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

October 25, 2002

EPA-SAB-EEC-03-001

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Review of the Office of Solid Waste's Study, *Industrial Surface Impoundments in the United States*: An EPA Science Advisory Board Report

Dear Governor Whitman:

The Surface Impoundments Study Subcommittee of the Science Advisory Board's Environmental Engineering Committee recently reviewed the Office of Solid Waste's study, *Industrial Surface Impoundments in the United States*. The study was conducted to assess human-health and ecological risks associated with surface impoundments used to manage nonhazardous industrial waste. The Environmental Protection Agency invited the Science Advisory Board to review the study because the Agency will use the study results to decide whether, and if so, how, to apply the land disposal restrictions or take other appropriate actions to address risks found and any regulatory gaps that may exist.

Overall, the Subcommittee finds the study provides a major advance in understanding the nature of industrial surface impoundments receiving non-hazardous liquid wastes in terms of their number, location, design, operation, chemistry, and potential human-health and ecological risks. The knowledge base obtained from the study is sound and can facilitate future policy and regulatory decisions. In particular, the Subcommittee finds that the approach used by the EPA in this risk analysis to be reasonable. Once the concerns raised in this review regarding exposure and health elements have been addressed, the study can be used to assess the adequacy of the current regulatory framework for addressing potential risks to human health and the environment from industrial surface impoundments. In assessing the adequacy of this framework, the Subcommittee urges the EPA to take into account the study's scope and limitations. These are transparently detailed in both the study report and the attached review. Consideration of these limitations will further enhance the reliability of future regulatory decisions addressing industrial surface impoundments. The Subcommittee also encourages development of articles on this landmark study for publication in peer-reviewed journals to benefit researchers and practicing engineers in relevant fields.

The study addressed the direct-pathway human health risks in a relatively quantitative manner (Tier III risk modeling). Risks associated with transient events (*e.g.*, overtopping) were excluded and human health risks from indirect exposures and potential ecological risks from all pathways were assessed at a screening level. Although this approach resulted in uneven assessments with a varying degree of uncertainty, the Agency's decisions about which approach to take for various endpoints and exposures were reasonable given the time constraints, lack of available data in many areas, and the current state of understanding in some areas.

Decision-making need not rest on the Tier III risk modeling analyses alone. Because the Tier II chemical release assessment analyses are especially rich, the Subcommittee suggests that the Agency develop conclusions on national risk profiles by expanding its empirical analysis of the chemical release assessment data. Establishing risk profiles based on Tier I (Preliminary Screen) and Tier II (Release Assessment) analyses has the advantage that technically sound decisions can be reached and supported while the need to commit additional resources for quantifying uncertainty is minimized. In the future, the Subcommittee recommends that the Agency study more fully those risks that received screening-level assessments only or were not considered in this study. Such research would enlarge the understanding of the risks posed by these facilities. The Executive Committee notes that an anticipated report of the Ecological Processes and Effects Committee, "*A Framework for Reporting on Ecological Conditions: An SAB Report*" (EPA-SAB-EPEC-02-009, September 30, 2002) would provide guidance on endpoints appropriate for the assessment of ecological risks.

The Subcommittee was also very impressed by the staff who prepared for the review. In particular, the deep and extensive knowledge displayed by Barnes Johnson, Director, Economics, Methods, and Risk Analysis Division of the Office of Solid Waste and Division staff members Becky Cuthbertson and Jan Young were notable. In its efforts to provide a sound scientific basis for decision-making, the staff sought and utilized input from the SAB and other external peer reviewers in developing the study and made use of the Agency's Quality System in its execution. These measures, coupled with the hard work of the staff, contributed to the quality of the study and should provide a positive example to others undertaking similar work.

We look forward to your consideration of and response to the enclosed report.

Sincerely,
/ Signed /

Dr. William Glaze, Chair
EPA Science Advisory Board

/ Signed /

Dr. Domenico Grasso, Chair
Environmental Engineering Committee
EPA Science Advisory Board

/ Signed /

Dr. Byung Kim, Chair
Subsurface Impoundment Study Subcommittee
Environmental Engineering Committee
EPA Science Advisory Board

NOTICE

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1 EXECUTIVE SUMMARY

The Office of Solid Waste (OSW) of the U.S. Environmental Protection Agency (EPA) conducted a multi-year study to assess human-health and ecological risks associated with surface impoundments used to manage nonhazardous industrial waste. The study was prompted by the Land Disposal Program Flexibility Act and an Environmental Defense Fund-EPA consent decree. The extensive survey conducted as part of the study indicates there approximately 18,000 such surface impoundments in use throughout the United States. Until this study, relatively little was known about these facilities with regard to their actual and potential human-health and ecological risks and regulatory gaps associated with managing the risks. OSW requested that the EPA Science Advisory Board (SAB) review the study results reported in *Industrial Surface Impoundments in the United States* (USEPA, 2001), the appendices, and attachments to the appendices, along with other relevant materials. The request was made because EPA will use the study results to decide whether, and if so, how, to apply the land disposal restrictions or take appropriate action to address risks found. The SAB's Environmental Engineering Committee (EEC) formed a Surface Impoundments Study Subcommittee for the review. The Subcommittee conducted the review through a face-to-face meeting October 24-26, 2001 along with a series of public conference call meetings before and after the face-to-face meeting to respond to the six major charge questions on scientific aspects of the study, to address research needs, and to provide some remarks on EPA's responsiveness to the previous SAB review and its use of other external peer review processes. The Subcommittee was not requested to address the issues associated with the regulatory gaps.

Overall Assessment of the Study

Overall, the Subcommittee finds the study provides a major advance in understanding the nature of industrial surface impoundments receiving non-hazardous liquid wastes in terms of their number, location, design, operation, chemistry, and potential human-health and ecological risks. The knowledge base obtained from the study is sound and can facilitate future policy and regulatory decisions. In particular, the Subcommittee finds that the approach used by the EPA in this risk analysis to be reasonable. Once the concerns raised in this review regarding exposure and health elements have been addressed, the study can be used to assess the adequacy of the current regulatory framework for addressing potential risks to human health and the environment from industrial surface impoundments. In assessing the adequacy of this framework, the Subcommittee urges the EPA to take into account the study's scope and limitations. These are transparently detailed in both the study report and the attached review. Consideration of these limitations will further enhance the reliability of future regulatory decisions addressing industrial surface impoundments

The study addressed the direct-pathway human health risks in a relatively quantitative manner (Tier III risk modeling). Risks associated with transient events (*e.g.*, overtopping) were excluded and human health risks from indirect exposures and potential ecological risks from all pathways were assessed at a screening level. Although this approach resulted in uneven assessments with a varying degree of uncertainty, the Agency's decisions about which approach to take for various endpoints and exposures were reasonable given the time constraints, lack of available data in many areas, and the current state of understanding in some areas.

