Drinking Water and Health, Volume 7), and it appears that these issues are more complex than perceived by the study's evaluation.

Finally, the Subcommittee notes that exposures from indoor air, both residential or occupational, were not addressed in Phase I. Also, the study did not consider exposures due to episodic releases of air contaminants. Exposures through dietary intake, dermal contact, and soil ingestion (primarily by infants) were not addressed in Phase I, nor is there an indication that they will be considered in Phase II. As a result, the health risks due to exposure to PAHs, lead and other metals via dietary intake and soil ingestion will remain unresolved unless considered in Phase II of the study.

F. Scientific Uncertainty

Many questions arise regarding uncertainty in the risk analysis. How do the uncertainties in the source and emission data or estimates, transport modeling, exposure and dose-response curves and extrapolation procedures propagate in the analysis of the health risks? Where uncertainties exist, they should be, to the extent possible, quantified and carried through the various analyses, and stated clearly in the report. This significant part of the analysis was not addressed as fully as desirable in the Phase I study. The effect of scientific uncertainties on priority-setting in Phase II was not considered, and this point should be revisited.

G. Communication of Scientific Information, and Public Perception of the Santa Clara Valley Study

The role of both the Intergovernmental Coordination Committee (ICC) and the Public Advisory Committee (PAC) was to provide the IEMP staff with feedback regarding local community concerns, and suggestions and critiques regarding the direction and progress of the study. The ICC and PAC also provided the forum that facilitated communication and, hence, integration of community involvment. Through the participation of the ICC and PAC, the IEMP staff succeeded in mobilizing the community to participate in the various stages of risk analyses and risk management. The IEMP staff appear to conceive of their role in this study as primarily that of process facilitators. This is a considerable departure from the role assumed by the IEMP staff in the early stages of the Phase I Baltimore study.

All parties perceive risk communication to be an important factor in the project. Some community participants interviewed by the Subcommittee argued that some of the underlying assumptions regarding the air and ground water contaminant transport models and their consequences were not clarified to the full satisfaction of the advisory committees. In general, however, members of the PAC and ICC have expressed enthusiasm and support for the continuation of the IEMP work in Santa Clara even in the light of an initially imperfect process.

A point of great concern to the Subcommittee is that it appears that the only independent scientific critique during the progress of Phase I of the study was provided by the ICC and PAC. Many members relied upon for peer review were not trained in the requisite scientific disciplines to conduct a thorough review. While it is encouraging that the PAC and ICC were concerned with various scientific assumptions of Phase I, it does not appear that they had much impact on the scientific approach taken. For example, suggestions made by the PAC that were not followed by the IEMP include: 1) requests for clarification of uncertainties associated

with risk numbers; 2) inclusion of indoor exposure assessment; 3) addition of some key pesticides to the chemicals evaluated by the IEMP; and 4) the request for quantifying the uncertainty associated with the assumptions made in the ground water contaminant transport models. Although the participation of the ICC and PAC committees helped to build in a system of checks and balances, they were not capable of providing a rigorous and impartial scientific review that would be recognized as such by the scientific community.

H. Synopsis of Major Subcommittee Comments

The task of the IEMP, as perceived by the public, is to identify risks to public health posed by exposure to toxic contaminants, to compare the risks from such exposures in order to prioritize research and management strategies, and to develop alternative approaches that can be used by local government to manage such risks effectively. Several expressions of this public perception (e.g., as indicated in the Bay Area Monitor Newsletter published by the League of Women Voters of the Bay Area, and as indicated by members of the PAC Committee) note that the IEMP applies the best available scientific knowledge and management skills to comprehensive, environmentally related public health issues. Consequently, despite the fact that risk numbers are highly approximate, they have been quoted as absolute numbers.

The Santa Clara Valley community depends on the IEMP to provide accurate risk analysis. Without the IEMP involvment as the organizing body, it is unclear whether the members of the various state and local organizations are likely to commit resources for a long-term endeavor.

Phase I of the study could have benefited from a more thorough process of scientific review during the design and implementation phases of the study. The Subcommittee understands that the IEMP sought to enhance local acceptance of the study by using local expertise but, in the future, it may be advisable to also achieve a better balance between experts with greater scientific stature for the issues under review and local knowledge. These deficiencies are exemplified by the desire expressed by some members of the advisory committees for having an IEMP team composed of a greater number of scientists as opposed to policy analysts.

The IEMP needs to improve its Phase I screening procedure. The identification of problems and detailed analyses in Phase II will require a great deal of specific expertise and sophisticated methods beyond those employed in Phase I. The Subcommittee also urges the IEMP to better formulate and document the general IEMP assumptions and approach so that it might serve as a framework for other regions of the country. Finally, the Subcommittee recognizes the advances achieved by the IEMP in communicating risk to the people of the Santa Clara Valley.

XI. DENVER IEMP PROJECT

Although not initially a part of the review, the Subcommittee believes it is appropriate to include comments on the design of the Denver IEMP project. Much of the information presented from other studies is now several years old, and the IEMP process has undergone significant changes in approach, methods and personnel. The Subcommittee's comments on the Denver study focus only on the overall study design and process described through a briefing since the study was in the early stages of implementation when presented to the Subcommittee.

Denver is not, in the true sense, a multi-media study. It is not designed to track the transport of pollutants. Rather, it is designed to identify and evaluate the major environmental problems in the Denver area from various media, with a clear emphasis on air toxics. The specific scientific objectives of this study remain vague, however. The non-scientific objectives of the project have been clearly articulated and to a far greater extent than in past studies. Managers of the Denver study are receiving direct input from other units of EPA. Hopefully, this broader participation of Agency scientists will not only improve the technical quality of the study, but will increase the resources available for the project and improve the utility and long-term impact of the findings.

Through cooperation with ORD, the Denver project staff currently plan to conduct extensive environmental monitoring. This will decrease the need to rely upon historical data files and will provide a mechanism for validating transport and exposure models, an element lacking in previous studies. In addition, the staff plan to use models that have undergone Agency review by ORD or outside scientific groups. This will include the use of the Agency's published guidelines in conducting health risk assessments.

Realizing that the value of the study's results may depend upon local community acceptance, project planning will include extensive state and local involvment. The importance of effective communication of results is also considered, and will be facilitated by an evaluation of local perception of risks as well as a risk education program.

