UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
July 9, 1982

OFFICE OF
THE ADMINISTRATOR

MEMORANDUM

Subject: Science Advisory Board Review of and Interim Report on the Guidance for the Preparation of Exposure Assessments

From: Earnest F. Gloyna, Chairman
Science Advisory Board

To: Courtney Riordan
Acting Assistant Administrator
for Research and Development

At its meeting on April 23, 1982, the Executive Committee of the Science Advisory Board reviewed the Guidance for the Preparation of Exposure Assessments (January 8, 1981).

The purpose of this interim report is to summarize the Executive Committee's major findings and conclusions to assist your office in the redrafting of the Guidance document. In general, the Committee members endorsed the need for an integrated Agency-wide approach for the preparation of exposure assessments and concluded that this document was a good beginning toward that end. Simultaneously, the Committee criticized both the conceptual and technical bases of the document and made a number of specific recommendations for its revision.

The major conclusions and recommendations of the Committee are summarized in the attachment to this memorandum. In addition, I have forwarded comments from individual SAB members who reviewed the document.

The Science Advisory Board hopes that its comments and recommendations will be helpful to your office. We look forward to reviewing a revised Guidance for the Preparation of Exposure Assessments in the near future.

Attachment

cc: Dr. Elizabeth Anderson
Dr. James Falco
Dr. John W. Hernandez, Jr.

Major Comments and Conclusions
on Guidance for the Preparation of
Exposure Assessments

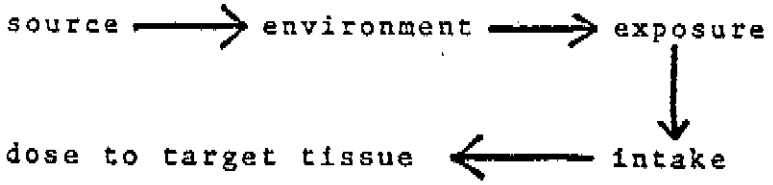
General Comments

The following points provide the conceptual basis for the document and should appear in the introductory sections of the Guidance and Handbook.

- The purpose of the Guidance document should be to articulate concepts and approaches that will be used Agencywide. The document should be used to provide guidance to assure that exposure assessments are of high quality and consistency regardless of where within the Agency they are carried out. The Agency should resist the preparation of an exposure assessment "cookbook." It should strive instead to define a set of scientific criteria that are of Agencywide applicability. Scientific judgment should be incorporated at all stages of exposure assessment. The document should discuss the adequacy of the data used for making a judgment and assess the types of information needed to improve the assessments.

- A clear definition of "exposure assessment" is needed early in the document. For those not familiar with the field, a one to three sentence definition would be helpful for understanding why this type of analysis is important to EPA in setting standards, setting research priorities, and establishing priorities for emission controls.

- There should be more identification and discussion of the structural elements of exposure assessment, i.e.,



- An exposure assessment is one of two key assessments needed to realistically assess the human health risk from pollutant exposures. This framework for risk assessment can be depicted as:

Exposure Assessment + Toxicity Assessment → Risk Assessment

Using this approach, it follows that a highly toxic material might pose a low overall risk to man because the exposure assessment identifies a low exposure of people. However, a material with a low degree of toxicity may pose a relatively high risk because of the large extent of human exposure. Exposure assessment and toxicity assessment should not be gathered independently and then combined; a decision will be more scientifically defensible if these interactions are ongoing.

- A systems approach, if not carried to excess, can be a very important tool. Exposure assessments track pollutants from one emission source to human uptake through various environmental routes. Such assessments involve environmental transport and transformation of pollutants. This complex chain of events can be studied effectively by using a systems approach with appropriate sets of differential equations that can be analyzed through standard techniques. For example, development of a sensitivity analysis coupled with a strong systems approach allows us to determine the most important parameters in such models, i.e., the ones to which the analysis is most sensitive. Tests at levels of biological organization other than single species are important. As one progresses from one level of biological organization to a higher or more complex level, new properties are added that were not apparent at lower levels. Properties, such as energy flow and nutrient cycling, cannot be studied at the species level but are important to ecosystem well-being. Although there are presently no practical tests for accomplishing this in a cost effective manner, that does not preclude the necessity of calling attention to the need for such tests.

The following criticisms apply throughout the document.

- There is insufficient attention given to language, format, and style. The document is often vague, confusing, inconsistent, and poorly written. It lacks coherence and should have a more authoritative tone.

- Model validation should be given increased emphasis. In general, model validation has received practically no attention in the past, especially where predictions based upon single species are concerned. In some instances, information on the specific material in question may be available; in other instances it may be necessary to use a well-documented material as a "surrogate" for a less well understood material.