Decision-making need not rest on the Tier III risk modeling analyses alone. Because the Tier II chemical release assessment analyses are especially rich, the Subcommittee suggests that the Agency develop conclusions on national risk profiles by expanding its empirical analysis of the chemical release assessment data. Establishing risk profiles based on Tier I (Preliminary Screen) and Tier II (Release Assessment) analyses has the advantage that technically sound decisions can be reached and supported while the need to commit additional resources for quantifying uncertainty is minimized. In the future, the Subcommittee recommends that the Agency study more fully those risks that received screening-level assessments only or were not considered in this study. Such research would enlarge the understanding of the risks posed by these facilities.

Responses to Specific Charge Questions

The six charge questions concern 1) validity of the general methodology and approach used for risk analysis; 2) need to consider abnormal operating conditions (*e.g.*, transient events); 3) validity of the screening-level risk characterization for human health risks (indirect pathways) and ecological risks (all pathways); 4) use and interpretation of survey data on chemical constituent presence/quantity; 5) analysis and interpretation of field sampling data; and 6) handling of the groundwater source term used for a groundwater solute transport model.

<u>Charge Question 1: Validity of General Methodology and Approach</u>.

EPA adopted a multi-tiered risk characterization methodology to assess human health risks via direct exposures. The Subcommittee endorses this approach. The probabilistic sampling design supported the generation of national human health risk estimates for this pathway under steady state conditions. To further strengthen the national risk profiles, the Subcommittee encourages EPA to consider expanding its current use of chemical release assessment indices (*i.e.*, Tier II methodology) to supplement the characterization of risk uncertainty conducted in Tier III analyses. However, the incomplete characterization of site-specific uncertainty factors means that risk assessment conclusions for any particular surface impoundment are more uncertain and therefore less reliable.

EPA used a less rigorous, risk-screening methodology to identify those surface impoundments posing potentially significant human-health risks via indirect pathways and ecological risks by any pathway. Although this approach resulted in uneven quantitative assessments of the risks considered in this study, the Subcommittee finds EPA's decisions reasonable given the time constraints, the data available for the study, and the current state of knowledge. However, the Subcommittee recommends that EPA address risks of additional indirect pathways including human consumption of contaminated wildlife and quantitative uncertainty analysis of the influence of lack of cancer potency values for known or suspected carcinogens on the health risk characterization.

Industrial Surface Impoundments in the United States was not intended to provide a complete and balanced characterization of all potential risks. While such characterizations may not always be possible because of the state of the science, they would be a worthy goal for studies providing a basis for regulatory decision-making. Therefore, the Subcommittee recommends that EPA continue to develop and implement a quantitative assessment of indirect human-health and ecological risks associated with surface impoundments in the future.

Charge Question 2: Need to Consider Abnormal Operating Conditions.

There are three types of abnormal operating conditions: changes in wastewater characteristics, overtopping events due to storms, and structural failures due to earthquakes. Of these abnormal operating conditions, overtopping events merit the most attention because they are more apt to result in the release of pollutants.

Based on survey results reported in *Industrial Surface Impoundments in the United States*, EPA estimates that about 25% of all facilities have experienced overtopping events. The scope of the study did not include consideration of the risks associated with abnormal operating conditions. However, given the frequency of these events, the Subcommittee strongly encourages that EPA consider as future research topics: mining collected information on the patterns of storm impact on impoundments; collecting additional data if needed; and evaluating the risks associated with overtopping events, possibly focusing on the more vulnerable parts of the United States. This information would allow EPA to draw some conclusions regarding those abnormal operating scenarios that are mostly likely to increase risks.

If the information indicates that transient events have had or could have significant impacts on risk factors, then EPA should conduct more detailed analysis to integrate methodologies with defensible assumptions into its overall risk assessment framework. The methodologies that should be considered for the integration include the factor of safety approach, the zero containment assumption, and modeling of impoundment degradation and consequent contaminant release during the active operating life of the impoundment. To adequately accommodate the effects of transient events, some elements of the risk assessment framework may need to be probabilistic, *i.e.*, the modeling of event occurrence frequency.

Charge Question 3: Validity of Screening-Level Risk Characterization.

EPA performed the screening-level ecological and indirect human-health risk analyses using appropriate methodology and the Subcommittee recommends that a more quantitative assessment of these risks be undertaken in the future. A more comprehensive risk assessment would add effects of transient events and additional pathways, including consumption of contaminated fish and waterfowl and indoor routes of exposure such as volatile chemicals in home shower water. Additionally, the Subcommittee was not able to evaluate the error associated with the lack of cancer potency values for several known or suspected carcinogens. The Subcommittee recommends that the conclusions of the screening-level risk assessments (*i.e.*, percentage of facilities) be presented in two categories: facilities with "potential risk" and those with "risk below threshold of concern". If EPA desires to further categorize facilities presenting potential risk, the Subcommittee recommends that they do so in a literal manner (*e.g.*, "potential risk from 2 or more pathways") rather than using subjective adverb descriptors. The ecological assessment strategy for ecological risk was intended to represent ONLY potential for adverse effects NOT actual risk posed to ecological receptors. The conclusion that the vast majority of surface impoundments pose potential ecological risk should be stated more clearly in the executive summary. It would be appropriate to conduct quantitative assessments at those sites judged to present significant potential for ecological risks.

Charge Question 4: Use and Interpretation of Survey Data.

Responses to the survey questions were often incomplete. For certain facilities the lack of concentration data inhibited risk assessment. To allow risk assessment to proceed, EPA developed surrogate protocols to address data gaps created by: missing sludge concentrations, non-detect data, and wastewater contaminants reported as present but with no concentration values. The Subcommittee found that these surrogate protocols were generally conservative from the perspective of protecting human health and the environment and suitable for the purposes of this study. Due to the importance of concentration data, the Subcommittee recommends that EPA explore the sensitivity of risk estimates to contaminant concentrations and to employ field-sampling data to groundtruth the surrogate protocols.

Charge Question 5: Analysis and Interpretation of Field Sampling Data.

EPA collected field samples at twelve judgmentally selected facilities to evaluate the accuracy of survey data. The concentrations measured during field sampling were generally less than the concentrations reported in the survey. The field sampling also indicated that the survey data were incomplete with significantly more contaminants being detected in the field samples than in the survey data. The Subcommittee recommends that EPA: a) explore the reasons for the positive bias and non-detect contaminants in the survey data and b) employ the field data to groundtruth the surrogate data protocols. The Subcommittee also found and concurs with EPA that a probabilistic selection of facilities and sampling locations within impoundments for the field sampling would have increased confidence in the representativeness of the samples and the ability to extrapolate to the larger national population of impoundments.

Charge Question 6: Handling of Groundwater Source Term.

