Peer Review Plan

Dose Coefficient Uncertainty and Human Variation Quantification Feasibility Study

Prepared by

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1 INTRODUCTION

This Peer Review Plan (PRP) was prepared by Oak Ridge National Laboratory (ORNL) for the NRC project entitled "Dose coefficient uncertainty and human variation quantification feasibility study". In this project, ORNL is responsible for demonstrating the feasibility of a larger project to evaluate the uncertainties in current radiation dose coefficients and variability of dose per unit exposure in human populations. The project will assess:

- strengths and weaknesses of the primary data used as inputs to biokinetic models
- variability in biokinetics and dose among humans
- uncertainties and limitations associated with the structure of the models
- the robustness of the models in terms of their sensitivity to uncertainties in the underlying data and biological variability

One of the main goals is to improve conventional methods of uncertainty assessment as they have been applied to radiation dose estimates. For example, an approach is needed that takes into account the relative merits of different types of biokinetic data and limitations associated with the logical foundation of the model structure.

This plan was prepared in accordance with the guidance provided by the EPA Peer Review Handbook (EPA Science Policy - Council Peer Review, EPA 100-B-98-001, January 1998).

2 DETERMINING WHICH PRODUCTS TO PEER REVIEW

The peer review process is intended to improve a scientific or technical work product so that any decision or position based on that product has a sound, credible basis. Peer involvement in the review process takes two general forms: peer input, i.e., ongoing discussions during the development of the work product; and peer review, i.e., evaluation of a preliminary product or a final expert evaluation of the work product. The approach best suited to a specific work product will depend on the nature and purpose of the product.

According to the EPA Peer Review Handbook, all major scientific and technical work products used in decision making should be peer reviewed. The process for identifying whether a product is "major" takes into account various criteria and the circumstances surrounding the use of that product. A scientific or technical product is a candidate for peer review if it meets some or all of the following criteria:

- It establishes a significant precedent, model, or methodology.
- It addresses significant controversial issues.
- It focuses on significant emerging issues.
- It has significant cross-Agency/inter-agency implications.
- It involves a significant investment of Agency resources.
- It considers an innovative approach for a previously defined problem, process, or methodology.

The scientific and technical products of this project include a database of dosimetric information for selected radionuclides and exposure scenarios, general methods for assessing the uncertainty and variability in dose on the basis of that information, results produced by illustrative applications of those methods to the database, and publishable manuscripts that describe and illustrate the data, methods, and results. These collective products meet several of the criteria for peer review listed above. In addition to representing a significant investment of NRC resources, they will provide technical and scientific methods that may form the foundation for later development of products used in decision-making, they will address significant issues with interagency implications, and they are intended to establish a significant precedent and innovative methodology.

The publishable manuscripts represent the collective products of this project and clearly should receive peer review. Also, it is expected that the individual products developed during the course of the project, i.e., the database, methods, and results for selected cases, would benefit from peer input during their development.

3 MECHANISM FOR PEER REVIEW

Based on the above considerations, the peer review process for this project will be divided into two main phases:

- Peer input during development of the database, proposed methods, and preliminary results for illustrative cases
- Peer review of manuscripts prepared for submission to the open literature

The second phase may be further divided into project peer review (i.e., by experts selected as peer reviewers for this project) and journal peer review (i.e., by anonymous experts selected by the journals to which the manuscripts are submitted). Journal peer review provides an extra level of scrutiny that may identify problems not revealed by project peer review.

To receive timely peer input, it is necessary to provide a fast and convenient mechanism of exchange of information and ideas. That mechanism will be the website indicated in the Quality Management Plan (QMP). The password-protected site will be accessible by the NRC Project Officer, his designees, and project reviewers. Files placed on this site will be formatted to allow addition of comments by anyone with a password. This will allow rapid exchange of ideas and will provide a convenient means of permanently recording review comments and responses on the peer reviewed products.

The investigators will carefully evaluate and analyze all peer review comments and recommendations and add responses to the same file on the website to which the reviewers added comments. That file with comments and responses will constitute the formal record of decision on the conduct of the peer review, the type of peer review performed, and a summary of the outcome of that peer review. The principal analyst will download the file to his computer at intervals of no more than one week and maintain a backup electronic file and a hardcopy of the latest downloaded review file.

With regard to peer input during developmental phases of this project, it should be expected that reviewers may tend to comment only on selected files due to time constraints and individual scientific interests. In addition to the automated messages to reviewers that a file has been added to the website, e-mail messages from the investigators may sometimes be directed to specific reviewers, based on their interests and areas of expertise, with requests for input with regard to specific files. It is anticipated that all reviewers will comment on the major end products of this project, i.e., the publishable manuscripts.

