United States Environmental Protection Agency

Science Advisory Board Washington DC

EPA-SAB-EEC-98-009
August 1998

EPA

AN SAB REPORT: REVIEW OF THE SURFACE IMPOUNDMENTS STUDY (SIS) PLAN

REVIEW OF THE OFFICE OF SOLID WASTE'S PROPOSED SURFACE IMPOUNDMENT STUDY BY THE ENVIRONMENTAL ENGINEERING COMMITTEE

August 17, 1998

EPA-SAB-EEC-98-009

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: Science Advisory Board's Review of the Office of Solid Waste's Proposed Surface Impoundment Study

Dear Ms. Browner:

The Land Disposal Program Flexibility Act of 1996 (PL 104-119) requires that the Agency, within five years of enactment, complete a study of " . . . [a subset of] hazardous waste . . . to characterize the risks to human health or the environment associated with such management..." The Act further requires that EPA's Administrator " ... shall evaluate the extent to which risks are adequately addressed under existing State or Federal programs and whether unaddressed risks could be better addressed under such laws or programs."

The Office of Solid Waste (OSW) moved to comply with the Act's requirements by first gathering public comment on the design of a Surface Impoundment Study (SIS), and then consulting with the Science Advisory Board's (SAB) Environmental Engineering Committee in September, 1996. Following the Consultation, OSW staff, assisted by a Technical Expert Panel, developed a proposed methodology for the SIS. The SAB Surface Impoundments Subcommittee, established by the SAB Environmental Engineering Committee, subsequently reviewed this methodology at a public meeting on April 30-May 1, 1997 in Crystal City, VA. The Charge for this review requested that the SAB comment on: a) the technical merits of the overall study structure; b) the technical merits of the proposed risk assessment; and c) the involvement of technical experts, affected facilities and the public at critical points in the study's design and implementation (The detailed charge appears in section 2.2 of this report).

The enclosed report presents the Committee's findings in detail. In general, however, the Subcommittee finds considerable technical merit in the proposed study structure. It uses accepted methods and practices to generate the information and conduct the risk assessment to support a regulatory decision in 2001. The proposed sample frame and sample design are appropriate to collect data needed for risk assessment, assuming the SIS does not become so broad (relative to the available resources) that overall precision becomes unacceptably low. OSW staff understand the major issues, and the Project Team is staffed with professionals qualified in the appropriate disciplines.

In considering the technical merits of the proposed risk assessment, the Subcommittee finds that OSW again proposes to use appropriate and well-established scientific practices. Due to resource limitations for site characterization, however, the Subcommittee suggests that EPA carefully apply screening level conceptual models to prioritize the potentially high risk sites requiring characterization. In addition, the Subcommittee recommends on-going peer review of the detailed implementation plan as it is developed by EPA. Such reviews are important, because a good implementation plan must be coupled with good analysis if the risk assessment is to be fair, transparent, and defensible. This important issue is discussed in detail in sections 3.1.2 and 3.3 of the enclosed report.

Because of the complexity, importance and long-term implications of this study, OSW must develop and implement the SIS carefully--and exercise the same care in communicating the results. There are tens of thousands of surface impoundments in the United States and great variety among them. The size and variety of the population together with the limitations inherent in any survey means that not every site will be characterized. The Agency may therefore need to develop and use an index of risk for screening purposes, so that resources can be prioritized and allocated to those impoundments that present higher risk. The Subcommittee recommends that “more risky” sites be characterized more fully than those that appear to present very little risk. As a result, not all subsets of sites will be characterized to the same degree.

The SIS is an ambitious undertaking. It will require the assembly and collection of physical, chemical, biological and operational information to characterize sites, the use of some models for transport and fate, and the application of other models to predict exposure, human health risks and environmental risks resulting from impoundments. If risk management/risk reduction issues also are to be addressed, then OSW also may need to collect additional data for risk management decisions.

The Subcommittee recommends that the SIS be conducted in phases, with the first phase made as simple as possible, using mostly existing data. The Subcommittee further recommends that OSW use “Tiers“ as a way of conceptualizing the SIS. Tier I would incorporate a review of existing data to separate the various impoundments into major categories that can be sorted and ranked. Tier I thus provides a basis for statistical stratification. Tier II then calls for collecting new information and using the data and models to estimate risks of surface impoundments to human and ecological health.

The Subcommittee commends OSW for seeking SAB review of its Surface Impoundment Study at an early stage. The Subcommittee's comments and recommendations recognize that our review reflects the state of the SIS early in its development. The Subcommittee is also very supportive of the Agency for conducting peer reviews (other than by the SAB) throughout this study. An SAB review at the end of 1999 which focuses on additional technical aspects is also recommended.

/signed/
Dr. Joan Daisey, Chair
Science Advisory Board

/signed/
Dr. Hilary Inyang, Chair,
Environmental Engineering Committee
Science Advisory Board

Dr. Ishwar P. Murarka, Past Chair
Environmental Engineering Committee
Science Advisory Board

Ms. Lynne M. Preslo, Chair
Surface Impoundments Study Subcommittee
Environmental Engineering Committee
Science Advisory Board

NOTICE

This report has been written as 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 balanced, expert assessment of scientific matters related to problems facing the EPA. This report has not been reviewed for approval by the EPA 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 a recommendation for use.

ABSTRACT

The Surface Impoundments Subcommittee of the Science Advisory Board's Environmental Engineering Committee reviewed the proposed methodology for the Office of Solid Waste's Congressionally required surface impoundments study. In summary, the charge for this review was to comment on: a) the technical merits of the overall study structure; b) the technical merits of the proposed risk assessment; and c) the involvement of outside technical experts, affected facilities and the general public at critical points in the study's design and implementation.

The Subcommittee reviewed the Agency's plans for conducting the congressionally mandated study to characterize risks from industrial waste waters managed in non-hazardous surface impoundments. Since this SAB review occurred at an early stage of the study, many of the comments and recommendations are offered to assist the Agency in making scientifically sound decisions in designing and implementing this study.

In general, the Subcommittee finds that the Agency's approach to conducting the study in a phased manner is appropriate and a pilot study is recommended. The use of existing data early in this study will help the Agency in prioritizing and allocating resources to obtain supplemental data from potentially high risk sites. There are, unavoidably, uncertainties in the choice of multimedia models for risk analysis.

The Subcommittee is pleased with the Agency's inclusion of ecological risk assessment and endorses the case study approach. In addition, the Subcommittee is very supportive of conducting peer reviews throughout the study. Finally an SAB review at the end of 1999 is also recommended.