The Subcommittee supports the EPA approach of using impoundment wastewater composition to define the groundwater source term for steady-state impoundment operation, and does not recommend a bounding analysis using available sludge data. The available sludge data are inadequate in the scope of constituents and conditions represented, and calculating leachate concentrations from sludge concentrations would necessitate assumptions that would lead to substantial uncertainty in the estimates obtained. The use of impoundment wastewater composition to represent impoundment leachate composition for steady-state impoundment operation is a reasonable, conservative approach given the limited submittal of leachate data by survey respondents and the fact that the leachate concentrations did not exceed impoundment wastewater concentrations for those facilities for which both types of data were reported. It would be useful to demonstrate systematically that the main conclusions from the groundwater pathway risk analysis would not be changed if source area constituent concentrations were higher, *e.g.*, by an order of magnitude as a conservative upper bound estimate. A sensitivity analysis could be performed to examine the effects of increases in constituent source concentrations. It seems unlikely that differences in the source area concentrations in the range of an order of magnitude will change the main conclusions reached in the study.

Recommended Future Research Topics

The Subcommittee has made a recommendation for additional research in the short term. This relates to the collection of additional data, and/or mining of collected information on the patterns of storm impact on impoundments to allow EPA to draw some conclusions regarding those abnormal operating scenarios that are mostly likely to increase risks.

The Subcommittee also recommends several areas for future research to improve estimation of human health and ecological risks associated with industrial surface impoundments. These areas deal with issues of performance of surface impoundments, human health, ecological risks (including bioaccumulation), fate and transport (through air, groundwater, soil, and sludge), fate and transport (through uptake and bioaccumulation), risk assessment methodologies (model development and validation), and risk mitigation measures. Many of the areas should be prioritized based on their relative impact on the reduction of uncertainty for estimating the risks. Therefore, it would be helpful to conduct sensitivity analyses to identify critical parameters. For these parameters, a higher priority should be given to those that have not been considered in estimating the risks or do not have sufficient data.

Use of External Peer Reviews

The Subcommittee considered how well EPA followed the advice provided in the 1998 report, *Science Advisory Board's Review of the Office of Solid Waste's Proposed Surface Impoundment Study* (EPA-SAB-EEC-98-009). and found that EPA-implemented design followed to a great degree the SAB's advice, (*e,g*., phased approach based on conservative assumptions). In its report, the SAB recommended that EPA use a structured planning process to design the entire study. Although EPA used the structured planning for the field sampling only, their contemporaneous peer-review process, to a great degree, provided the appropriate level of quality assurance necessary for ensuring that the risk characterization results were scientifically defensible. Indeed, the Subcommittee commends EPA on its use of peer review during the different phases of the study. The attention that OSW paid to this essential quality assurance mechanism should become an example for future studies.

2 INTRODUCTION

This chapter of the report provides the background, context, charge for the review and the procedural history. Specific responses to charge questions can be found in Chapter 3.

2.1 Background

2.1.1 What are Surface Impoundments?

Essentially, surface impoundments are artificial ponds containing wastewater of one sort or another. In the United States there are thought to be 30,000 or more surface impoundments containing wastewater from agriculture, industry, mining or storm water. EPA estimates that, in the 1990's, there were approximately 18,000 industrial nonhazardous surface impoundments in use. These surface impoundments were present at about 7,500 facilities located primarily east of the Mississippi River and in Pacific Coast states. Approximately 12,000 impoundments have high pH, low pH, or one or more chemicals of concern and are located at about 4,500 facilities.

Industrial impoundments vary greatly in size, from less than a quarter of a hectare (1/3 of an acre) to several hundred hectares. The larger impoundments provide the bulk of the total national industrial impoundment capacity.

In the United States, industrial surface impoundments are an important and widely used industrial materials management unit. Surface impoundments serve a variety of beneficial uses in a number of industrial processes. Industrial facilities that produce wastewaters often use surface impoundments to perform necessary wastewater treatment prior to discharge into surface waters. In other cases, industrial facilities may need to control wastewater flows and use surface impoundments for storing excess wastewater. In still other cases, industrial facilities may use surface impoundments to manage their excess wastewaters through evaporation or seepage into the ground.

Industrial impoundments frequently use management techniques that increase the potential for chemical releases and frequently are found in environmental settings that increase the potential for impacts to humans or ecosystems in the event of a chemical release. In this study, EPA found that most industrial impoundments are located only a few meters above groundwater and that, in most cases, shallow groundwater discharges to a nearby surface waterbody. More than half of the impoundments do not have liner systems to prevent the release of wastes to soil or groundwater. In addition, about 20 percent of impoundments are located within 150 meters of a fishable waterbody, so migration through the subsurface to the nearby surface water is possible. Finally, while aeration can have certain benefits, it also increases volatilization and the potential for airborne contaminant migration. EPA found that about 45 percent of the total wastewater quantity managed in impoundments is aerated.

2.1.2 What Kinds of Wastes are Stored in Industrial Surface Impoundments?

Wastewaters that are neither "characteristic" or "listed" hazardous wastes under the Resource Conservation and Recovery Act (RCRA) may be found in industrial surface impoundments[1]. In developing its report (USEPA, 2001), EPA requested information on the presence and quantities of 256 chemical constituents of concern in the impoundments. More than half of the impoundments with chemical constituents or pH of concern are in the chemical, concrete, paper, and petroleum industries. The paper and allied products sector is of special interest because two thirds of the volume of wastewater managed in surface impoundments comes from that industrial category.

2.1.3 What did Legislation and the Consent Decree Require?

The RCRA provides a "cradle to grave" regulatory scheme for hazardous wastes. The 1984 amendments to RCRA required that EPA restrict the practice of placing hazardous wastes in land-based waste management units. A June 1, 1990 regulation implemented this restriction for "characteristic" hazardous wastes that are managed in wastewater systems. In that regulation, EPA interpreted the 1984 amendments to allow land placement of wastes that were formerly characteristic hazardous wastes, and were managed in wastewater systems, but that had been treated or diluted so that the characteristic hazard was removed. For simplicity, EPA refers to these wastes as "decharacterized" wastes, meaning the characteristic hazard has been removed, and they are no longer characteristic hazardous wastes. EPA was sued by Chemical Waste Management, Inc. over this interpretation. The court's opinion was that RCRA required EPA to set treatment standards that minimize threats to human health and the environment.[2]

To comply with the court's opinion, EPA promulgated a 1996 final regulation that in certain cases imposed treatment requirements before, during or after their placement in surface impoundments. Soon after the regulation was signed, Congress enacted the Land Disposal Program Flexibility Act (LDPFA) of 1996, which effectively rescinded the 1996 regulations (but kept the treatment requirements in effect in limited circumstances).

In addition to these developments, in 1989, the Environmental Defense Fund (EDF) sued EPA, in part, for failing to meet the statutory deadlines of Section 3001(e)(2) of RCRA (RCRA;

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1 The RCRA regulatory scheme delineates "characteristic" hazardous wastes as one type of hazardous waste; the other type is known as "listed" hazardous wastes. Characteristic hazardous wastes exhibit one or more of four separate hazardous properties: corrosivity, ignitability, reactivity, or toxicity.