XII. Appendices

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
POLICY, PLANNING AND EVALUATION

Dr. Ronald Wyzga
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Dear Dr. Wyzga:

This letter responds to the following request in your letter to me of October 3, 1986:

"(please) outline:

a) the current objectives of IEMP,

b) the current organization,

c) the current modus operandi of the program including descriptions of interaction with local committees and other groups within EPA,

d) the major achievements to date of the program, and

e) the criteria by which you feel IEMP should be evaluated."

The panel has frequently expressed concern about the changing nature of IEMP objectives and organization -- your request is evidence of that concern. While the panel is certainly accurate in its perception of change, to IEMP this has seemed like a reasonably natural evolution of what was originally a pilot program over the course of the last five years.

I believe it is difficult to understand fully current IEMP objectives and organization without having a sense of the history of the program. On the other hand, I want to answer forthrightly your request for information. Hence, this letter begins with an historical overview of IEMP, but you can skip directly to page for response to the questions you raise.

A. History

If IEMP were a family, its story would be told in terms of three generations of progress: the Report of the first year, then the ensuing lengthy hibernation (1981-1982); the beginning of the first studies in January, 1983 to the Office of Policy Analysis reorganization in April, 1985; and from then to now.

1. First Generation: 1981-1982

IEMP began as nothing more than an idea that there ought to be a better way to integrate EPA's regulatory and scientific procedures, particularly as those were changing to meet the new challenge in the late 1970's of toxics pollution.

There have been integration programs at EPA since its formation in 1970. They were designed around varying initiatives which promised better coordination among Agency program offices, especially the air, water, and hazardous waste programs. IEMP began similarly, as sponsor of several task forces asked to recommend improved methods for coordination of chemical-specific regulations and to increase scientific consistency.

But IEMP staff became impatient, rather quickly, with integration goals of coordination and consistency. Past efforts with this premise had all failed because they seemed to ignore a fundamental organizational imperative: the first loyalty of an environmental program is to its statutory requirements. A program office decisionmaker, when confronted with a request to compromise current procedures for the sake of an amorphous larger purpose ("Agencywide consistency"), could almost always argue that current practices reflected the intent of his program's legislation. Past integration programs became, in sum, a lot of talk (the Office of Program Integration, under TSCA at IEMP's inception, had a staff of 40 and a $4 million budget) and little action.

So the first IEMP task was to redefine "integration." We reemphasized the central purpose of the Agency as the reduction of risk to human health and the environment from pollution. We proposed using quantitative risk analysis as the logical common denominator for establishing risk reduction priorities among EPA's air, water, and hazardous waste programs, for tracking unintended pollution transfers resulting from regulation, and for measuring environmental protection progress. We suggested using cost-effectiveness techniques to help select pollution control technologies. And inherent in these redefinitions was the notion that more efficient

integration of environmental functions required more centralization of decisionmaking.

In practice, the Administrator's Office of EPA has always been weak, though it was not originally intended to be. The Ash Commission, whose recommendations structured the new Agency, recognized the potential devisiveness and inefficiencies of an Agency thrown together around eight major statutes with no common charter. The Commission contemplated a reorganization of EPA, soon after its formation, along functional lines. Administrator Ruckelshaus, however, during his first tenure, was stymied in his attempt to implement that recommendation by the many sub-committees of Congress intent on maintaining their jurisdictional authority.

IEMP's early notions, then, required an administrative strengthening of the Agency. Integration by establishing cross-media regulatory priorities and leading to more efficient risk reduction assumed the Administrator as sole client of better management practices. IEMP's job, then, was to provide tools the Administrator could use for this more hands-on Agency management.

At the end of the summer, 1981, IEMP wrote and submitted to the Administrator a Report proposing substantive and management recommendations to enhance toxics (IEMP's mandate was not broadened beyond toxics until 1983) integration. I am including a copy of that Report with this letter and ask that you take a few minutes to skim its findings. In several ways, it represents a halcyonic moment in the history of EPA's attempts to integrate its functions. The Report was far-reaching. Much more important, however, the Report represented the consensus of a review committee consisting of the ten managers of EPA's major programs. It was an unusual moment, in other words, during which significant change was promised with broad civil service support.

Alas, the new Administration saw it as their historical moment, not our's. They suspected IEMP to be just another attempt by bureaucrats to launch a new program; their plan was to get rid of programs. The Report was shelved, and IEMP was essentially disbanded for a year.

2. Second Generation: 1983 to April, 1985

Toward the end of 1982, IEMP was partially resurrected. While the program was given only part of the resources and none of the authority requested in the 1981 Report, IEMP was asked to begin industry and geographic studies.

a. Industry Studies

It is hard, now, not to grimace at some of our original naivete, but here, anyway, is the short story of Industry Studies.

In 1981, it seemed to be the case that most environmental regulation was of point sources in large, and largely aging, manufacturing industry sub-sectors. In searching for a way to demonstrate the practical management value of quantitative tools applied cross-media, a logical target was these industry sectors.

The objective of these studies was, specifically, to provide the Administrator with a ranking of the pollution control technology options that maximized risk reduction while taking into account risk transferred by that technology, and optimizing for cost-effectiveness. The idea was that that the Administrator could compare this priority list with the current regulatory activity affecting the industry being studied, jettison program initiatives not on IEMP's priority list, and initiate program work on those initiatives that were high on the priority list. Assuming that the main business of EPA was regulation of these industries, achieving this objective would, by our definitions, assure significant Agency integration.

You have been briefed in some detail about how IEMP went about these industry studies. In short, we constructed large computer models designed to produce cost-effective technology options consonant with study objectives. With iron/steel, our first real application of the industry method, IEMP followed through with recommendations to the Administrator, including an analysis of the incongruity between priorities from the IEMP model and regulatory work for iron/steel then underway in the air and water programs. The Administrator told IEMP to work out its differences with the affected programs.

IEMP initiated four other industry studies, much in the same vein. But by the Spring of 1985, it had become clear that these industry studies were serving no great purpose; they were becoming particularly unsupportable given their great thirst for contract resources.

In sum, the industries approach to integrated environmental management did not turn out to be very successful -- for the following reasons:

First, uncertainties, or lack of consensus regarding the credibility of quantitative information possessed by the Agency, was even more overwhelming than IEMP expected. IEMP always

argued that some information was better than decisionmaking based on almost no information at all. But in fact, EPA's data bases were so thoroughly suspect that cross-media analyses carried out through huge modeling projects were seen to more likely compound error and assumptions to the point of uselessness.