Keywords: impoundment, decharacterized wastes, industrial waste waters, human health risks, ecological risks

U.S. Environmental Protection Agency
Science Advisory Board
Environmental Engineering Committee
Surface Impoundments Subcommittee
April 29 - May 1, 1997

CHAIR

Ms. Lynne M. Preslo, Earth Tech, Long Beach, CA

MEMBERS

Dr. William J. Adams, Kennecott Utah Copper Corp., Magna, UT

Dr. Stephen L. Brown, Risks of Radiation and Chemical Compounds, Oakland, CA

Dr. Richard O. Gilbert, Battelle Washington Office, Washington, DC

Dr. F. Owen Hoffman, SENES Oak Ridge, Inc., Oak Ridge, TN

Dr. Hilary I. Inyang, Center for Environmental Engineering Science and Technology, University of Massachusetts, Lowell, MA

Dr. Richard Kimerle, Monsanto Company (Retired), St. Louis, MO

Dr. John P. Maney, Environmental Measurement Assessment, Hamilton, MA

Mr. Nick Molina, Division of Hazardous Waste Management, Pennsylvania Department of Environmental Protection, Harrisburg, PA

Dr. Ishwar P. Murarka, ISH Inc, Cupertino, CA

Science Advisory Board Staff

Kathleen W. Conway, Designated Federal Official, Science Advisory Board (1400), U.S. Environmental Protection Agency, Washington, DC 20460

Dorothy M. Clark, Management Assistant, Science Advisory Board (1400), U.S. Environmental Protection Agency, Washington, DC 20460

TABLE OF CONTENTS

1 EXECUTIVE SUMMARY

The Charge for the review of the Office of Solid Waste's Surface Impoundments Study (SIS) requested that the SAB comment on: a) the technical merits of the overall study structure; b) the technical merits of the proposed risk assessment; and c) the involvement of technical experts, affected facilities and the public at critical points in the study's design and implementation. The detailed charge appears in section 2.2 of this report.

The Surface Impoundments Subcommittee finds considerable technical merit in the proposed overall study structure. This study is an applied project using accepted methods and practices. No additional fundamental research will be required to generate information and conduct the risk assessment to support a regulatory decision in 2001. The sample frame development and sample design to collect data for risk assessment are appropriate, the OSW staff understand the major issues, and the Project Team is staffed with professionals qualified in the appropriate disciplines.

In considering the technical merits of the proposed risk assessment, the Subcommittee finds that OSW proposes to use appropriate and well-established scientific practices. Due to resource limitations for site characterization, however, the Subcommittee suggests that EPA carefully apply screening level conceptual models to prioritize the potentially high risk sites requiring characterization. In addition, the Subcommittee recommends on-going peer review of the detailed implementation plan as it is developed by EPA. Such reviews are important, because a good implementation plan must be coupled with good analysis if the risk assessment is to be fair, transparent, and defensible. This important issue is discussed in detail in sections 3.1.2 and 3.3 of this report.

Because of the complexity, importance and long-term implications of this study, OSW must develop and implement the SIS carefully--and exercise the same care in communicating the results. There are tens of thousands of surface impoundments in the United States and great variety among them. The size and variety of the population, together with the limitations inherent in any survey, mean that not every site will be characterized. The Agency may therefore need to develop and use an index of risk for screening purposes, so that resources can be prioritized and allocated to those impoundments that present higher risk. The Subcommittee recommends that "more risky" sites be characterized more fully than those that appear to present very little risk. As a result, not all subsets of sites will be characterized to the same degree.

The SIS is an ambitious undertaking. It will require the assembly and collection of physical, chemical, biological and operational information to characterize sites, the use of some models for transport and fate, and the application of other models to predict exposure, human health risks and environmental risks resulting from impoundments. If risk management/risk reduction issues also are to be addressed, then OSW also may need to collect additional data for risk management decisions.

The Subcommittee recommends that the SIS be conducted in phases, and that the first phase made as simple as possible, using mostly existing data. The Subcommittee further recommends that OSW use “Tiers“ as a way to conceptualize the SIS. Tier I would incorporate a review of existing data to separate the various impoundments into major categories that can be sorted and ranked. Tier I thus provides a basis for statistical stratification. Tier II calls for collecting new information and using the data and models to estimate risks of surface impoundments to human and ecological health.

The Subcommittee commends OSW for seeking SAB review of its Surface Impoundment Study at an early stage. The Subcommittee's comments and recommendations recognize that our review reflects an early involvement. The Subcommittee is also very supportive of the Agency for conducting peer reviews (other than by the SAB) throughout this study. An SAB review at the end of 1999 to review the science aspects is also recommended.

2 INTRODUCTION

2.1 Background

The Land Disposal Program Flexibility Act of 1996 (PL 104-119) requires that:

(10) Not later than five years after the date of enactment of this paragraph, the Administrator shall complete a study of . . . [a subset of] hazardous waste . . . to characterize the risks to human health or the environment associated with such management. In conducting this study, the Administrator shall evaluate the extent to which risks are adequately addressed under existing State or Federal programs and whether unaddressed risks could be better addressed under such laws or programs.

On February 10,1996, the Office of Solid Waste published a notice in the *Federal Register* (Vol. 63 page 6752-4) requesting comment on the design of such a study. On September 26, 1996, the Science Advisory Board's Environmental Engineering Committee consulted with the Office of Solid Waste on the surface impoundments study design. (An SAB Consultation is a public meeting between the SAB and the Agency where individual members offer technical views on the topic being discussed. No SAB report is prepared).

Office of Solid Waste staff, assisted by a Technical Expert Panel, then developed a methodology for the SIS. The SAB Surface Impoundments Subcommittee, established by the SAB Environmental Engineering Committee, subsequently reviewed this methodology at a public meeting on April 30 - May 1, 1997 in Crystal City, VA.

2.2 Charge for the Review

The detailed charge for this review was:

a) Please comment on the technical merits of the overall methodology structure:

   1) Please comment on the proposed methodology's ability to achieve the stated study objectives.

   2) OSW is proposing a specific approach to develop the sample frame and select the sample of impoundments for analysis. What

advantages and disadvantages do you see from this proposed approach?

3) OSW is proposing an approach to identify the strongest predictors of risk before initiating data collection. Will this approach accurately identify the strongest predictors, or might it miss certain critical risk predictors?

4) OSW intends to “pilot” the data collection instrument to assure that it collects the desired data, and will propose other specific data quality assurance techniques. Is the proposed quality assurance plan for data collection, management, and use appropriate?

5) Please comment on the proposed analytical outputs and approach for quantifying uncertainty of those outputs.

6) Please comment on OSW’s proposed approach for verifying the analytical outputs.

b) Please comment on the technical merits of the proposed risk assessment. Specifically:

1) OSW is proposing use of certain mathematical modeling techniques for characterizing the pollutant source, the pollutants’ transformation (if any), dispersion, and human and ecological receptor exposure and dose. Can you suggest alternate modeling techniques that will produce more accurate results?