2 The specific issue in the case was the continued presence of 'underlying hazardous constituents' in the waste, even after the characteristic hazard was removed.

EDF vs. Whitman; Civ.No. 89-0598 D.D.C.). To resolve most of the issues in the case, EDF and EPA entered into a consent decree that sets out an extensive series of deadlines for promulgating RCRA rules and for completing certain studies and reports. A 1997 amendment to the consent decree required EPA to study human health risks from air inhalation of 105 chemical constituents present in surface impoundments. In the consent decree requirement, the waste in the impoundment is classified as nonhazardous under the federal RCRA regulations, but is also not the decharacterized waste at issue in the preceding two paragraphs. Together, the two provisions - the legislation and the consent decree - called on EPA to conduct a study of the risks associated with all nonhazardous waste surface impoundments.

Currently any ultimate discharge from industrial surface impoundments is subject to regulation under the Clean Water Act (CWA).

2.1.4 What was the Scope of the EPA's Surface Impoundments Study?

As mentioned earlier, there are approximately 18,000 industrial nonhazardous surface impoundments in use throughout the United States, located at about 7,500 facilities. Because of the scope of the universe, EPA conducted the study focusing on a sample of U.S. facilities that use impoundments to manage industrial nonhazardous waste.

Most of the facilities selected for the study were chosen randomly to ensure that the sample facilities would be representative of the facilities in the study population. EPA sent surveys to 221 facilities to collect information on their impoundments and the wastes managed in them. EPA requested information on the presence and quantities of 256 chemical constituents of concern in the impoundments, as well as on the impoundments' design and operation. EPA used these data to characterize the potential risks that may be posed by managing the wastes in impoundments. The survey responses on the presence and concentrations of specific chemical constituents were particularly central to EPA's analysis. EPA also collected and analyzed wastewater and sludge from impoundments at 12 facilities in the study and used that information to illuminate the completeness and accuracy of the survey data. EPA also used data from a variety of other sources such as facility permit files, U.S. Census data, and technical references.

OSW's report (USEPA, 2001), discusses risks to human health and the environment that may be posed by managing industrial nonhazardous wastes in surface impoundments. It provides:

a) estimates of cancer and non-cancer human health risks for individuals, or “receptors,” who may be exposed to releases from surface impoundments used to manage wastewaters and wastewater treatment sludges,

b) a screening analysis of other indirect pathway human health risks, and

c) a screening analysis of the potential risks to ecological receptors.

2.2 Context

EPA will use the study results, along with the analysis of existing regulatory and nonregulatory programs designed to address the risks (described in Chapter 4 of the report) to decide whether, and if so, how, to apply the land disposal restrictions or take other appropriate actions to address the risks found.

2.3 Charge Questions

EPA requested that the SAB's EEC review the *Industrial Surface Impoundments in the United States* report (2001), its appendices, and attachments to the appendices, dated March 2001, along with other relevant materials. EPA developed general and specific questions for the SAB. Appendix A contains the full charge. Relevant portions of the charge are repeated in Section 3 of the Subcommittee report with the relevant findings. The remainder of Section 2.3 of is an abridged version of the charge.

1. Validity of General Methodology and Approach

a) Does the SAB believe that the general methodology, EPA chose for developing its risk analysis, was appropriate for the policy questions posed in the statute and consent decree?

b) Regarding the overall study implementation, from design through sample selection, data collection and analysis, what areas of strength does the SAB see in the overall methodology, and what areas of potential improvement or additional analysis does the SAB recommend?

c) Did EPA adequately characterize the risks? Are the risk analysis and findings transparent? That is, are they explicit in:

- describing the assessment approach, assumptions, extrapolations and use of models
- describing plausible alternative assumptions
- identifying data gaps
- distinguishing science from policy
- describing uncertainty, and
- describing the relative strength of the assessment?

d) Please provide an SAB's assessment of the accuracy of EPA's overall study conclusions regarding risks to human health and the environment. Were the conclusions either false-positive or false-negative (finding risks of greater or lesser magnitude than the risks that likely exist)?

2. Need to Consider Abnormal Operating Conditions

a) In light of the findings of the report, should EPA perform a more detailed evaluation of abnormal operating events, would the data collected point to additional studies or research to provide more detail about this issue? If so, what methods or approaches would the SAB recommend regarding collecting more reliable data, and modeling the probability and impacts of such events?

3. Validity of Screening-Level Risk Characterizations.

a) For the indirect human health and ecological screening-level analyses, in the SAB's view, do the results point to areas of potential future research? If so, does SAB have recommendations on prioritizing future studies in these areas?

b) Based on the screening-level estimates EPA developed for other indirect and ecological risks, did it appear that EPA overlooked potential problem areas?

c) Did EPA clearly describe and properly characterize the other indirect human health and ecological risk analyses?

4. Use and Interpretation of Survey Data.

a) Is it likely that EPA's data imputation protocol, or "surrogate data protocol" for imputing waste composition data markedly affected the ultimate conclusions regarding potential risks? If so, in what direction did the protocol probably bias the conclusions?

b) Should EPA have used any other approaches for qualifying or presenting the data?

c) Was using the assumption that a chemical could be present up to the detection limit, when it was reported as being present below a detection limit, a reasonable concentration to choose for risk screening purposes? Was this assumption reasonable in cases where the constituent was not expected to be present at the facility?

d) Did EPA-generated default detection limit protocol provide reasonable approximations of likely detection limits encountered in the field by the facilities, when the detection limits were not reported in the laboratory analysis?

e) Do the results that are based on imputed/detection limit data suggest that further analysis is needed?

5. Analysis and Interpretation of Field Sampling Data

a) Although there are limitations of performing the comparison of survey and field sampling waste composition data, what is the SAB's view on EPA's conclusions about the accuracy of the reported survey data on chemical constituent concentrations/quantities?

b) What is the SAB's view on EPA's conclusion on the potential incomplete reporting of chemical constituents present?

c) Would the SAB recommend alternate approaches, in order to obtain the best possible information regarding the exact chemical constituents present, given the same budget and time constraints?

6. Handling of Groundwater source term

a) Would the SAB recommend another approach for representing the groundwater source term, for example, performing a bounding analysis, using the sludge data, where available, to represent an upper bound of the groundwater source term, and using wastewater data as the lower bound, for those chemical constituents for which this situation may be an issue?

b) Compared to other sources of uncertainty in the groundwater and groundwater to surface water pathway analyses, how large a source of uncertainty does the decision to use wastewater composition data appear to introduce into the overall study conclusions?