Second, data was too limited in many instances, further undermining the credibility and robustness of the industry models. Almost nothing was known, for instance, about the human health risks associated with complex mixtures in waste dumps. We could not convincingly represent non-cancer health effects, nor were there methods for quantitatively assessing ecological impacts. Huge as these models became, in other words, they were never enough to mirror what others suspected were possible effects of pollution. How could their outputs, then, be real Agency priorities?

Third, and perhaps most unnerving, was the realization by 1985 that only a rather small fraction of EPA regulation was addressing the old industry sub-sectors. For a variety of reasons, regulatory attention had begun shifting rather dramatically to hazardous waste, pesticides, and other issues not easily amenable to industry modeling.

Fourth, the business end of the industries approach, re-orienting regulatory work in the programs, relied too much on the Administrator. It required an impractically large amount of an Administrator's time to understand and continually enforce IEMP recommendations. This shortcoming would have been addressed if suggestions in the 1981 Report had been implemented.

From about mid-1984 onward, then, the Industries Branch increasingly shifted attention to policy studies which involved cross-media analysis -- sludge, and pesticides, for instance. These studies employ many of the techniques of the industry analyses: use of quantitative risk analysis to define problems across media and to track pollution transferred by potential control options, and cost-effectiveness. And the objective of the sludge study, for instance, was to develop a list of cost-effective pollution control options which EPA's water program would then implement through sludge regulation. IEMP's sludge work, now finished, is being reviewed by another SAB panel, but included as appendix to this letter is a recent memo from IEMP to the Administrator which conveys findings of this IEMP work.

b. Geographic Studies

The original grand vision of IEMP assumed successful integration of federal operations during the first 3-4 years,

then a shift of emphasis to regional, state, and local integration. We anticipated that environmental protection would increasingly be carried out through non-federal authorities from the late 1980's onward. We assumed this because it seemed the most efficient approach: while gross, ubiquitous pollution problems might best be handled through federal regulation, environmental problems unique to local areas and driven by particular local exposure situations (Houston ship channel, Los Angeles smog, New Jersey waste sites) should obviously (it seemed) be resolved through special pollution control strategies tailored locally for that purpose.

Independent, then, of IEMP's difficulties implementing the federal or industries integration recommendations, we did expect to shift attention over time to local integration studies.

The initial challenge of the geographic approach was to translate general concepts -- use of quantitative risk assessment applied across media to establish priorities, minimization of pollution transfer, use of cost-effectiveness to help select pollution control technologies -- into a workable, practical environmental planning and management process at the local level. Our work first in Philadelphia, then Baltimore, Santa Clara, and now Denver is mostly, as you know, a story of trial-and-error leading toward a functional process model for local integrated environmental management.

While it is not necessary to retrace these projects on which the panel has already received lengthy presentations, it may make sense to summarize several of the major lessons learned from past studies that helped lead IEMP to its current model or objectives for geographic projects.

1) In Philadelphia, we began with a very comprehensive process for selection of problem chemicals. The project compiled a list of about 450 potential chemicals, then attempted to generate a data base consisting of all available information of those chemicals. The plan was to assess the risk for all those chemicals as a first step in setting priorities for further study.

This kind of comprehensive pollutant selection, or winnowing process became far too expensive and time-consuming given IEMP project limits. Since Philadelphia, we have relied far more heavily on the expert judgment of local, regional, and federal officials involved in the project for initial definition and selection of problems. This means, in particular, that the actual scope of geographic projects is ultimately based on the judgment of IEMP staff, advised by local experts and reviewed by local technical committees. It also underlines the point that IEMP projects are in no sense comprehensive. Instead, they are limited studies whose scope

is guided by the following general criteria:

- what seem to expert officials to be the major environmental problems which EPA has the tools to further analyze (for instance, we would select air carcinogens over a diffuse wetlands pollution problem) and which may be possible to control using non-federal authorities?

- problems selected should encompass more than one environmental media; and

- ideally, problems selected already have a data base because IEMP can contribute risk and cost analyses far more easily than it can provide large resources for data acquisition.

2) IEMP also learned, in Philadelphia, its first lesson about the importance of local participation in the study process. (This point was driven home to you directly, and unfortunately for us, by the statements of Philadelphia officials at the July panel meeting.) Local officials must not only be involved at every step of the way in IEMP projects, they must be given some control over project decisionmaking. The question is: what is the best balance between IEMP and local control?

In Baltimore, IEMP shifted strongly in the other direction: the Baltimore technical and management committees are primarily responsible for substantive project decisions, with IEMP staff serving as support to those committees. This method too, however, though quite workable in Baltimore, does carry some disadvantages. The pace at which unfettered local committees analyze and decide, and the resource demands they are inclined to make, conflict with bureaucratic imperatives at EPA. It is very difficult to support (outside of the Office of Research and Development) long, expensive projects which have few practical interim products.

Santa Clara seems to represent the best balance. On one hand, the project emphasizes the broadest feasible community participation in all aspects of work -- an often harrowing process, but one which seems to lead to public understanding and acceptance of project decisions. On the other hand, federal officials maintain operating control over the project during the first, risk assessment stage -- thus contributing to efficient delivery of results. The balance of control then shifts to local committees during

the risk management phase, which is appropriate given IEMP's objective of having local officials take maximum responsibility for reducing pollution in their jurisdiction.

3) To be candid, IEMP is not certain at this point about whether and to what extent projects should employ non-cancer health effects methods in selecting pollutant priorities. IEMP has encouraged use of this information, because it promises fuller understanding of pollution effects in a local area, but limits its applicability to the initial screening stage of analysis. There is little scientific support, however, for using more than the Agency's RfD (reference dose) numbers, and for making a qualitative judgment about characterization of the risk for local populations. Until there is more scientific credibility supporting quantitative dose-response relationships for non-cancer effects, should IEMP limit itself to the qualitative approach even in the initial screening phase of geographic projects?

3. Third Generation: May, 1985 - present

Before summarizing recent organizational changes which affect IEMP, I should touch on another aspect of the program during the past several years. This aspect is an aside from the discussion of federal and local integration projects.

To the extent that your panel is interested in knowing what IEMP has more generally defined for itself as its mandate, it is important to note that the program has or is sponsoring many projects related to integration which are not captured within the industry/geographic rubric. These projects have not formed the panel's review of IEMP to date; perhaps they are unreviewable, at least in a technical sense. Nevertheless, ironically, these projects may be among IEMP's more important contributions to long-term integrated environmental management. Almost all of them are aimed, not at developing practical, usable integration models, but at strengthening the credibility of the concepts undergirding IEMP's approach to integration: use of quantitative risk assessment and management techniques.