2) OSW is proposing a case study approach for the ecological effects part of the risk assessment. The case studies would define the endpoints of the ecological effects risk assessment at the geographic locale of the impoundments in the study sample, and would evaluate habitat modification, presence or absence of endangered or threatened species, and identify particular species for which there are clear causal relationships between the species members’ contact with the pollutants from the impoundments in the study sample and observed effects. Does the Subcommittee have specific ideas about ecological risk assessment approaches?

3) Will OSW’s strategy for involving technical experts, affected

facilities, and the general public at critical points in the study's design and implementation assure sound technical results? Can you suggest specific points in the proposed methodology, or in your suggested changes to the proposed methodology, which would benefit the most from the involvement of technical experts, the affected facilities, or the public?[1]

[1] Note: the structural organization of the Charge places questions about the involvement of technical experts, affected facilities and the general public--item b(3) above--as a sub-element under comments on the risk assessment. In responding to the charge, however, the Subcommittee has addressed these questions of involvement of technical experts, affected facilities and other stakeholders within the larger context of the overall study design, not only in regard to the risk assessment.

3 DETAILED FINDINGS

3.1 Overall Methodology

3.1.1 Methodology for Attaining the Study's Objectives

Charge a(1) asked for the Subcommittee's comments on the technical merits of the overall structure of the methodology, as well as the methodology's ability to achieve the study objectives.

The Subcommittee finds that the overall study approach is sound and reasonably well-defined conceptually. Three recommendations are offered to enhance the overall effectiveness of the methodology:

a) The Subcommittee recommends that EPA identify, early in the planning process, the regulatory and legal framework for the study objectives.

b) The Subcommittee recommends that the design of the SIS be kept simple and rely heavily upon existing data (both site-specific and general).

c) The Subcommittee recommends that OSW solicit assistance from the Office of Research and Development (ORD) and other EPA offices, as well as researchers in academia and the private sector.

3.1.2 Sample Frame Approaches

Charge question a(2) asked for comments on the specific approach used by OSW to develop the study sampling frame.

In general, the sample frame development and sample design for risk assessment selected by EPA seems appropriate, assuming the SIS does not become so large and complex that the available resources are insufficient to maintain the overall quality of the study at an acceptable good level.

Two approaches for developing the sampling frame were presented to the Subcommittee: the List approach and the Area approach. Primary Sampling Units for the List approach are the individual facilities selected as target facilities for surveys. Primary Sampling Units for the Area approach are expected to be U.S. Geological Service quadrangles, since these units are consistent and represent a primary unit in mapping and satellite imagery. Quadrangles are also large enough (7.5 minutes) to reduce intra-cluster correlation. The Agency currently is evaluating both approaches.

The Subcommittee recommends that OSW use expert opinion and available information about risk to construct risk "strata" for the many impoundments, i.e., to group various impoundments by risk level, developing a stratification of risk. The goal is to establish the groupings so that there are clear differences in risks for the different strata.

Of course, the number of impoundments to be examined and allocated to each stratum also must be determined. Stratification into categories/regions would be primarily a technical device to arrive at a more precise estimate of *average* risk for the entire target population of impoundments. This approach, in which a random set of impoundments is selected for study from each of the strata is consistent with the state-of-the-art for sampling. The strata should be defined so that the expected variability in risk among impoundments within strata is smaller than the expected variability in risk between the strata. Further, the allocation of sampling effort to the various strata should be selected to achieve the best estimate of the overall average risk.

3.1.3 Identifying Predictors of Risk

The SIS is concerned with the health and environmental risks posed by surface impoundments. Question a(3) of the Charge asked the Subcommittee to review OSW's methods for identifying the best predictors of risk.

A principal objective of the SIS is to characterize the risks to human health or the environment associated with management of industrial waste water, in surface impoundments. The Subcommittee does not know if this means focusing on the risks to highly exposed persons or ecological units within a narrowly defined nearby area adjacent to a surface impoundment, or focusing on the society-wide impact of waste management in impoundments. The former measure is of significance in addressing environmental equity, while the latter is more meaningful to assessing the public health at large. Although the SIS design team is clearly cognizant of these measures of risk and has stated its intention to characterize both, much of the planning focuses on characterizing risk to nearby highly exposed receptors, such as is done in making site-specific permitting decisions for a hazardous waste facility. How OSW will estimate and characterize the societal risks is not clear, and the data gathering and modeling efforts currently envisioned may not be adequate to do that job well.

The Subcommittee therefore recommends that the Agency clearly establish its focus on risk measures (highly exposed populations, public heath, or both) and refine the data gathering efforts accordingly.

3.1.4 Assessing the Pilot Study

Charge a(4) noted that OSW intends to pilot the data collection instrument and called for review of the proposed quality assurance plan for data collection, management, and use. The Subcommittee found that OSW's plan to carry out a pilot study is appropriate, given that there are so many factors to consider, including application of the EPA's data quality objectives (DQO) process. The Subcommittee, however, recommends that the study include 15-20 impoundments (preferably similar types of industry with similar waste streams) covering a spectrum of impoundment designs from unlined to those with state-of-the-art liner technology. If possible, EPA should select impoundments from different geographical and geological areas of the country. The Subcommittee also recommends the use of multimedia models to assist in the analysis of the data collected during the pilot study. To the extent feasible, the pilot study data should be analyzed to determine whether any impact to the environment is related to design used (unlined impoundment) or to operational procedure (spillage, malfunction of equipment).

3.1.5 Proposed Analytical Outputs and Uncertainty

Charge question a(5) requested comments on the proposed analytical outputs of the model, and the methodological approaches for dealing with uncertainty.

There are many methodological issues, processes and procedures that must be evaluated and implemented to conduct a study of this magnitude. The geographical, temporal, and human/ecological scope of the proposed project is very broad indeed. Expert opinion, modeling, and data gathering could be used to narrow the focus to a smaller set of impoundments that would represent either the full spectrum of low, medium and high risk impoundments or a set of impoundment types that represent just the high end of the risk scale.

During the public meeting, the OSW identified some specific questions (see Appendix A) which they believe must be answered by the SIS. One of them (number 6) is to provide a “comparison of the results of quantifying human health effects due to exposure to the pollutants in RCRA section 3004 (g)(7) surface impoundments and other nonhazardous industrial waste impoundments."

This objective implies that OSW will compare the risks of RCRA surface impoundments with the risks of other non-hazardous waste impoundments. There are several questions the Subcommittee suggests OSW consider when it determines how those comparisons would be conducted:

a) Will Monte Carlo analyses be conducted to develop subjective distributions of projected risks so that these distributions can be compared visually and using statistical methods?

b) If this type of analysis is needed, are the time and funding resources available sufficient to support this activity for the full range and scope of the SIS?

c) If not, how will generalizations be made from the developed distributions of risk to cases where distributions could not be generated due to time and funding constraints?

d) How will the uncertainty inherent in these distributions be expressed?

e) How will differential failure rates at RCRA vs. non-RCRA sites be reflected in the risk assessment?

