Guidelines for Human Exposure Assessment

Charge Questions for Interagency Review

INTRODUCTION

The mission of the U.S. Environmental Protection Agency (hereafter "EPA" or "the Agency") is to protect human health and the environment by understanding, characterizing and reducing health risks associated with exposure to environmental contaminants. Exposure science characterizes, estimates and predicts exposures and provides information for developing exposure and risk assessments as well as effective strategies for reducing exposure and risk. The Agency needs to understand whether an agent might cause a health effect and how exposure to the agent can be reduced. The increasing number and complexity of risk assessments that the Agency conducts, and the corresponding risk management decisions, present significant challenges. Furthermore, advances in the field of exposure science require the Agency to use the best available science for conducting exposure and risk assessments.

The *Guidelines for Human Exposure Assessment* provides an updated resource on assessing human exposure for exposure and risk assessors in the Agency, consultants, contractors or others who perform this type of work under Agency contract or sponsorship, as well as academic, industrial and other persons who perform this type of work in accordance with EPA policies and procedures. This document builds on and supersedes the 1992 *Guidelines for Exposure Assessment*, incorporates advances in the field that have occurred since the 1992 document was published, and reflects current scientific practice across Agency programs. This guideline document also includes pertinent topics identified during public meetings and from a survey of the literature, including publications issued by National Academies of Sciences. It briefly describes the principles of exposure science and assessment, provides guidance on the various approaches that can be used to conduct an exposure assessment and identifies references for more detailed information. It does not, however, serve as a detailed instructional manual or supplant specific exposure guidance in use by Agency programs, offices or regions, nor does it endorse specific models or approaches that could have limited applicability or have become outdated. It also provides links to exposure assessment tools and technical documents that address particular exposure assessment needs.

The focus of the *Guidelines for Human Exposure Assessment* is on human exposure to chemical agents (stressors) in the non-occupational environment. The exposed populations (e.g., receptors) to which this document refers are adults and children or other vulnerable groups within the human population.

This document is organized into chapters, each of which explores a component of the exposure assessment process.

- Chapter 2 provides a review of exposure science concepts and principles, including approaches and tools, that can be considered when planning and conducting exposure assessments.

- Chapter 3 describes a process for planning, scoping and problem formulation for an exposure assessment. It emphasizes the importance of: establishing goals and objectives; building an interdisciplinary team; developing a conceptual model; identifying assessment options, available resources and data needs; producing an overall assessment plan; engaging and involving appropriate stakeholders; engaging and involving the community; establishing data quality objectives; and the importance of peer review.

- Chapter 4 discusses how lifestages, vulnerable groups and populations of concern could be at increased risk for adverse health effects from environmental contaminants due to disproportionate exposure or varied responses to exposure, or both. This chapter invokes existing Agency guidance, along with examples of case studies, to discuss where techniques and considerations associated with lifestages, vulnerable groups and populations of concern can be applied in exposure assessments.

- Chapter 5 discusses data used for exposure assessments, including determining what data are needed; whether data are currently available and the quality of the available data; and when data are not available, whether the data should be developed to meet the needs of the project. Guidance on the assessment of data uncertainty and variability is also presented in this chapter.

- Chapter 6 highlights concepts in modeling, including the principles of the modeling process. It provides an overview of modeling for exposure assessment, outlines the criteria for choosing appropriate models based on the goals and data quality objectives and describes how to evaluate a model that might be useful for an exposure assessment. Chapter 6 also includes information on modeling inventories and clearinghouses, and resources that support the use of models of various levels of complexity.

- Chapter 7 provides details on planning an observational human exposure measurement study. These studies are used in parts of the Agency to quantify people's exposures to chemicals in their everyday environments during their routine activities. This chapter discusses the issues surrounding planning an observational human exposure measurement study, including budget and logistical planning, establishing a study design, planning and executing both a pilot study and full field study and the importance of peer review. It also addresses ethical considerations that exposure assessors need to consider when interacting with study participants and the community.

- Chapter 8 considers uncertainty and variability in exposure assessments, incorporating them into planning, scoping and problem formulation (Chapter 3) and data quality objectives (Chapter 5). This chapter highlights how these concepts are used in the application of models in an exposure assessment.

- Chapter 9 highlights communication, emphasizing the importance of identifying the intended audience, the types of communication products, communication strategies that might be appropriate for different exposure assessments and related ethical considerations.

PURPOSE OF THIS PEER REVIEW

EPA's Risk Assessment Forum is submitting this document for peer review to assess how well the approaches, methods, and policies conform to traditional approaches for exposure assessment. To assist reviewers in focusing their review, the technical panel is asking the peer reviewers to address the following elements.

Overview Comment

- Please comment on the overall utility of the draft *Guidelines for Human Exposure Assessment* to exposure assessors conducting traditional exposure assessments.

Individual Chapters

Chapter 2. Principles of Exposure Science/Exposure Assessment

- Please comment on the completeness of the discussion of exposure science and its application to exposure assessment.

Chapter 3. Planning and Scoping and Problem Formulation

- Please comment on the content, organization, and presentation of the planning and scoping and problem formulation chapter.

Chapter 4. Consideration of Lifestages, Vulnerable Groups and Populations of Concern in Exposure Assessments

- Please comment on the content, organization, and presentation of the information on lifestages and populations of concern.

Chapter 5. Data for Exposure Assessment

- Please comment on this chapter's discussion of the selection, assessment, and use of data in exposure assessments.

Chapter 6. Computational Modeling for Exposure Assessment

- Please comment on the presentation of issues related to selection and use of exposure models.

Chapter 7. Planning and Implementing an Observational Human Exposure Measurement Study

- Please comment on the discussion of planning and implementing an observational human exposure measurement study.

Chapter 8. Uncertainty and Variability in Exposure Assessment

- Please comment on the application of uncertainty and variability to exposure assessment.

Chapter 9. Presenting and Communicating Results

- Please comment on the discussion of communicating exposure and risks.

Additional Comments

The peer reviewers, individually or as a group, can provide any additional comments that they feel would benefit the draft document.