Below is a list of the major projects:

a. Writing all of Ruckelshaus' major speeches during his second tenure, through which risk assessment, risk management, and the importance of local decisionmaking were detailed and popularized;

b. Preparation of Risk Assessment and Risk Management: Framework for Decisionmaking, a primer on these concepts over 10,000 of which have been supplied in response to requests from a variety of sources;

c. Development of new training courses on risk assessment and risk management, which have been given to over 1600 environmental employees, media representatives, Congressional staffers, and others during the past year;

d. Staffing, for Ruckelshaus directly, the interagency Risk Assessment Council;

e. Preparation of EPA's Six Month Report on Air Toxics, which used innovative work done in the Philadelphia study on area and other non-traditional pollution sources to help define the nature and extent of cancer incidence from selected toxic air pollutants in urban areas of the United States. Results of the Study also reinforced other IEMP assumptions, such as the importance of understanding the cumulative risk to an individual from many pollutants and the variability of exposures among geographic areas; and

f. Responsibility for directing and staffing the Toxics Integration Task Force under Al Alm, which sponsored, among other things, the development of EPA's five risk assessment guidelines.

The Office of Policy Analysis reorganization in April, 1985, did two things: it added hazardous waste policy analysis to IEMP, now renamed the Regulatory Integration Division, and it led to the imminent demise of industry and policy studies in favor of a purely science/technical support Branch. The only integration functions now remaining in the new Division are geographic projects.

Other than the Kanawha project, to be discussed at another meeting of your panel, the major recent initiative of IEMP has been the selection of Denver as the next geographic project. (IEMP has also helped support and been strongly involved in a new program to encourage integrated environmental management and planning at the State level. That initiative and its implications for the future are briefly described at the end of this letter.) This history section concludes with a discussion of the criteria IEMP used -- though the Administrator made the final decision -- to select the next site for a geographic project.

The criteria were:

a. A site not in Region III or Region IX, where IEMP already has projects. We wanted to proselytize in heathen areas;

b. a site that appeared to contain a major environmental problem, so IEMP would not be wasting significant resources on trivial issues;

c. a site that appeared to have more than one significant problem, given the premise of integrated or cross-media analysis;

d. a site whose problems, if verified, were controllable, particularly with maximum use of local authorities;

e. a site in which IEMP could tamke a significant, perhaps unique, contribution through use of its analytic tools;

f. a site at which IEMP would have strong support from the Regional Office and, hopefully, local officials;

g. a site at which a reasonably extensive data base already existed for the major issues likely to be studied; and

h. a site to which IEMP staff could travel reasonably cheaply and easily.

The final four candidates -- Boston, a county in New Jersey, Jacksonville, and Denver -- were all viable. The Administrator decided, on balance, to pick Denver, presumably because of the importance of attempting to address Brown Cloud issues and hazardous waste problems at that site.

B. Current Objectives of IEMP Geographic Projects

The general goal of IEMP is to develop a model for local environmental management that (1) is integrated, to the extent that it has an analytically defensible basis (quantitative, if possible) for establishing pollution risk reduction priorities across media; (2) that takes into account both cost-effectiveness and potential for pollution transfer in selecting pollution control remedies; (3) that can be practically used by local officials; and (4) that contains an implementation process which maximizes the potential for broad public understanding and acceptance of management decisions.

Specific project objectives are:

° to develop an initial list of potentially significant problems, limited in number by

the resources available to the project, for further analysis, and based on the judgment of the widest possible range of local and federal technical experts;

- to gather data necessary for further analysis of these problems, limited again by project resources;

- to analyze problems on the initial list using, to the extent possible, quantitative analysis but balancing quantitative uncertainties with expert local judgment;

- to prepare a report, at the conclusion of the risk assessment phase, which summarizes data and analysis regarding the nature and extent of the risks associated with problems on the initial list, and which assists local decisionmakers in establishing priorities both for further study and for control actions;

- to develop a list of potential pollution control options for priority problems not already being addressed by local officials, and then assess the cost-effectiveness and pollution transfer potential of those options;

- to prepare a second report which again assists local decisionmakers in selecting specific control actions. These actions should employ, to the maximum extent feasible, local authorities;

- to secure implementation of report recommendations;