The following discussion presents the Subcommittee's findings on the coverage and scope of the SIS: constituents of concern, radionuclides, modeling sensitivity analysis, categories of impoundments, and survey sampling methods.

3.1.5.1 Constituents of Concern

Along with pathway parameters, the constituents of concern (COC) significantly influence risk. EPA must define the COC. Once it has chosen the relevant COC, the EPA can determine the feasibility of sampling, analyzing and assessing the risk of the chosen COC in light of budgetary and schedule constraints. EPA will use a variety of models to transform the COC and impoundment data into a risk value. The models include parameters other than the COC, such as geophysical characteristics of the surrounding area and constituent volatility factors, which will influence their release and transport through the environment.

The OSW Project Team has not yet defined the constituents of concern. These must be selected early and should be part of the Problem Formulation. Narrowing the list will help define the “problem” and the tools needed to solve the problem. The Subcommittee strongly encourages EPA to restrict the number of constituents of concern to a manageable list. Given the scope of the project and the resources available, it is impossible to measure/model and calculate human health and ecological risk for a wide variety of chemicals at a multitude of sites.

The SIS plan does not intend to cover radionuclides. The Subcommittee understands that RCRA specifically excludes Atomic Energy Act materials from its scope. However, those radionuclides not excluded could contribute significantly to the risk estimates from certain classes of impoundments (e.g., those associated with cement or fertilizer production). As a result, the risk calculations could be misleadingly optimistic for such impoundments. The Subcommittee therefore recommends that the final risk characterization carefully point out the exclusion of radionuclides and explain the possibility of risk mischaracterization.

3.1.5.2 Survey Sampling Methodology

Several Subcommittee members are confident that there is considerably more information available about the numbers and locations of impoundments in the U.S. than that currently assembled by OSW. Contact with representatives of appropriate state agencies should provide a wealth of information on surface impoundments, including: numbers, types, locations, chemicals, type of lining, subsurface soils, hydrogeologic settings, and potential losses to the environment. This expanded database provides a much more robust universe for sampling than would the current, more limited database.

The Subcommittee encourages the Project Team to involve both the states and industry in implementing the study and also in obtaining the data for screening and for more definitive analyses. Organizations such as the Chemical Manufacturers Association and the Water Environment Federation should be able to provide useful data. There are many impoundments in the U.S. for which there are considerable data on chemical input, output, and loss to the environment (via subsurface transport or into the air).

States also can provide OSW with information. A large portion of the needed information may be found in existing computer databases, case files and within offices providing regulatory or enforcement oversight. The Subcommittee recommends that OSW send the survey, with appropriate modifications, assessing the number of surface impoundments to State authorities, as well as industry.

3.1.5.3 Impoundment Categories

Impoundments may be categorized using information on industry, configuration and hydrogeological environment. Complete randomization may not provide an adequate number of impoundments within a category to allow an informed expression of how management controls or remedial measures could affect risks. For example, there are at least thirteen impoundment configurations/designs. It is desirable that this diversity of configurations be represented in the group to be analyzed. A complete randomization may miss too many configurations.

The Subcommittee recommends that (after the questionnaires are returned by respondents and state/industry data are received) OSW select an adequate number of impoundments in each of the following categories:

a) impoundment configuration
b) management controls
c) hydrogeological environment
d) impoundment contents, in broad categories
e) jurisdictional/location.

For each of these categories, there are sub-categories (the data stratification approach). The Project Team should identify the significant parameters within these categories for use in the modeling effort.

3.1.5.4 Modeling and Sensitivity Analysis Issues

Models are more sensitive to some parameters than others. In other words, if the values of some parameters are changed from very high to very low, the effects on the modeling results (risk) could be negligible; the reverse is also possible, with small changes in a critical parameter causing a large change in an output value. The Subcommittee recommends that the Project Team identify the necessary model inputs (for source term, pathway, and effects); analyze the sensitivity of the model estimates for the high and low ends of the anticipated parameter distributions; and rank the parameters by sensitivity. The SIS can then focus on the highly sensitive, highly uncertain parameters.

Descriptive modeling allows the SIS to extrapolate from 300 (plus or minus) impoundments to make judgments about thousands of other impoundments. Given the nature of the SIS, extrapolation from some subsets to the larger population of impoundments will be necessary. With extrapolation come inherent limitations and uncertainty. The paramount statistical issue becomes the degree to which the sampled impoundments are representative of all types of impoundments; hence the manner in which the sampling plan identifies, captures, and analyzes data become paramount. The Subcommittee recommends that OSW address carefully the issue of sampling plan design. In particular, the plan needs to recognize and account for the uncertainties associated with the selection of specific data ranges. This type of analysis supports extrapolating to the population, with statements such as "We are 90% confident that between 10% and 40% (the lower and upper bound of a 90% confidence interval) of impoundments that have sludges dredged frequently (a management measure) do not leak."

No modeling beyond simple statistical analyses will be needed to make the type of extrapolations stated above. In fact by simply classifying the responses to questionnaires and data from other sources, it is possible to make similar statements for thousands of impoundments. This statistical analysis and resultant extrapolation are merely expressions of the *pattern* of observations. It does not predict performance for impoundments that are deemed to be "similar."

Predictive modeling extrapolates from current data to predict future performance of an impoundment or classes of impoundments. To predict performance, OSW must use a numerical model with specific magnitudes or ranges of values for significant parameters and express the associated uncertainties. Almost all the modeling terms will have time parameters. Fortunately, the Agency plans to draw from existing models. The Subcommittee understands the Agency's conceptual framework for using models in this study. Multimedia, multipathway risk analysis methodology is still being defined and developed. The Agency has indicated the preference for using the Hazardous Waste Identification Rule risk analysis methodology expected to be available for use in 1999. The Subcommittee finds that the modeling options retained by the Agency are appropriate at this stage of the study provided that the input data are appropriately collected and utilized for these models.

3.1.5.5 Uncertainty Issues

To achieve scientific and public credibility, the Subcommittee recommends that EPA describe, in simple and understandable terms, the uncertainty associated with risk assessments taken beyond a conservative deterministic screen. The need to separate issues of uncertainty from those of variability will depend on the definition of the required endpoints of the assessment.

If the assessment endpoint is a risk defined as the "reasonably maximally exposed individual" (RME), the assessment should disclose the uncertainty in this estimate as a 90% to 95% credibility interval (or subjective confidence interval) about the "best estimate," (50th percentile) of the RME. If the assessment endpoint is the risk to a "more typically exposed individual," the assessment should include a "best estimate" of the more typical exposure and a credibility interval. The difference between the estimate of the RME and the "most typically exposed individual" (MLE) is a representative measure of the variability of risks in the exposed population. If the assessment endpoint is a frequency distribution of individual risks in an exposed population (which treats inter-individual variability as a random process), the assessment should disclose the uncertainty about the "best estimate" of this frequency distribution. This uncertainty would be expressed as a 90% to 95% credibility interval for individual risk about each quartile of the frequency distribution. This issue has been extensively discussed in the literature on risk analysis (Hoffman and Hammonds, 1994; IAEA, 1989; NCRP, 1996).