2.4 Procedural History of the Review

Barnes Johnson, Director, Economics, Methods, and Risk Analysis Division of the OSW requested the review during the SAB's call for project nominations for FY2001. The SAB's EEC considered this request at a public meeting December 5-7, 2001. The EEC appointed Dr. Kim as chair of a Surface Impoundments Study Subcommittee originally to include Drs. Dellinger, Kavanaugh, Maney, McFarland, and Theis of the EEC. The EEC had done a consultation on the plans for the surface impoundment study for OSW in September 1996 and reviewed a plan for the study in 1997. (USEPA, 1998) The OSW also briefed the EEC about its study and noted that it had arranged for an external peer-review of certain elements of the study.

The EEC discussed the Surface Impoundments Study at two subsequent conference calls on March 7 and May 2, 2001. During this period the review documents became available and a preliminary charge was drafted. Also, the SAB began to move towards a different approach to Subcommittee formation known as "wide cast/narrow cast". Because the EEC had named Subcommittee members in December, a modified version of this new process was used to complete Subcommittee formation. Also, as the charge became clearer and other demands were made on the members of the EEC, Drs. Dellinger and Theis were reassigned from this Subcommittee to other activities.

The Subcommittee conducted its review on public conference calls (June 26, July 19, August 27, September 17, 2001 and February 1, 2002) and at a face-to-face meeting October 24-26, 2001. The Environmental Engineering Committee considered the Subcommittee's report at a public conference call March 13, 2002 and the Executive Committee approved the report, with minor edits for clarification, at a public conference call May 8, 2002.

3 RESPONSE TO THE CHARGE

3.1 Charge Question 1: Validity of General Methodology and Approach

This section addresses the three questions raised by OSW in their overall charge and, where relevant, provides separate discussions for human health effects and ecological risks.

3.1.1 Does the SAB believe that the general methodology EPA chose for developing its risk analysis was appropriate for the policy questions posed in the statue and consent decree?

The relevant policy questions posed in the LDPFA statute and consent decree were addressed by the EPA through the characterization of the human health and ecological risks associated with never characteristic and decharacterized wastes managed in surface impoundments. Although neither the regulatory statute nor the consent decree explicitly mandates a quantitative assessment of human health and ecological risks associated with management of wastes in surface impoundments, the EPA chose to conduct a multimedia risk assessment to characterize potential direct–pathway human health risks. Screening-level analyses were used to characterize those risks associated with indirect-pathways for human health and all pathways for ecological risk. This resulted in unevenly rigorous assessments of the risks considered in the study. Because of the paucity of relevant data and the current state of understanding, it is not possible to analyze the risk for all pathways and all effects to the same degree of rigor. Therefore, this uneveness reflects the state of the science, not an uninformed choice by those who conducted the study.

With regard to direct-pathway human-health risks, the Subcommittee supports the EPA's decision to conduct a quantitative risk assessment to address the specific policy questions posed in the statute and consent decree as well as for establishing a defensible framework for future risk management decision-making. Despite the endorsement of the general methodology selected by the EPA, several Subcommittee members expressed concern that the final quantitative risk assessment results generated in this study are of limited value to EPA decision-makers if not adequately supported by a quantitative assessment of uncertainty (and, in some cases, variability). Defensible risk management decisions based on a quantitative risk assessment approach typically require estimates of both the magnitude of the risk as well as the level of confidence (*i.e.,* probability) that the risk will be observed. In this study, the EPA identified and clearly described the major sources of uncertainty but did not quantitatively evaluate the impact of uncertainty on the final risk characterization results. Further, the risk assessment was conducted for steady-state operating conditions, and did not account for transient events. Acute ecological and human health risks were not evaluated but should be if transient events are determined to be important.

Given the various sources of uncertainty and the potential costs associated with quantifying their impact on the final risk results, the Subcommittee recommends that the EPA reevaluate its use of a quantitative risk assessment as the sole basis for developing national risk profiles. Modification of the technical approach used to characterize risk could potentially allow the EPA to reach defensible decisions with more confidence than would be obtained solely relying on the quantitative evaluations of uncertainty conducted in Tier III analyses. A broader use of the risk indicator methodology in support of risk management decisions would basically require that the EPA consider the impact of a larger number of site-specific factors on the release, transport and exposure of chemicals from surface impoundments. These site-specific factors (*e.g.,* existence of a surface impoundment liner, depth to groundwater, frequency of floods, *etc*.) could be quantitatively combined to generate national human health and ecological profiles that accurately reflect the risks associated with chemicals managed within these facilities.

The principal advantage of establishing national human health and ecological risk profiles based on an expanded use of the Tier I (Preliminary Screen) and Tier II (chemical release assessment) methodology rather than on the results from the Tier III (risk modeling) methodology is that the EPA will be in a position to draw technically defensible conclusions regarding the potential risks posed by these facilities while minimizing the need to commit additional resources for quantifying uncertainty.

When additional data are available and the state of understanding is advanced, it would be useful to conduct studies of the Tier III type (risk modeling) on those risks that were excluded or addressed only by screening in this study. The results could be used to further refine *(i.e.,* ground truth) the risk management decisions made based on currently available information by providing comprehensive and rigorous quantitative assessments of all risks to human health and the environment. The results could also provide a technical basis for prioritizing future research projects.

3.1.2 Regarding the overall study implementation, from design through sample selection, data collection and analysis, what areas of strength does the SAB see in the overall methodology, and what areas of potential improvement or additional analysis does the SAB recommend?

The Subcommittee supports EPA's decision to employ a multi-tiered approach for characterizing human health and ecological risks associated with surface impoundments. The use of preliminary risk screening to eliminate constituents and/or constituent-impoundment combinations that constitute a negligible risk from further quantitative analysis is a technically defensible approach for optimizing the use of limited resources and a major strength in the overall risk characterization approach. The Subcommittee commends the EPA for developing and implementing conservative assumptions within the risk screening procedure to minimize the elimination of constituents that could potentially represent significant risks to public health and the environment. Furthermore, the Subcommittee endorses the EPA's use of a probabilistic approach for quantifying human health risks associated with the groundwater exposure pathway. Employment of a probabilistic risk assessment approach provides the EPA decision-makers with a means of quantifying both the range of potential human health risk and the probability (or confidence) that the risk will be observed.

The Subcommittee endorsed EPA's decision to apply a stratified random sampling procedure in designing their industrial risk screening survey; this is another area of strength in the overall risk characterization methodology. By employing a statistical approach to select those surface impoundments that would comprise the study sample, EPA established a defensible scientific basis for extrapolating sampling results to generate national risk profiles. Although EPA's decision to develop national risk profiles from the survey data was supported, several Subcommittee members expressed reservations regarding the use of risk modeling (*i.e.,* Tier III) results as the basis for drawing final conclusions regarding the potential risks posed by surface impoundments. Specific concerns regarding EPA's use of the risk modeling results to characterize potential risks include the absence of:

a) clearly defined quality criteria established for each type of data element used in the models,

b) a technically defensible and transparent process for quantifying the impact of uncertainty (and variability) on final risk modeling results,

c) an evaluation of the potentially disproportionate risks posed by surface impoundments to vulnerable human receptor populations including infants, pregnant women, elderly *etc*.,

d) an assessment of the effects of chemical and/or biological transformations of compounds released from surface impoundments on the estimated human health risks, and

e) a quantitative evaluation of the effects of transient events (floods, earthquakes, *etc*.) on risk results.