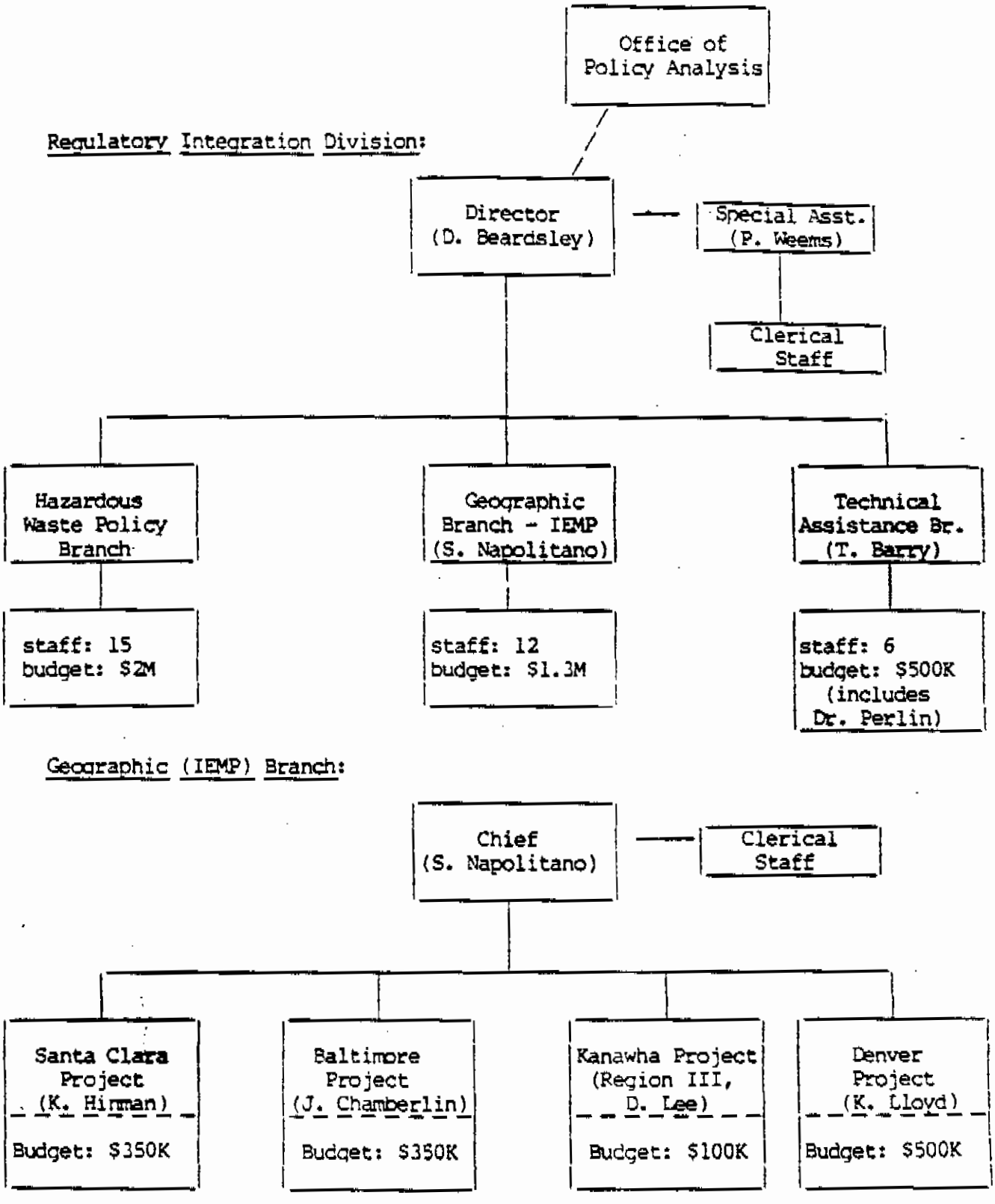
- to develop, from the beginning of the project, local technical advisory and management committees. The technical committee, at least, should be broadly representative of general public, as well as technical, interests;

- to establish working relationships with these committees in which all significant project information, analysis, and decisionmaking is shared;

- to transfer the balance of management control of the project to the local management committee during the second, risk management phase; and

° to provide training in risk assessment, risk management, and risk communication to local officials as is necessary and appropriate.

C. Current Organization of IEMP



Some technical support is provided to the Geographic projects by staff members in the Technical Assistance Branch.

D. Current Modus Operandi of IEMP

The objectives of our interaction with local committees for IEMP projects are listed above. I assume that details of these interactions, and IEMP's effectiveness in structuring and managing this process, have become clear to those members of the panel who were involved in the site visits to Baltimore and Santa Clara.

IEMP does not currently have any standing arrangements with other groups within EPA for review or comment purposes. Our usual procedure is to call upon individuals within program offices for technical advice or review on a particular issue within a geographic project -- staff have had hundreds of conversations and meetings of this type during the past several years. Occasionally, more formal advice/review processes are established for a specific purpose, such as the recent workshop sponsored by the Office of Research and Development on the proposed air monitoring plan for the Denver project. The committee established for the six-month air toxics study is another example in which members from OAQPS, ORD and OPPE participated in the study from its inception.

IEMP has considered several times the idea of developing a formalized ORD review group for geographic projects. We have always decided against this because ORD has never been able to dedicate its own scientists to IEMP work. Instead, we established the local peer review panels for Baltimore, Santa Clara, and now, Denver.

E. Major Achievements of IEMP

It would be convenient, if not appropriate, to be able to take credit for much of the work done in the Agency during the past several years to expand the understanding and credibility of key concepts supporting IEMP's approach to integration: management uses of quantitative risk assessment, for instance. It is certainly the case that IEMP has performed a service in this area through its non-routine activities, and in particular for ensuring that regulatory proposals by Agency program offices take into acocunt the potential for mere transfer of pollution to another media.

For specific accomplishments, I asked my staff to list what they see as the benefits of the local geographic projects. Rather than summarize their responses, I am including their memos to me as an appendix to this letter. I think they convey, directly if not impartially, an "in the field" sense of the utility of improved approaches to local environmental management.

F. Criteria By Which IEMP Should Be Evaluated

I think just two questions, now, are important.

1. Has IEMP developed an analytic and process model, as defined by current objectives, which will assist local officials in better management of their environmental problems, and is IEMP's approach practical to implement?

2. Based on your review of the Baltimore and Santa Clara projects, is IEMP using scientific and other analytic techniques appropriately and effectively? In a related matter, what would you recommend regarding future methods for research on and use of quantifying non-cancer health effects?

G. IEMP In The Future

IEMP was never intended -- by the Agency or by the Office of Management and Budget -- to be a permanent program. Policy offices traditionally do not manage line functions over the long term. Hence, there has been an increasingly immediate expectation that IEMP would become "institutionalized" or taken over as a regularized function of another office. To that end, we began participation several years ago in a State Pilots Program (SPP). This year, we are assuming responsibility for that program; beginning next year, it will replace local projects like Baltimore, Santa Clara, and Denver as the primary focus of IEMP. Subsequent funding for IEMP will diminish as we expect EPA's regional offices and the States to take responsibility for integrated environmental management.

SPP began in 1984, under the sponsorship of EPA's Office of Regional Operations, as a limited experiment in assisting the States to develop integrated data management and environmental pollution mapping functions. Since 1984, IEMP has been providing partial support -- funds and staffing -- for this initiative. During the past year, IEMP has encouraged a stronger emphasis on States' use of data and risk/cost analysis techniques, as well as practical use of these tools in environmental decisionmaking. In other words, IEMP has increasingly viewed the SPP as a vehicle for implementing IEMP objectives at the State and regional levels.

This year, SPP will again be a limited effort. Final funding and objectives are still under review by the Administrator, but we will probably fund small (about $150,000 apiece) demonstration projects in Region IV -- Kentucky, Georgia and the regional office itself. These projects will reflect

our experience with IEMP local projects and the Office of Regional Operations' past work with the SPP.

Thank you for allowing me to respond to some of your concerns regarding IEMP. I look forward to seeing you again at the panel meeting in December.