3.1.6 Verifying Analytical Outputs

The Subcommittee recommends that EPA apply the risk characterization scheme to a few impoundments early in this study with actual site monitoring data used to provide "groundtruth." "Groundtruthing" is a necessary "posterior analysis," meaning that only events that have happened can produce data on parameters that are included in the risk assessment and associated models. However, the models also will be used in the predictive mode to estimate future risks.

Conservative assumptions can be useful for the purpose of screening, but caution must be exercised in extrapolating and communicating these results. The idea of using conservative assumptions for a screening-level risk assessment is well established when the results of the assessment will be used to support a risk management decision. For example, if a permit can be issued when lifetime individual cancer risks are below one in ten thousand (10^{-4}), and the screening-level assessment shows risks below that level, then the permit can be issued without resorting to a more realistic analysis with site-specific data and distributional analyses. The utility of screening is less clear when the objective is to characterize risk, not to manage it.

The goal of screening is to prioritize sites, contaminants, etc. for further study so that funds and time are expended efficiently. Often screening exercises are based on conservative and non-conservative estimates of risk. The conservative screen identifies those sites which are definitely of low priority while the non-conservative screen identifies sites which are definitely high priority. In this type of two-tiered screening analysis, decisions can be made based on estimates of screening indices as they are compared to a predetermined decision level. For example, in a conservative screening analysis, if a screening index falls below the predetermined screening criterion, then the contaminant or site is assigned low priority for further study; if the screening index falls above the predetermined screening criterion, then the contaminant is processed through a nonconservative screening analysis. In a nonconservative screening analysis, if a screening index is above the predetermined screening criterion, then the contaminant or site is assigned high priority for further study; if the screening index falls below the predetermined screening criterion, then the contaminant or site should get attention as time and money permit.

The Subcommittee therefore recommends that if the SIS team decides to use conservative assumptions for screening purposes, it must define the screen size (cut point) below which no further risk characterization will be conducted, and must characterize impoundments with those low risks only as meeting the risk criterion.

3.2 Evaluation of the Risk Assessment

3.2.1 Conceptual Model for Characterizing Human Health and Ecological Risks

The current model for human health risk assessment appears to be quite complex, and will require appropriate detailed input data for the proposed 200-300 impoundment sample. Consequently, the Subcommittee suggests OSW consider a screening-level model to identify whether or not a given chemical is released to air, migrates to groundwater, or stays in solution and whether there is a receptor population (or lack thereof). This screening and the conceptual model would provide the basis for data collection and modeling.

In addition, the Subcommittee recommends that OSW reorganize the SIS into a series of smaller, simpler, more manageable pieces, i.e. "Tiers." The results of the early work can then be used to help design subsequent parts of the study.

Tier I could focus narrowly on ecological risk assessment, comprising collection and analysis of existing data. In Tier II, the SIS team would resolve whether or not certain categories of impoundments identified in Tier I actually present any significant risks to human and ecological health.

For the health risk assessment, Tier I would constitute a review of existing data on as many impoundments as makes statistical and budgetary sense. It is essential that all the appropriate stakeholders in state agencies and industry be involved in this

Tier I collection and assessment of existing data. Results of this existing data collection and subsequent risk assessment would enable many impoundments to be judged as very low risks to human and ecological health and probably not warranting further attention at this time. Some impoundments may be identified as having unacceptable risks and thus constituting a high priority for additional understanding and risk management efforts. Lastly, some impoundments will be in the "gray" area, because the potential exposures are too close to the toxicological effects concentrations and within the "noise" of data uncertainty and variability. Uncertainty can be reduced. Both uncertainty and variability can be better understood. However variability can not be reduced.

Conduct of the Tier I analyses will separate the various impoundments into major categories that can be sorted and ranked. There will be considerable uncertainty in the data. Because of the associated data uncertainties, Tier I is appropriately designed to be conservative. This Tier I assessment should be kept simple and implemented as soon as possible. Finally, EPA should communicate the preliminary Tier I findings--and their limitations--fully, carefully, and accurately to policy makers and the public as well as to the scientific community.

Execution of the Tier II analyses will resolve whether or not certain categories of impoundments identified in Tier I actually present significant risks to human and ecological health. New data on exposure (modeling and measuring) and/or human health and ecological effects will be collected to fill data gaps. Understanding and reducing the uncertainty and variability in the data may require significant effort. After OSW resolves the uncertainty, some categories of impoundments may turn out to be more risky or less risky than the Tier I analysis indicated. Conduct of Tier II will require considerably more resources than will be required for Tier I.

At present, OSW should limit Tier II planning to the conceptual level. Once the Tier I results are available, OSW can use them to develop the detailed Tier II study plan.

3.2.2 Ecological Risk Assessment

Item 2(b) of the Charge asks for comments on approaches for ecological risk assessment and the conceptual models underlying these approaches.

The OSW is proposing a case study approach for the ecological effects part of the risk assessment. The case studies would define the endpoints of the ecological effects risk assessment at the geographic locale of the impoundments in the study sample, and would evaluate habitat modification, establish presence or absence of endangered or threatened species, and identify particular species for which there are clear causal relationships between the species members' contact with the pollutants from the impoundments in the study sample and observed effects.

Similarly the conceptual model for ecological risk is more complicated than needed to assess potential risk to the surrounding ecosystems. Use of a screening level conceptual model can eliminate the need to assess all 200-300 impoundments in the SIS sample. Experience dictates that the primary concern for ecological risk is three-fold: a) chemicals in the food chain for higher trophic level organisms (birds, mammals); b) impacts on habitat; and c) chemicals in water released from the site. The air route is almost never important (with little or no data to assess air concentrations), and the groundwater pathway is rarely a concern.

The Subcommittee strongly supports the inclusion of the ecological risk assessment. The foundation of the ecological risk assessment was contained in two important sections of the presentation to the Subcommittee. The diagram of the "Ecological Risk Assessment For Waste Impoundments--Conceptual Model" and the "Risk Assessment/Management Framework" diagram from the Draft *Proposed Guidelines For Ecological Risk Assessment* (USEPA, 1996; 1998a) are both very appropriate and represent current scientific practices. The Subcommittee reminds OSW that it will need to clarify many details regarding the conduct of the ecological risk assessment.

3.2.3 Model Validation

To avoid a common criticism that models are used to estimate risk without appropriate validation and/or monitoring data, EPA can first use the models to assess impoundments in order to identify those with the potential for a higher level of risk. Later, EPA should use the models to select a set of impoundments for which EPA will develop risk estimates based on field monitoring data. This approach places the emphasis of the program on field data, and not a modeling effort, as the actual determinant of risk.