In addition to the technical concerns associated with risk modeling uncertainties, the Subcommittee noted that only human health risks from direct exposure to chemicals managed within surface impoundments were fully evaluated in the multi-tiered risk characterization methodology. The three tiers, which included the risk screening, chemical release assessment and risk modeling procedures, provided the technical framework for identifying and analyzing those facilities that represented significant risks to public health and the environment. The Subcommittee concluded that since human health risks associated with indirect chemical exposure as well as ecological risks were only evaluated through Tier I (*i.e*., risk screening), additional quantitative risk analyses were warranted before these risks could be adequately captured within national profiles. The Subcommittee recommended specific activities for developing defensible national profiles that incorporate both human health risks resulting from indirect chemical exposure and ecological risks. These included the following:

a) More effective application of transport and/or multimedia fate models to improve estimates of indirect and ecological chemical exposure.

b) Development and implementation of ecological models that utilize home ranges for terrestrial vertebrates.

c) Application of more accurate bioaccumulation models or factors for describing the wildlife foods that may be found in sludge/soil matrices.

d) Evaluation of the impact of using a higher threshold hazard quotient (*e.g.,* 10 rather than 1) for evaluating the potential risks posed by chemicals managed in surface impoundments to the plant community.

e) Development of defensible assumptions about piscivore diets (*i.e.,* what fraction of these surface impoundments really has a fish community dwelling in them that would support a population of piscivores?).

f) Evaluation of the impact of chemical exposure to ecological receptors through the air exposure pathway.

The Subcommittee supports the EPA's decision to employ the results from the Land Disposal Restriction (LDR) program and the consent decree to identify the 256 chemicals or groups of chemicals that were evaluated in the current surface impoundment study. In general, the use of existing and appropriate federal regulatory programs provides a defensible process through which chemicals of concern can be selected. Although the Subcommittee endorsed the process adopted by the EPA to generate the list of chemicals evaluated in this study, the human health risks posed by surface impoundments were evaluated using only those chemicals for which cancer potency values and non-cancer reference doses or concentrations were readily available. Chemicals or exposure routes without such health risk indices were excluded from the risk analyses. Similarly, the effects of biophysical and photoconversion of chemicals (*e.g.,* conversion of mercury to methylmercury) were not accounted for on the validity of the final risk results.

To fully describe the potential risks associated with chemicals managed within surface impoundments, the EPA is encouraged to evaluate and document the impact of excluding these chemicals on the final cancer and noncancer risk results. Furthermore, the Subcommittee recommends that the EPA develop, where possible, defensible approaches to generate surrogate health indices that could be applied to estimate the cancer and noncancer risks for all chemicals identified in the study as posing a potential risk when managed in surface impoundments. In the absence of evaluating the risks associated with all identified chemicals and their potential transformation products, there is limited assurance that the chemicals posing the greatest hazards were actually captured by the risk characterization study. Finally, because of the variability associated with human health response to chemical exposure, the Subcommittee recommends that the EPA consider characterizing the distribution of risk associated with surface impoundments to determine if these facilities represent a disproportional health concern for children and other high-risk groups.

3.1.3 Did EPA adequately characterize the risks? Are the risk analysis and findings transparent? That is, are they explicit in:

Describing the assessment approach, assumptions, extrapolations and use of models

Describing plausible alternative assumptions

Identifying data gaps

Distinguishing science from policy

Describing uncertainty

Describing the relative strength of the assessment

3.1.3.1 Describing the assessment approach, assumptions, extrapolations and use of models

In general, the multi-tiered approach adopted by the EPA for characterizing human health and ecological risks associated with chemicals managed in surface impoundments was well described and technically defensible. The Subcommittee endorses the EPA's use of a graded risk characterization approach to focus limited resources on those facilities that warrant a detailed quantitative risk evaluation from those that clearly negligible risk to human health and/or the environment. Moreover, EPA's decision to use peer-reviewed fate and transport models coupled with risk indicators to evaluate the behavior of chemicals released from surface impoundments (Tier II) was technically sound and fully supported by the Subcommittee. The EPA's application of both Tier I (risk screening) and Tier II (chemical release assessment) methodologies was effective in identifying the relatively small fraction of surface impoundments that represented a potential risk to human health.

Although there was unanimous support for the EPA's development and use of the multi-tiered approach, several Subcommittee members expressed reservations regarding the development, implementation and extrapolation of results from the Tier III (risk modeling) methodology in supporting Agency risk management decisions. During Tier III, the human health risks associated with those surface impoundments that were not eliminated as a result of applying the chemical release assessment (Tier II) methodology were evaluated using peer-reviewed risk assessment models coupled with site-specific parameter information. Potentially critical deficiencies of the risk modeling (Tier III) approach included the absence of:

a) clearly defined quality criteria established for each type of data element used in the models,

b) a technically defensible and transparent process for quantifying the impact of uncertainty (and variability) on final risk modeling results,

c) an evaluation of the potentially disproportionate risks posed by surface impoundments to vulnerable human receptor populations including infants, pregnant women, elderly *etc*.,

d) an assessment of the effects of chemical and/or biological transformations of compounds released from surface impoundments on the estimated human health risks, and

e) a quantitative evaluation of the effects of transient events (floods, earthquakes, *etc*.) on risk results. Beyond the technical concerns associated with Tier III (risk modeling) results, the Subcommittee noted that neither the risks associated with indirect human exposure to chemicals managed within surface impoundments nor the potential impact of these chemicals on ecological endpoints were evaluated beyond Tier I (risk screening).

Given the myriad of technical deficiencies associated with the Tier III (risk modeling) methodology as well as the potential time and level of resources needed to correct them, the Subcommittee recommends that the EPA consider the potential advantages of expanding the chemical release assessment methodology (Tier II) to address the specific legal questions posed in the regulatory statute and consent decree. By judiciously selecting and combining risk indicators that reflect those site-specific conditions that significantly impact human and ecological exposure to chemicals managed in surface impoundments, the EPA may develop technically defensible national profiles that describe the risks posed by these facilities. The Subcommittee suggests that EPA modify the chemical release assessment (Tier II) methodology to include a greater number of risk indicators because such change will not only provide a scientifically defensible process for the EPA to meet its legal mandate but may also reduce the need for the EPA to commit considerable resources to refine the risk modeling (Tier III) methodology.