At the beginning of each phase of the review process (peer input or peer review), the reviewers will be notified of the time frame for review and the charge to the reviewers. It will be considered that peer review may lead to new information and analyses or otherwise alter the work product and that sufficient time must be allowed to respond appropriately to challenging comments. The charge will identify recognized issues and invite comments or assistance. It will present specific questions and concerns, focused mainly on the scientific and technical merits of the work product and whether the underlying studies have been applied in a sound manner.

4 SUGGESTED PEER REVIEWERS

A reviewer should be an expert in one or more of the major areas addressed in this project. It is important to include a broad enough spectrum of experts to evaluate the relevant impacts on other less obvious concerns. Accomplishments and publication of each reviewer should indicate a concern with the problem of uncertainties in radiation dose estimates and/or variability of dose in the population. Reviewers are more likely to contribute significantly to this project if they regard it as an important resource for their own work. On the other hand, the possibility should be considered that a proponent of conventional methods of parameter uncertainty analysis may be resistant, for personal or professional reasons, to the development of innovative uncertainty methods. More generally, it should be considered that some persons regarded as experts in uncertainty analysis may have a conflict of interest that would limit their usefulness as a peer reviewer in a project that will address flaws in conventional methods of uncertainty analysis.

The following persons are suggested as peer reviewers due to their expertise in major areas of research addressed in this project; their reputations as thoughtful, creative scientists; their interests in the specific area of uncertainty analysis; and their lack of apparent conflicts of interest with the goals of this project.

Bruce Boecker (retired) is Scientist Emeritus at Lovelace Respiratory Research Institute in Albuquerque, NM. He a member of Committee II (Doses from Radiation Exposures) of the International Commission on Radiological Protection (ICRP) and chairman of the ICRP's Task Group on Reference Man. He received his Ph.D. in radiation biology from the University of Rochester in 1962. Since that time he has conducted numerous studies on biokinetics and biological effects of radionuclides in different animal species and has over 130 publications in that area. It is expected that he will provide valuable input with

regard to uses and limitations of data on the behavior of radionuclides in different animal species and uncertainties in interspecies extrapolation of biokinetic data.

John Boice is a distinguished epidemiologist with over 350 peer-reviewed publications. He received a Sc.D. in epidemiology from Harvard University School of Public Health in 1977. He is currently the Scientific Director of International Epidemiology Institute in Rockville, MD and Professor of Medicine at the Vanderbilt University Medical Center in Nashville, TN. He has been a member of the Main Commission of the ICRP since 1997. He has conducted a number of epidemiological studies concerned with the effects of radiation and in that capacity has given much consideration to the problems of uncertainty and variability in radiation dose estimates.

Jerry Puskin received his Ph.D. in physics from Harvard University in 1970. He worked from 1970 to 1982 in the Department of Radiation Biology and Biophysics at the University of Rochester, from 1982 to 1985 at the NRC, and since 1985 at the EPA as leader of the group responsible for developing and implementing models to assess radiation exposure, dose, and risk. He has been especially involved in estimating carcinogenic risks from internal and external emitters and in quantifying uncertainties in these estimates.

John Harrison is Leader of the Radionuclide Effects Group of the Radiation Effects Department of the National Radiological Protection Board (NRPB) in Great Britain. He received his Ph.D. in Biochemistry at St. George's Hospital Medical School, University of London and joined the NRPB in 1974. He is a member of the ICRP Task Group on Internal Dosimetry (INDOS) and Task Group on the Human Alimentary Tract (HAT). His research work has centered on radionuclide biokinetics, dose, and effects, including uncertainties in these entities. In the mid-1990s he helped design the joint study by the NRC and CEC (Commission of European Communities) on probabilistic accident consequence uncertainty analysis. He is the lead author of a recent publication on uncertainties in the absorption of ingested radionuclides and the effect on dose estimates (Radiation Protection Dosimetry 95:295-308; 2001).

Robert Stewart is a graduate of the University of Tennessee with an M.S. in mathematics. He has expertise in numerical analysis, statistics, and software development. He is a staff member of the University of Tennessee but is currently assigned to ORNL, where he has worked on projects dealing with software design, human health risk assessment, decision analysis, sampling design, web site design, and database construction and management. He is the creator of Spatial Analysis and Decision Assistance (SADA), a Windows based software that integrates geospatial analysis tools, human health risk assessment, cost benefit analysis, secondary sampling design, remedial decision making, statistical analysis, and visualization methods in a user-friendly package that connects scientific analysis and decision making.