Due to the large number of impoundments and the lack of field monitoring data for many sites, multimedia models are needed to estimate human health and ecological risk. Because models typically tend to err on the side of conservatism, the use of multimedia models raises concern for the accuracy of the resulting calculated risk estimates. This concern emphasizes the need for obtaining extensive field monitoring data to compare with the calculated (modeled) risk estimates.

Using mathematical models, exposure, dose, and effects information can be combined to obtain a risk estimate. Usually dose-response curves are based on controlled laboratory studies, but they can be based on population studies. If we want to know the risk a specific facility presents, then we need to identify and quantify the exposures that result from the facility.

The best way to identify and quantify the exposures is to measure the presence of specific toxicants in the relevant part(s) of the environment. Where direct measurement is not possible, other mathematical models (transport and fate models) may be used. The Subcommittee prefers field monitoring data to values derived from model outputs, so that ground truthing can occur. The Subcommittee recommends that EPA take advantage of existing monitoring data from impoundments that have been collected by industry and other facility owners and provided to their respective state offices. Additionally, the Subcommittee recommends that the SIS collect monitoring data to “ground truth” the multi-media models used in the risk assessment process.

With regard to these issues, the Subcommittee recommends that during the five-year course of the EPA Surface Impoundment Study, efforts be made to quantify the uncertainty associated with the EPA toxicity factors in those cases:

a) where the risk assessment calculations are taken beyond the stage of initial screening, and

b) where the toxicity factor is suspected to be a dominant source of uncertainty, and

c) the risk approaches or exceeds established EPA decision criteria (e.g., Hazard Index~1.0 and cancer risks of about one in ten thousand).

In the absence of extensive data, this uncertainty can be quantified using the informed opinion of qualified experts (NCRP, 1996).

3.2.4 Episodic and Catastrophic Releases

In the SIS, there is a plan to characterize the risks of episodic and catastrophic releases, but how it will do so is unclear. The methods described in detail by the Project Team are best suited to characterizing the risks of chronic releases that do not vary much over time, so that conventional risk measures such as the individual lifetime risk for cancer or the chronic hazard quotient are appropriate. The Project Team wants to be able to cover episodic releases (such as overtopping during storms) or catastrophic releases (such as dike failure), and has proposed methods for calculating concentration patterns for such events. In principle, those patterns could be translated to estimates of doses received over various periods of time and related to health or ecological consequences on acute or chronic scales. The SIS plan lacks, however, a specification of how these consequence calculations will be linked with frequency or probability estimates for the episodic and catastrophic releases. For example, how will the possibility of a dike failure causing a cancer risk of 10^{-3} for a most exposed individual be coupled with the annual probability of dike failure, a number that might be much lower than unity? How will the frequencies and probabilities be estimated? Are empirical data available or will fault trees and expert elicitation of probabilities be used? Will techniques from the Risk Management program process (e.g., a matrix of probability vs. magnitude of impact) be used?

The Subcommittee thus recommends that the SIS plan describe how the risks of episodic and catastrophic releases will be estimated and characterized and provide a plan for gathering the data needed for carrying out that proposal. The Subcommittee also notes that the Agency does not seem to have an over-arching scientific policy on dealing with sporadic releases, as opposed to managing risk from chronic releases Within the context of the SIS, EPA needs to make explicit the manner in which it will utilize risk estimates for these two types of releases.

3.2.5 Source Term Formulation

The Project Team has identified adequately the factors that will affect the source term concentrations of contaminants, including the different types of impoundments and the possibility of treatment in impoundments. This proposed use of mass balance as one of the techniques for estimation of source terms is appropriate. However, for the groundwater pathway, OSW should consider that some impoundments have leachate removal and collection systems, implying a reduction in source-term concentrations.

Once the Project Team has established a time-frame (into the future) for which the analysis is to be conducted, a deterioration model for the buried components of the impoundment should be used--otherwise source terms may be underestimated. The Team may wish to use the Weibull model or any other defensible model.

For regions in which high-impact natural hazards are known to be frequent, the team should incorporate their assessment into source term analysis. The two significant hazards are earthquakes and floods. These hazards are characterized by magnitude and frequency. Several contour maps on these hazards have been developed for the United States.

As evident in the materials developed, source term formulations are still at the conceptual stage. It is not possible to make detailed comments on the approach now because they are being developed by the Project Team.

3.3 Involving External Technical Expertise

Question b(3) of the Charge addressed the use of outside experts for review of the SIS and timing of such reviews. In this vein, the Subcommittee compliments EPA for requesting SAB involvement early in the process prior to finalizing its plans for the SIS. Advice during the formative stages of the study allows OSW to improve its plans. Naturally, at these preliminary stages no detailed plans were available for review, thus the Subcommittee can make no findings regarding how existing SIS plans will address this issue. However, the Subcommittee has the following suggestions for EPA to consider as it starts to finalize its approach:

a) The EPA should employ a formal planning process such as the Data Quality Objective (DQO) Process (QA/G4) (USEPA, 1994) that documents, at a minimum. the EPA's logic, the stakeholders, the questions to be answered, decisions to be made, data inputs, SIS boundaries and SIS objectives. While an argument can be made not to employ statistical hypothesis testing, as described in QA/G4 and other planning processes, the substance of the first 5 steps of the DQO process should be addressed such that the logic and objectives are well documented and available for review and referral. Also, OSW should be aware that the Quality Assurance Division (QAD) of EPA is currently developing DQO guidance for research projects. A draft of that guidance should be available in early FY 1999. That guidance may be more directly relevant to the SIS than is QA/G4.

b) During the planning phase the EPA should take advantage of lessons learned from past surveys of oil and gas, utility and municipal impoundments and from the Office of Water, which has been characterizing waste waters on a large scale since the late 1970s.

c) All quality assurance project plans (QAPP) and/or sampling and analytical plans (SAP) should be subjected to a multi-disciplinary (e.g. field, lab and QA personnel, toxicologists, risk assessors, statisticians and data-users) review to ensure that data collection will be appropriate for model validation and will achieve project objectives as defined by the DQO planning process.

The word "peer review" can mean many different things. At times, it seems that "peer review" can be used to describe any comment by anyone on any topic. Nevertheless, peer review of the right things by the right persons at the right time can be a very valuable process. In conducting a peer review, there are variations in what is reviewed (plan, program, product), when it is reviewed (before, during, or after a study), who selects the reviewers, who reviews it (internal, external, independent, disciplines, organizational "address"), and how (written, anonymous, behind closed doors, and in public). As a result, EPA should be able to find a variety of peer review options suited to the different peer review needs of the project.