3.1.3.2 Describing plausible alternative assumptions:

In general, the EPA clearly identified the assumptions used in the multi-tiered risk characterization methodology including those associated with the various chemical fate and transport models employed in the chemical release assessment (Tier II) and risk modeling (Tier

III) methodologies. Moreover, in most cases where alternative assumptions could have been adopted, the EPA provided sufficient technical justification to support their decisions as well as adequate documentation of the potential impact on the final risk results if competing assumptions were employed. Despite the general approval of the graded risk characterization approach, several Subcommittee members were concerned that the mathematical models used in Tier II and Tier III did not consider the impact of several potentially important chemical fate and transport mechanisms including biotransformation, chemical transformation, colloidal transport and fracture flow on the final risk results. The Subcommittee recommends that the EPA evaluate the consequences of not considering these potentially important fate and transport mechanisms on the scientific validity of the study conclusions.

Finally, the Subcommittee was uncomfortable with the technical approach developed by the EPA to characterize the human health risks associated with indirect exposure to chemicals managed within surface impoundments. The EPA's approach was inherently biased and had the potential to generate risk results that reflect a level of accuracy that was not only unwarranted but that, in some cases, could be misinterpreted and/or misapplied. The EPA's indirect human exposure risk analysis approach basically consisted of defining a set of exposure pathways each of which was associated with a specific release scenario. The exposure pathway/release scenario combinations were quantitatively described using arbitrarily defined facility-specific and environmental-setting risk criteria values. The risk criteria values were summed to rank each facility-impoundment combination after which facilities were placed in an appropriate "bin" reflecting the magnitude of their indirect exposure risk. Since alternative risk criteria values could have been assigned that would have resulted in significantly different final risk distributions, the Subcommittee encourages the EPA to eliminate the use of binning to portray the human health risks associated with indirect chemical exposure.

3.1.3.3 Identifying data gaps:

Throughout the surface impoundment risk characterization study, various sources of data were used to quantify the potential risks associated with chemicals managed in surface impoundments including survey data, sampling data, literature values, modeling results and professional judgment. The estimated risks were then compared to defined human cancer, noncancer and ecological benchmarks to establish national risk profiles for these types of facilities. As the risk analysis of surface impoundments progressed from risk screening (Tier I) to the more refined analytical procedures, the risk results increasingly depended on the use of more accurate, site-specific information. The EPA documented the sources of these data sufficiently and identified, where appropriate, the existence of data gaps when addressed that would significantly reduce the uncertainty in the final risk results.

The Subcommittee commends the EPA's description and application of peer reviewed fate and transport models, including the industrial waste air model (IWAIR) and the industrial waste exposure model (IWEM), in estimating the human health risks associated with the air inhalation and groundwater exposure pathways. Moreover, the dependency of these models on the output of various intermediate models was sufficiently described and documented. The Subcommittee supports the EPA's decision to assign standard EPA exposure factors to specific parameter values (*e.g.,* inhalation rate, body weight, exposure duration, *etc*.) for quantifying long-term chronic health risk from chemicals managed within surface impoundments. However, because specific environmental and facility management factors (*e.g*., contaminant concentration, level of aeration, pH, wind speed, temperature, *etc*.) can have a significant effect on contaminant emission rates, the Subcommittee encourages the EPA to quantitatively evaluate the sensitivity of intermediate model output values to changes in the value of input parameters. Furthermore, for those parameters that were evaluated probabilistically, the Subcommittee encourages EPA to provide explicit descriptions of:

a) the selection process used to identify those groundwater fate and transport parameters that were modeled probabilistically,

b) the methodology used to assign the shape of the probability distributions,

c) how functional dependencies of probabilistic input parameters were modeled and

d) the process employed for assigning the locations for probability distribution truncation.

Similarly, due to the importance of accurately defining groundwater flow direction in characterizing the risks associated with the groundwater exposure pathway, the Subcommittee encourages the EPA to provide a transparent and detailed description of the process used by experts to assign flow direction and to describe how the uncertainty associated with "professional judgment" was captured in the final risk modeling results.

Finally, based on its review of the EPA's discussion of the Tier I ecological risk screening results, the Subcommittee concluded that the EPA fully recognizes the existence of the numerous data gaps that preclude full characterization of either the types of chemical exposure that a particular species may confront or its anticipated biological response to the exposure. Moreover, since ecological risks were only evaluated using the Tier I (risk screening) methodology, the Subcommittee anticipates that EPA will identify additional data gaps when it evaluates ecological risks using the more refined chemical release assessment (Tier II) and risk modeling (Tier III) methodologies.

3.1.3.4 Distinguishing science from policy:

The Subcommittee commends EPA for its successful translation of the relevant policy questions posed in the regulatory statute and consent decree into specific human health and ecological endpoints against which the surface impoundment study results could be compared. In developing a scientifically defensible project scope, the EPA effectively utilized the USEPA Science Advisory Board (SAB) peer review process to refine the goal and objectives of the surface impoundment study so that the conclusions drawn from the final results would be technically sound and legally defensible.

Although the EPA provided a clear description of how the scientific goals of the surface impoundment study were supported by legal and policy requirements, several Subcommittee members were uncomfortable with the EPA's decision to employ a probabilistic model to evaluate the human health risks associated with the ingestion of contaminated groundwater while adopting deterministic models to evaluate the human health risks associated with the other contaminant exposure pathways including air inhalation, groundwater to surface water and indirect chemical exposure. The EPA's decision to employ fundamentally different approaches to evaluate the human health risks associated with alternative exposure pathways does not appear technically justifiable given the extensive use of probabilistic modeling in other regulatory programs (*e.g.*, Hazardous Air Pollutants Residual Risk Program – EPA-453/R-99-001). The Subcommittee understands that some additional model development and data collection would be needed to apply probabilistic modeling to all pathways.

3.1.3.5 Describing uncertainty:

The Subcommittee supports the EPA's decision to explicitly identify and qualitatively evaluate the major sources of uncertainty associated with the multi-tiered risk characterization methodology. Although a qualitative assessment of uncertainty is important to EPA decision-makers, quantifying the impact of uncertainty (and variability) on the final risk results provides the EPA with an invaluable tool for defensible risk management decision-making. Not only is a quantitative assessment of uncertainty and variability critical for developing a meaningful interpretation of the risk results but the process also enables the EPA to technically evaluate the need for conducting additional data collection and/or research. Because of its importance in supporting risk management decisions, the Subcommittee recommends that the EPA establish a formalized and transparent process to quantify the influence of uncertainty and variability on all final risk estimates.

With regard to direct-pathway human-heath risks, the Tier III description of uncertainty was unable to address several important uncertainties that are difficult to characterize quantitatively. These include those that arise from animal to human extrapolation and use of cancer potency measures obtained from studies conducted with exposures to adult animals and not earlier or later life stages. While this is justified given our current state of knowledge, it nonetheless indicates that the reliability of the uncertainty analysis is inherently limited. Other aspects of uncertainty, such as the influence of lack of cancer potency values for known and suspected carcinogens on the health risk characterization, can be quantitatively addressed and the Subcommittee recommends that EPA address them.