- Clearer examples of multimedia exposure and multisource inputs are needed. There is usually a greater need for exposure assessments for pollutants, such as lead, which have multimedia routes of human uptake. Because of the complexity, producing useful general guidance will be very difficult. It may often be necessary to provide ad hoc analyses to deal with each chemical species or group of species. Care should be taken to avoid guidelines that are too rigid and which may not be applicable to certain pollutants.

- Greater recognition of population variability in exposure and target tissue dose is needed. Conclusions applicable to the entire United States should not be based on local or limited environmental situations without verification at other points. Population variability has been considered in the literature on lead and covered by Cuddihy et al. in the Journal of Toxicology and Applied Pharmacology (Variability in Target Organ Deposition Among Individuals Exposed to Toxic Substances. Vol. 49: 179-187. 1979).

- The Guidance needs to set minimum criteria for quality control and verification of data used in an exposure assessment. Data representative of all sides of an issue should be reported. Reliable data and quality assurance are necessary to back up the logic used in decision-making.

- It is important, within the Guidance document, to specify minimum standards concerning reproducible results and documentation of quoted results.

- The Guidance document tends to convey the view that exposure assessments can be done with a greater degree of precision than is generally possible. For the most part, single significant figures and order of magnitude estimates are adequate.

- The guidelines do not adequately address some of the technical requirements for conducting risk assessments. A critical requirement for assessing risk is the specification of averaging or integration times, and the sensitivity and uncertainty of impacts to exposure and variations. These criteria, in turn, define the requirements of the exposure assessment in terms of spatial and temporal resolution and, subsequently, implicitly determine the nature and the depth of the technical approach. The most probable exposures should be used for risk assessments, taking into consideration special needs and recommendations for highly sensitive members of the population. These aspects have not been considered in the Guidance document.

- The sequence, in the Guidance document, for conducting and reporting various analytical tasks in the exposure assessment is often inconsistent. There are considerable overlap and inconsistency among three of the components of exposure assessment: sources; exposure pathways and environmental fate; and monitoring or estimating concentration levels. As an example, the materials balance is included in the source component, which is usually one of the first components of the work program. The materials balance, however, requires the use of monitoring or modeling data, often not available until later in the program. A generalized flow chart of the work tasks, with possible variations for different types of emission sources/locations and transport media, would identify all possible steps, their sequence, and their interactions. A clean logic path will help to identify the purpose, narrow the targeting process, and focus the exposure issue more clearly.

- Interdisciplinary peer involvement by experts outside the Agency and a final SAB in depth review of the Guidance for the Preparation of Exposure Assessments would ensure that all issues are being considered in both exposure and toxicity assessments.

Specific Comments

A number of very specific comments were made by members of the Executive Committee who reviewed this document. A few of these comments are discussed below, but the bulk of these specific comments are appended for your information.

- Personal communications should not be used as references unless the information is not available in the published literature. In that case, the data must be on file and the names and addresses of the individuals provided.

- The U.S. Department of Energy and the Nuclear Regulatory Commission have carried out numerous exposure assessments. At a minimum, these analyses should be discussed in the Guidance document.

- Discussion of deposition of inhaled materials (III-18) should refer to the International Commission on Radiological Protection's Task Group on Lung Dynamics, published in the 1960's in the Health Physics Journal. Reference should also be made to more recent literature on this subject, e.g., the recent EPA Air Quality Criteria Document for Sulfur Oxides and Particulate Matter.

- The glossary should be critically reviewed. Some of the definitions have serious flaws. For example, the terms "chronic" and "acute" have definitions specific to the medical profession. Chronic effects are not necessarily "adverse effects resulting from long-term and/or frequently occurring exposures to a pollutant" because brief exposure to methyl mercury, for instance, may produce chronic neurological disease.

- A Table of Contents is needed for the Guidance document.

- An editorial review is needed to determine if some key references have been omitted.

- The purpose of Appendix B needs to clarified and individual case studies of program office exposure assessments need to be discussed in a standard format with three to four pages of narrative discussion for each example.

- The Handbook begins with a discussion of exposure assessment needs and the procedure of key EPA Program Offices. This leads to a conceptual problem, because the Program Offices are a mixed group. Some deal with pollutant by type (toxic substances, pesticides, and radiation) and others with media (air and water). Exposure assessment is multimedia, not limited to air or water.

- The IEAM (Integrated Environmental Assessment Methodology) system, developed at EMSL-Las Vegas over two years ago, found that there already existed in the literature the constants of mobility or exchange between various media and across various membranes. This should be acknowledged in the Guidance document.