In 1985, the American Chemical Society and The Conservation Foundation published *Issues in Peer Review of the Scientific Basis for Regulatory Decisions* (ACS, 1985). This is by no means the only useful document on peer review, but three quotes from it will be helpful here:

a) *A distinction can be made among three types of peer review: (1) the peer review for minimum disciplinary acceptability of the information; (2) the validity of the technical interpretation, and (3) the relevance of the technical data and interpretation to a policy decision.*

b) *As performed by the technical community, peer review is the expert scrutiny of a technical report by professionals in the same field of expertise for independent confirmation that (1) the report is presented in a technically sound, understandable and internally consistent manner; (2) the observations were obtained by methods approved by the particular scientific discipline; and (3) the communication as a whole is a worthwhile contribution to the discipline. In their scrutiny of the work, peer reviewers are not acting as colleagues when providing rigorous criticism but rather are serving as independent professional doubters.*

c) *[for the purpose of peer review in regulatory decision making, peer review means] the critical scrutiny of a report or policy statement by independent technical experts to determine (1) the accuracy of technical data, (2) the* *validity of the technical interpretation, and (3) the relevance of the technical data and interpretation to a policy decision. Peer review is used at various stages of the policy making process to reduce the chance of omission or mistaken application of key technical material.*

In 1994, the EPA issued a Peer Review Policy and Agency-wide standards. Operating plans for implementing this policy have also been prepared (USEPA, 1998b). Nevertheless, the Subcommittee has some suggestions.

Because the SIS is long-term, complex, and involves a large number of industries and municipalities, a high level of peer review and stakeholder involvement is desirable. In general, the Subcommittee recommends the Project Team consider, plan for, and seek all three types of peer review distinguished in the first quote above. Peer review might be appropriate at several points during the development and conduct of the SIS. For example, peer review of the revised SIS plan, preliminary and final results might be useful. A final review by the SAB is recommended. Additionally, the Subcommittee believes the Project Team will find it helpful to use a variety of mechanisms for peer review as well. As a rule of thumb, earlier review (of the plan rather than the product) is better than later because there is more opportunity to apply the advice of the experts.

During the SAB review, the EPA described a multi-step risk assessment process. This process consists of six multi-component steps that ranged from characterization of the target population to the final output of risk characterization. EPA provided the Subcommittee with the names and responsibilities of the Technical Expert Panel members who were convened to assist in the design and implementation of the SIS. The EPA has also identified two key points during the study at which the technical experts would review the findings and progress. The Subcommittee considered this information as it responded to its charge of evaluating the EPA's use of technical experts and peer review.

The Subcommittee has arrived at the following findings regarding the use of technical experts and implementation of the peer review process:

a) Employing a Technical Expert Panel is a sound strategy when the members have an accurate and common understanding of the study objectives and are managed such that there is good communication between the different disciplines.

b) The experts who perform the peer review should be different from those who constitute the Technical Expert Panel. Like the OSW staff on the Project Team, the Technical Expert Panel has participated in the design of the study and will probably participate in its implementation. Because of that participation in creating the work to be reviewed, no one from the Project Team--whether from OSW or the Technical Expert Panel--should peer review the SIS.

c) Peer reviewers should have recognized technical expertise. Some of the reviewers should also have an appreciation for the positions of the various stakeholders including those of State regulators and industry. Peer reviewers should not have been previously involved in the design or implementation of the SIS. Nor should they be affected by the results of the SIS.

d) Additional peer review of interim products, if it can be done expeditiously, will help the Project Team more than the two times presently scheduled. It would be advantageous to have some--but not all--of the reviewers involved in the peer review process over the life of the SIS.

e) The SIS currently plans peer review after completion of two important events--the Pilot Study/Model Sensitivity Analysis steps and the Risk Characterization step. Peer reviews should occur prior to the implementation of these events so that reviewers can have input before significant expenses are incurred and before the program commits to an approach.

f) Significant scientific expertise resides in EPA. The importance of the SIS justifies involvement of experts from other Offices, such as the Office of Research and Development and the Office of Water, to ensure that a multi-media expertise is applied to the study.

g) To the extent that the SAB has an on-going involvement with the SIS, it loses its independence. The Project Team may brief the EEC on the progress of the study, but, if the EEC will be reviewing the product of the study, it should not conduct peer reviews of interim products.

The Project Team includes both EPA Staff and the Technical Expert Panel. The Project Team has been assembled to work on the SIS; it appears to have the appropriate background and experiences to cover the disciplines necessary to perform this project. However, it will be necessary periodically to assemble the team for face-to-face meetings to review the program. This is especially important during the problem formulation stage of the risk assessment. Additionally, the Subcommittee recommends that the team be expanded to include a broader array of EPA scientists and offices. It is suggested that the Offices of Water, Research and Development, and Air be represented on the team.

To provide validation to the SIS , the Subcommittee recommends that the Project Team develop a formalized protocol (to ensure consistency) for major steps in the study. This would include the survey design, data collection, model selection, model verification and implementation of the pilot study. During each step (time permitting), the Subcommittee recommends that EPA seek input from the affected stakeholders as well as federal, state and local government--beyond the minimum required by law and EPA policy.

Where peer review of the planned protocols can also be expeditiously undertaken, it is desirable to do so. The Subcommittee suggests that EPA consider a workshop format that the EPA has used successfully on other involved and longer term projects. The workshop approach allows the EPA to take advantage of the expertise of industry, academia and other regulatory scientists and obtain peer review at the same time. EPA's National Risk Management and Research Laboratory in Cincinnati might be a logical partner for such a workshop.

The stakeholders group should consist of representatives from risk managers, affected industries, various trade associations and public interest groups. Intra-agency peer review should be conducted to insure consistency across program areas. State and local government peer review should be conducted by the appropriate environmental entities to protect their interest in the process.

4 CONCLUSIONS AND RECOMMENDATIONS

In terms of the overall effort, the Subcommittee finds that EPA has done quite well in developing the proposed SIS study structure. The study will use accepted methods and practices; consequently it will not require additional fundamental research to generate the information and conduct the necessary risk assessment to support a regulatory decision by the year 2001.

Because of limited resources to carry out the site characterization, however, the Subcommittee suggests that EPA use screening level conceptual models to rank the potentially high risk sites requiring characterization. The Subcommittee also recommends that the OSW obtain a peer review of the implementation plan when it is completed. Such a review is important because a good implementation plan must be coupled with good analysis if the risk assessment is to be fair, clear to decision makers and stakeholders, and defensible.

Because of the complexity, importance and long-term implications of this study, OSW must develop and implement the SIS carefully--and exercise the same care in communicating the results. The tens of thousands of surface impoundments vary greatly. The size and variety of this population, along with the limitations inherent in any survey, mean that not every site will be specifically characterized. The Agency may therefore need to develop and use an index of risk for screening purposes, so that resources can be prioritized and allocated to those impoundments that pose higher risk. The Subcommittee recommends that “more risky” sites be characterized more fully than those that appear to present very little risk. As a result, not all subsets of sites will be characterized to the same degree. With respect to risk characterization, the Subcommittee therefore recommends that the Agency clearly establish its focus on risk measures (individual, population, or both) and refine the data gathering efforts accordingly.