Cordially,

Dan Beardsley

Dan Beardsley
Director
Regulatory Integration Division

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 27, 1987 SAB-EC-87-031

Honorable Lee M. Thomas
Administrator
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

OFFICE OF
THE ADMINISTRATOR

Dear Mr. Thomas:

The Science Advisory Board's Integrated Environmental Management Subcommittee has completed its review of EPA's Draft Kanawha Valley Toxics Screening Study and is pleased to transmit its final report to you. The Subcommittee met in public session on March 16, 1987 in Philadelphia, Pa., to review the study. During March 11-13, 1987, three representatives of the Subcommittee visited the Kanawha Valley to become more familar with its environmental problems.

The Subcommittee unanimously concludes that the Kanawha Valley study represents an important component of EPA's overall effort to develop methodologies to define public health and environmental priorities. Studies such as this provide valuable technical challenges and experiences to EPA staff, particularly those working in regional offices. And, finally, they provide a valuable means for developing closer working relationships with state and local officials and the general public.

This letter is the Subcommittee's second communication to you. On July 30, 1986 it expressed "many concerns about the ability of the current study to satisfy a number of technical issues. A chief concern is the incongruity between [the study's] .... objectives and the fact that the study design itself is not an integrated multimedia effort, nor a response to Bhopal."

Since the transmittal of that letter, EPA staff have modified the study's objectives and technical design, and have conducted supplementary analyses to support the revised objectives and design. In general, the Subcommittee believes that the staff have made appropriate responses to its major concerns. The study reaches a number of scientifically supportable conclusions about health risks from cancer in the Kanawha Valley. The study also points EPA and other interested parties in a direction for conducting further analyses of problems related to accidental releases of pollutants and acute health effects.

Specific issues addressed during the Subcommittee's review include: the study's objectives and scope; pollution sources; pollution transport and fate by media; health effects; risk communication; and recommendations for additional follow-up efforts. Attachment A presents additional, more-detailed recommendations for modifying the current study and future activities in the Kanawha Valley. Attachment B lists the Subcommittee members.

In general, the Subcommittee views the Draft Kanawha Valley Toxics Screening Study as one step of a continuing process to assess risks. The current study addresses chronic health exposures to carcinogens which represent one of many public health concerns in the Valley. As a follow-up to the current study, the Subcommittee recommends two additional steps that include:

- o Expanded monitoring of air toxics, and use of monitored values to obtain more precise estimates of exposure and health risks.

- o Greater focus on accidental releases and fugitive emissions as areas of public health concern.

The Subcommittee appreciates the opportunity to conduct an independent scientific review of these important public health issues in the Kanawha Valley. We request that EPA formally respond to our scientific advice.

Sincerely,

Ronald Wyzga, Chairman
Integrated Environmental
Management Subcommittee
Science Advisory Board

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

SAB-EC-87-031

MAJOR FINDINGS AND RECOMMENDATIONS

OF THE

INTEGRATED ENVIRONMENTAL MANGEMENT SUBCOMMITTEE

ON THE

U. S. ENVIRONMENTAL PROTECTION AGENCY'S DRAFT

KANAWHA VALLEY TOXICS SCREENING STUDY

INTEGRATED ENVIRONMENTAL MANAGEMENT SUBCOMMITTEE

SCIENCE ADVISORY BOARD

U. S. ENVIRONMENTAL PROTECTION AGENCY

May, 1987

U. S. ENVIRONMENTAL PROTECTION AGENCY

NOTICE

This report has been written as a part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency, and hence the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute endorsement of recommendation for use.

Study Objectives and Scope

The objectives of the Kanawha Valley study are limited, but reasonably well-defined. In most instances, the study seeks to derive an upper bound for the health risks associated with airborne carcinogens for which EPA's Cancer Assessment Group has derived potency estimates. Other potential carcinogens are minimally considered, and the health risks of non-carcinogens, including those risks associated with the accidential release of chemicals such as occurred at Bhopal, are not considered. Hence, the health assessment of airborne toxics is far from complete, but this is clearly articulated in the study report. Available resources did not allow a more comprehensive assessment.

The study attempts "to develop a sense of potential public health concerns" associated with carcinogens in drinking water, surface water and hazardous wastes. The efforts are not multimedia efforts, but medium-specific efforts based upon very limited data; thus, conclusions from these efforts are subject to considerable uncertainty.

Sources

The air analyses depend very heavily upon an emissions inventory of some 450 substances developed by the West Virginia Air Pollution Control Commission (APCC). The inventory is as extensive and comprehensive as any other available information. Nevertheless, there exist some uncertainties in the inventory, particularly with respect to fugitive emissions, which the study identifies as a major source of health risk in some Kanawha Valley communities. The possibility that the inventory is incomplete is also suggested by the fact that ethylene oxide was not included for either the Belle or Nitro communities despite some limited monitoring evidence that it may be present. If a compound was not in the inventory it was not included in subsequent EPA modeling. This discrepancy underlines the need for including ethylene oxide in future monitoring programs.

The drinking water and surface water analyses depend upon monitored levels of toxics in water supply systems and fish fillets, respectively. Data are limited to a subset of all public water suppliers, with no private well samples, and to a very small number of fish sampled from only one location for a very limited number of toxic substances. The hazardous waste inventory is based upon a priority pollutant screening of inventories for a subset of RCRA and potential CERCLA sites. No information was available on the total quantity and overall composition of toxic wastes that may be entering surface or ground water. For this reason alone, the results of this part of the study are, at best, suggestive.

Transport and Exposure

The transport models used in the studies generally appear to be congruent with the study objectives. The air transport modeling addresses the concerns of the Subcommittee in its July 30, 1986 letter, although better

documentation of this modeling is needed. There is a factor of two uncertainty on point source air emissions and another uncertainty of a factor of two in dispersion modeling. The current modeling efforts do not address these potential uncertainties, although "worst case" scenarios should recognize their existence. Drinking water exposure was estimated by assuming that individuals consume two liters of the water delivered to their neighborhoods. Similar assumptions are often made in risk assessments. The surface water and hazardous waste studies are greatly hampered by a lack of data, making large assumptions necessary to estimate exposure to toxics.

Health Effects

The study evaluated 20 known or suspected cancer causing chemicals from the West Virginia APCC inventory of more than 450 compounds. The Subcommittee concludes that the current study provides useful information on health effects from cancer and environmental loadings of these 20 compounds. After finalizing the current study, EPA should conduct additional efforts that include:

- Using the APCC inventory and information on toxicity to evaluate the potential health effects of some of the remaining compounds. Of the remaining 430 or so compounds, relatively few merit further attention, but EPA and APCC should work together to identify compounds that need additional evaluation. These should be identified by defining the set of those compounds to which some exposure may be likely at known toxic levels.