The SIS will require the collection of physical, chemical, biological and operational information to characterize sites, the use of some models for transport and fate, and the application of other models to predict exposure, human health risks and environmental risks resulting from impoundments. If risk management/risk reduction issues also are to be addressed, then OSW also may need to collect additional data for risk management decisions. Given this complexity (and the ambitious scope of the effort), the Subcommittee recommends that the SIS be conducted in phases, with the first phase using primarily existing data in order to keep the effort as simple as possible.

The Subcommittee further recommends that OSW use “Tiers” as a way of conceptualizing the SIS. Tier I is a review of existing data to separate the various impoundments into major categories that can be sorted and ranked. Tier I provides a basis for statistical stratification. Tier II will involve collecting new information and using the data and models to estimate risks to human and ecological health.

The Subcommittee commends OSW for seeking SAB review of its proposed Surface Impoundment Study at an early stage. Consequently, these Subcommittee comments and recommendations are offered recognizing that our review addresses an effort that is still under development. An SAB review at the end of 1999 that would focus on additional technical aspects is also recommended. Finally, the OSW's plan to conduct on-going peer reviews (other than by the SAB's) throughout the course of this study is commended.

APPENDIX A TECHNICAL APPENDIX

Principal Study Questions of the SIS

a) Determine, with an acceptable degree of certainty, what risks to human health and the environment are posed by industrial wastewaters managed in surface impoundments. (OSW believes that in order to adequately respond to Congress's mandate, there are six objectives (listed below) that the study must meet.)

1) identification of the study population, consisting of RCRA section 3004 (g)(7) surface impoundments (i.e., those holding "decharacterized" wastes) and other nonhazardous industrial wastewater impoundments, and identification of a representative sample from that study population

2) analysis of the pollutants in the impoundments' influent and effluent, and the pollutants' mass flux, degradation, and metal speciation changes within the impoundment

3) quantification of human health effects due to exposure to the pollutants in RCRA section 3004 (g)(7) surface impoundments and other nonhazardous industrial waste impoundments

4) quantification of human health effects due to exposure to the pollutants in the RCRA section 3004 (g)(7) and other nonhazardous industrial waste impoundments

5) identification of the most significant factors influencing the results of 3) and 4) above

6) comparison of the results of 3) and 4) above for the RCRA section 3004 (g)(7) surface impoundments versus the other nonhazardous waste impoundments

GLOSSARY

AEA	Atomic Energy Act
API	American Petroleum Institute
CLP	Contract Laboratory Program
CMA	Chemical Manufacturers Association
COC	Constituents of Concern identified by EPA for consideration in the
SIS	Surface Impoundments Study
Cs-137	Cesium-137, a radioactive element
CWA	Clean Water Act
DQO	Data Quality Objective
EEC	Environmental Engineering Committee of the SAB
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Table
IRIS	EPA's Integrated Risk Information System
LDFA	Land Disposal Flexibility Act of 1996 that amended RCRA
MLE	the most typically exposed individual
NPDES	National Pollutant Discharge Elimination System
NOEC	No Observed Effects Concentration
ORD	Office of Research and Development at EPA
OSW	Office of Solid Waste at EPA
OW	Office of Water at EPA
Project Team	Office of Solid Waste Staff and the Technical Expert Panel designing and implementing the SIS
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QSAR	Q uantitative Structure Activity Relationship
RfD	Reference Dose
RME	the reasonably maximally exposed individual
SAB	Science Advisory Board at EPA
SAP	Science Advisory Panel at EPA (deals with pesticides)
SDWA	Safe Drinking Water Act
SIC	Standard Industrial Code
SIS	Surface Impoundments Study
Slope factor	the average daily exposure to a known or suspected carcinogen in a lifetime estimate of the risk of an excess incidence of cancer.
Source Term	The parameters that describe the magnitude (often, concentration) of a hazard very close to or at the initiating or release point.

Strata	Subdivisions of the total population of impoundments that do not overlap and are constructed to improve risk estimation for the study.
Technical Expert Panel	An identified group of experts from outside of OSW and, generally, outside of the Federal Government, which is assisting OSW with the development and implementation of the SIS
Tier I	a review of existing data on as many impoundments as makes statistical and budgetary sense to determine those requiring further study
Tier II	additional studies to resolve whether or not categories of impoundments present significant risks to human and ecological health.
Tier III	follow up on the findings of Tiers I and II but focuses on monitoring and risk reduction issues
Toxicity Factor	Reference doses (RfD) for chemicals that are toxic but noncarcinogenic, and the slope factor for a known or suspected carcinogen
Uncertainty	Lack of knowledge about the true value of a parameter
Variability	Variation in a variable or parameter over time, space, people, impoundments, etc.
WEF	Water Environment Federation
WET	Whole Effluent Toxicity

REFERENCES

ACS. 1985. *Issues in Peer Review of the Scientific Basis for Regulatory Decisions*. American Chemical Society and The Conservation Foundation. Washington DC. 29 pgs.

Hoffman, F.O. and Hammonds, J.S. 1994. *Propagation of Uncertainty in Risk Assessments: The need to Distinguish between Uncertainty due to Lack of Knowledge and Uncertainty due to Variability. Risk Analysis* 14(5):707-712.

IAEA. 1989. *Evaluating the Reliability of Predictions Made Using Environmental Transfer Models*. International Atomic Energy Agency. Vienna, Austria.

NCRP. 1996. *A Guide for Uncertainty Analysis in Dose and risk Assessments Related to Environmental Contamination*. National Council on Radiation Protection and Measurements. NCRP Commentary No. 14., Bethesda, Maryland.

USEPA. 1994. *Guidance for the Data Quality Objectives Process (QA/G-4)*. Office of Research and Development, Quality Assurance Management Staff, US Environmental Protection Agency, Washington, DC.

USEPA. 1996. *Draft Proposed Guidelines For Ecological Risk Assessment*. Office of Research and Development, US Environmental Protection Agency, Washington, DC.

USEPA. 1998a. *Guidelines for Ecological Risk Assessment.* Office of Research and Development, US Environmental Protection Agency, (EPA/630/R-95/002Fa), Washington, DC.

USEPA. 1998b. *Peer Review Handbook.* Office of Research and Development, Science Policy Council, US Environmental Protection Agency, (EPA 100 B98 001), January 1998, Washington, DC.

DISTRIBUTION LIST

The Administrator
Deputy Administrator
Regional Administrators, Regions 1-10
Assistant Administrators
Directors, Office of Research and Development Laboratories
Director, Office of Air and Radiation
Director, Office of Atmospheric and Indoor Air Programs
Director, Office of Policy Analysis and Review
Director, Office of Environmental Processes and Effects Research
Director, Office of Policy Analysis
Director, Climate Change Division
EPA Headquarters Library
EPA Regional Libraries
National Technical Information Service
Congressional Research Service
Library of Congress