- Broadening the health endpoints of concern to include non-cancer and acute effects. Concern about the potential effects from acute releases is strong within the community; hence, some priority should be given to addressing this issue. The methodologies used to address these endpoints require further development, particularly in estimating the effects of accidential releases. Some fault-tree or alternative analysis should be designed to address this possibility. Experts from other groups within the EPA should be enlisted in this effort.

- Incorporating frequency plots of pollutant concentrations versus time, in addition to stating average pollutant concentrations.

- Assessing the conversion of reference doses from the ingestion to the inhalation pathway, where reference dose information for the inhalation pathway is not available.

- Evaluating whether to develop or use biological markers for health assessment.

- Comparing risks from high mass emissions of pollutants with low toxicity, with low mass emissions of pollutants with high toxicity as a means to identify priority risk management needs.

- o Exploring other potentially useful sources of data for compounds of concern, including monographs prepared by the International Agency for Research on Cancer, Health Effects Profiles developed by the Office of Research and Development, Reportable Quantities for hazardous compounds and gaining access to information through the community right-to-know provision of Superfund.

Communication of Risks

The Subcommittee encourages EPA to continue its efforts of working with officials and citizens of the Kanawha Valley to update them on the sources and magnitude of risks they experience. In particular, EPA should seek to further improve its presentation of technical information to better enable lay persons to understand the results of technical analyses and to ensure it is understood that the risk numbers reflect upper bound estimates. Clarification of the latter issue is also needed in the executive summary of the study.

It is important for citizens, scientists and public officials to understand that the principal value of the Kanawha Valley study is as a screening study of airborne carcinogens. As the study acknowledges, a screening study should strive to ensure that all potential risks are identified even at the expense of calling attention to risks that subsequent analysis may not confirm, or will be less than indicated in the screening study. Accordingly, assumptions in screening studies are conservative in nature; assumptions should be avoided that might cause potential risks to be ignored. Within the stated scope of the study, conservative assumptions are made; for example, individuals are assumed to be exposed continuously to ambient outdoor levels of industrially emitted toxics and upper bound risk estimates are given. There are a few instances, however, where the study did not rigorously pursue conservative assumptions. These include potential uncertainties or omissions in the emissions inventory. The study suggests that point estimates could be too small (or too large) by a factor of two. For fugitive emissions it could be greater. It is important that these uncertainties and their likely direction be clearly articulated in the report along with a discussion about whether additional scenarios are necessary to consider these uncertainties.

In addition, the air quality models are equally likely to under-and-over predict ambient concentrations. The biases of the models are fairly predictable. Exposures are likely underestimated at the peaks of ridges where the river turns and when overlapping models were not used. On the other hand, the use of the Box model probably overpredicts exposure in some neighborhoods on the Valley floor, which are not adjacent to emissions sources. Although it is to the study's credit to have implemented two different modeling approaches to estimate exposure, further discussion in the report is merited on the potential model biases and on their implications for the risk estimates.

ADDITIONAL RECOMMENDATIONS TO THE AGENCY

A. Current Report

1. The technical assumptions for the underlying transport models should be documented and made accessible to readers of the report.

2. Given the comprehensive nature of the airborne toxic risk assessment in contrast to the rudimentary nature of the other three studies, it may be desirable to more clearly separate the air toxic studies from the others; moreover, the various studies are undertaken for differently defined geographic areas.

3. The risk estimate bounds are probably more clearly defined than in most similar documents; nevertheless, further clarification may be necessary. Cases could be presented as <X rather than the number X; attribution of cases/risk bounds by categories (industrial sources, fugitive vs. point emissions) should be more carefully qualified. Moreover, the conservatism of total case estimates is likely to be greater than estimates attributed to a single substance because of the joint probability that all substances require conservative assumptions is lower than that for a single substance.

4. Parts of Appendix C might be moved to the body of the report.

B. Future Work

1. A major public health concern among the residents of the Kanawha Valley is the risk associated with sudden accidental releases of airborne toxics. There is an urgent need to address this issue. Moreover, the current study addresses chronic health exposures, which are only one component of the many public health concerns in the Valley. A simple first step is to obtain some index of the toxicity of the remaining compounds. Information sources such as Health Effects Profiles, monographs of the International Agency for Research on Cancer, Reportable Quantities and data obtained from community right-to-know efforts, should be used. The preparation of exposure analyses will be more difficult as potential exposures to various lengths of time, including acute exposures, are estimated. Methodological help should be sought from other parts of the Agency.

2. The West Virginia Air Pollution Control Commission has developed an air emissions inventory, but the inventory represents an approximation of emissions from stationary sources. For the chemicals of the greatest public health concern, officials should undertake further monitoring to help validate the inventory. Where discrepancies arise, additional efforts will be warranted to more accurately determine sources and emissions levels.

3. The hazardous waste data considered are very limited. CERCLA requirements can perhaps provide some useful information. Other parts of EPA should be enlisted to improve the source inventory for these data. Analysis of historical operations and land use may also be useful to characterize the types of chemicals in waste sites. The fundamental approach to consider risk from hazardous waste should be replaced, however, by one that examines specific waste sites.

4. Increased monitoring data can aid the analysis of drinking water, surface water, and ground water. For chemicals of concern in the Valley, such efforts should be instituted to help ensure that no major problems are overlooked.

5. Health surveys and measurement of biological markers could provide some validation of the estimated health profile of the Valley. Such efforts will not, however, be useful when incremental risk estimates are small.

Attachment B

U. S. ENVIRONMENTAL PROTECTION AGENCY

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Integrated Environmental Management Subcommittee

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Appendix C

INTEGRATED ENVIRONMENTAL MANAGEMENT PROGRAM SUBCOMMITTEE

AGENDAS

1. April 24-25, 1986

2. July 1-2, 1986

3. September 18-19, 1986

4. December 4-5, 1986

5. March 16-17, 1987

U. S. ENVIRONMENTAL PROTECTION AGENCY

SCIENCE ADVISORY BOARD

INTEGRATED ENVIRONMENTAL MANAGEMENT SUBCOMMITTEE

OPEN MEETING APRIL 24-25, 1986

Thursday, April 24

9:00 a.m.	Opening Remarks	Dr. Wyzga Dr. Yosie
9:15 a.m.	Discussion of the Charge to the Subcommittee	
9:45 a.m.	General Integrated Environmental Management (IEM) Methodology	Mr. Beardsley Dr. Gruber
10:30 a.m.	Break	
10:45 a.m.	General IEM Methodology, Continued	
11:45 a.m.	Office of Research and Development Peer Reviews	Dr. Spitzer
12:15 p.m.	Lunch	
1:15 p.m.	Applications of the IEM Methodology	
	o Regional Hazardous Waste Pilot Project	Ms. Deborah Martin
3:15 p.m.	Break	
3:30 p.m.	o Santa Clara Project	Mr. Keith Hinman
5:30 p.m.	Recess	

Friday, April 25

9:00 a.m.	Health Scoring Methodology and Application	Dr. Sue Perlin
11:00 a.m.	Break	
11:15 a.m.	Further Discussion of the Subcommittee Charge	
11:30 a.m.	Subcommittee Discussion and Future Plans	
12:00 noon	Adjourn	

U. S. ENVIRONMENTAL PROTECTION AGENCY

SCIENCE ADVISORY BOARD

Integrated Environmental Management Subcommittee

July 1-2, 1986 Opening Meeting

Location: U. S. EPA Region 3
841 Chestnut Street
Conference Room 8 A
Philadelphia, Pa. 19107

Tuesday, July 1

9:00 a.m.	Welcome from the Regional Office	Mr. James Seif Regional Administrator
9:15 a.m.	Opening Remarks	Dr. Ronald Wyzga Dr. Terry Yosie
9:30 a.m.	Briefing on Planning and Managing an IEM Study: Philadelphia as a Case Study	Mr. Daniel Beardsley OPPE Mr. John Williams OPPE
11:00 a.m.	Break	
11:15 a.m.	Continuation of Philadelphia IEM Briefing	
12:00 noon	Lunch	
1:00 p.m.	Continuation of Philadelphia IEM Briefing	
2:30 p.m.	Break	
2:45 p.m.	Methodology for Kanawha Valley Study	Mr. Greene Jones Region III Mr. David Lee OPPE
4:30 p.m.	Recess	
7:00 p.m.	Subcommittee Dinner	

Wednesday, July 2

9:00 a.m.	Further Discussion of the IEM Health Scoring Methodology and Its Applications	Dr. Susan Perlin OPPE
11:00 a.m.	Break	
11:15 a.m.	Statements from the Public	Mr. Cragg Halogenated Solvents Industry Alliance Representative from the Chemical Manufacture Association
11:25 a.m.	Subcommittee Discussion and Future Plans	

U. S. Environmental Protection Agency
Science Advisory Board
Integrated Environmental Management Subcommittee
Open Meeting--September 18-19, 1986

Thursday, September 18

9:00 am	Opening Remarks	Dr. Wyzga Mrs. Conway
9:10	Briefing on Objectives of the Denver IEM Study	Mr. Beardsley
9:45	Revisitation of Objectives and Technical Design of the Kanawha Valley Study	Mr. Beardsley Mr. Jones
12:00 pm	Lunch	
1:00	Briefing on EPA Internal Review of the Baltimore IEM Study	Mr. Weissman
1:45	Subcommittee Discussion of Baltimore and Santa Clara Valley IEM Studies	
3:30	Subcommittee Discussion	
4:30	Recess	

Friday, September 19

9:00 am	Opening Remarks	Dr. Wyzga Mrs. Conway
9:05	Further Subcommittee Discussion of the IEM Health Scoring Methodology	
12:00 pm	Lunch	
1:00	Subcommittee Discussion of Preparing a Draft Report and Writing Assignments	
3:00	Adjourn	

U. S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
INTEGRATED ENVIRONMENTAL MANAGEMENT PROGRAM SUBCOMMITTEE

December 4-5, 1986 -- Open Meeting

Location: **U. S.** Environmental Protection Agency
401 M Street, S. W.
North Conference Center, Room #3
Washington, D. C. 20460

Thursday, December 4

9:15 a.m.	Opening Remarks	Dr. Wyzga Dr. Yosie
9:25 a.m.	Report of the Baltimore Working Group	Dr. Brown
10:30 a.m.	Break	
10:45 a.m.	Report of the Santa Clara Working Group	Dr. Cohen
12:00 noon	Lunch	
1:00 p.m.	Report of the Philadelphia Working Group	Dr. Davies
2:00 p.m.	Information Briefing on the Denver IEMP Project	Dr. Beardsley Mr. Napolitano
3:00 p.m. to 5:00 p.m.	Discussion of Preparing a Subcommittee Report on the IEMP	

- Structure
- Issues
- Strengths and Weakness
- Conclusions
- Recommendations

Friday, December 5

9:00 a.m.	Summary of Subcommittee Findings and Recommendations on the Health Scoring Methodology	
10:30 a.m.	Break	
10:45 a.m. to 2:30 p.m.	Continuation of Discussion of Preparing a Final Report on the IEMP.	
2:30 p.m.	Adjourn	

U. S. ENVIRONMENTAL PROTECTION AGENCY

Science Advisory Board

Integrated Environmental Management Subcommittee

Open Meeting ---- March 16-17, 1987

Location: U. S. Environmental Protection Agency
Region #3
841 Chestnut Street
Conference Room #8A
Philadelphia, Pa. 19107

Monday, March 16

9:00 a.m.	Welcoming	Mr. Laskowski, Deputy Regional Administrator
9:10 a.m.	Opening Remarks	Dr. Wyzga Dr. Yosie
9:20 a.m.	EPA Briefing on the Kanawha Valley Environmental Study o Overview of the Report o Objectives o Methodology o Results	Mr. Napolitano Mr. Jones
12:30 noon	Lunch	
1:45 p.m. to 4:00 p.m.	Subcommittee Review of the Kanawha Valley Environmental Study	
4:05 p.m.	Break	
4:15 p.m.	Subcommittee Conclusions and Recommendations	
5:00 p.m.	Recess	
6:30 p.m.	Subcommittee Dinner	

Tuesday, March 17

9:00 a.m. to 12:00 noon	Executive Session--Discussion of the Executive Summary of the Subcommittee's Draft Report of the Integrated Environmental Management Program	
12:00 noon	Lunch	
1:15 p.m. to 3:00 p.m.	Preparation of a Subcommittee Report on the Kanawha Valley Environmental Study	