With regard to the Tier I ecological risk screening characterization, the Subcommittee concluded that the qualitative evaluation of uncertainty was sufficient to identify those risk factors for which additional information will be necessary to support future risk modeling efforts. Moreover, the EPA's decision to differentiate the sources of uncertainty into separate categories (including parameter uncertainty, modeling uncertainty and results uncertainty) was particularly useful in providing a scientific basis for targeting research needs. Although the EPA's description of the potential impact of uncertainty on ecological risk results was beneficial in terms of prioritizing future risk management research programs, the Subcommittee identified several technical assumptions associated with the ecological risk screening uncertainty analysis that were inconsistent with the conservative approach established for the risk screening methodology. For example, when compared to values obtained from national research studies, the wildlife food uptake factors employed by the EPA to describe the consumption of several inorganic chemicals were not always conservative estimates (Efroymson *et al.*, 2001). Similarly, the Subcommittee encourages EPA to provide additional scientific justification to support its assumption that a constant chemical concentration would tend to overpredict the potential risks of chemical exposure to wildlife. Finally, the Subcommittee recommends that the EPA address the issue of whether ecological toxicity due to the simultaneous exposure of multiple chemicals may lead to risks that are additive, less than additive or, in some cases, synergistic.

3.1.3.6 Describing the relative strength of the assessment:

The Subcommittee endorses the multi-tiered risk characterization methodology adopted by the EPA to meet the legal requirements specified under the regulatory statute and consent decree. The statistical sampling design used in the survey of surface impoundments supports the generation of defensible national human health risk estimates associated with the steady state direct exposure from chemicals managed in surface impoundments. Although a national profile reflecting the probable human health risks associated with direct chemical exposure was achieved through application of the risk characterization methodology, the incomplete characterization of site-specific uncertainty factors and transient events reduces the EPA's ability to draw defensible risk assessment conclusions for any particular surface impoundment. The Subcommittee encourages the EPA to consider addressing uncertainty by expanding its current use of risk indicators (Tier II) in developing a risk characterization framework that is less dependent on a probabilistic assessment of uncertainty.

The Subcommittee endorses the EPA's use of the risk screening methodology for identifying those surface impoundments that represent potentially significant indirect human health and ecological risks. However, to ensure that future risk management decisions are based on a complete and balanced characterization of potential risks, the Subcommittee recommends that the EPA develop and implement a quantitative assessment of the indirect human health and ecological risks associated with managing chemicals within surface impoundments.

3.1.4 Please provide the SAB's assessment of the accuracy of EPA's overall study conclusions regarding risk to human health and the environment. Were the conclusions either false-positive or false-negative (finding risks of greater or lesser magnitude than the risks that likely exist)?

In general, the Subcommittee supports the level of accuracy associated with the screening level (Tier I) risk characterization. The use of conservative assumptions minimized the elimination of surface impoundments that could potentially represent significant risks to human health and the environment. The Subcommittee supports the EPA's decision to adopt conservative assumptions within the risk characterization process that will overestimate the risk and thus provide greater protection to public health and the environment. However, in many instances, potentially important contaminant fate and transport pathways (*e.g.,* groundwater colloidal and fracture flow, exposure of groundwater contaminants through inhalation, release of contaminants due to impoundment overtopping or berm failures, *etc*.) were not addressed within the risk characterization methodology. The Subcommittee encourages the EPA to evaluate the uncertainty associated with final surface impoundment risk results when these specific pathways are neglected.

With respect to the contaminant release assessment (Tier II) and risk modeling (Tier III) methodologies, the absence of established data quality criteria and quantitative estimates of risk uncertainty limited the ability to effectively evaluate the accuracy of the final risk estimates. The Subcommittee recommends that the EPA provide greater transparency in its description of both the types and quality of data used to support the contaminant release assessment and risk modeling efforts.

The Subcommittee identified a number of inherent biases associated with the multi-tiered risk characterization framework that could have led to false-negative results. Technical decisions that may have systematically confounded the study results included the EPA's decision to characterize risks based on:

a) a limited chemical selection,

b) a limited human health and

c) an assignment of zero potency and hazard for specific chemicals and routes in the absence of readily available indicators, a lack of detailed consideration of transient events.

As an example of the potential impact of bias on risk characterization results, the Subcommittee noted that the EPA assumed that certain chemicals posed no cancer risk by any exposure route (*e.g*., cobalt compounds, glyceraldehydes, lead, 1,4-dioxane, styrene oxide, styrene, naphthalene, and numerous others) while certain other chemicals were assumed to pose no cancer risk when associated with a specific exposure route (*e.g.,* polycyclic aromatic hydrocarbons, dimethylbenzidine, dimethoxybenzidine, pentachloronitrobenzene, hexavalent chromium, 1,3-butadiene, *etc*.) even though sufficient research literature exists that suggests that other hypotheses are plausible. To provide assurance that the most significant risks posed by chemicals managed in surface impoundments were adequately characterized in this study, the EPA is encouraged to quantitatively evaluate the impact of omitting these chemical/exposure route scenarios on the final risk results.

Finally, with regard to the ecological risk screening characterization, the results of Tier I provided an accurate description of the range of potential ecological risks if all potential risks are included (see Section 3.3.3 for caveats about the use of the term, "potential risks," in the surface impoundment study.). However, as with most screening-level risk assessments, many of the potential risks were likely to be false-positive which explains, at least in part, the large fraction of facilities (*ca*. 92%) remaining at the conclusion of the ecological risk screening methodology.

3.2 Charge Question 2: Need to Consider Abnormal Operating Conditions

3.2.1 In light of the findings of the report, should EPA have performed a more in-depth evaluation of abnormal operating condition events? If so, what methods or approaches would the SAB recommend regarding collecting more reliable data, and modeling the probability and impacts of such events?

OSW's study (USEPA, 2001) does not explicitly define the term "abnormal operating conditions". The Subcommittee defines this term as operating conditions involving changes in wastewater characteristics, severe weather or structural failure of one or more critical components of the surface impoundment. Abnormal operating conditions can influence concentrations of contaminants in the impoundment and hence, impact upon the rates at which contaminants migrate from the impoundment into the ambient environment. These conditions can also result in partial or total release of impoundment contents, with associated human health and ecological impacts.

In responding to this charge question, the Subcommittee addressed: completeness of the list of abnormal operating scenarios used by EPA for risk assessment; the effects of not considering relevant factors and scenarios on computed risk estimates; and the approach(es) that EPA may adopt to incorporate the factors and scenarios that are not presently considered.

A surface impoundment usually consists of a zone comprising the bulk of the volume of the containment, a sludge zone of minimal volume, and contaminated liner or soil at the base. This existence of the zones may also be a factor in the release potential of contaminants under abnormal operating conditions of sufficient intensity, which can affect the processes and flow of contaminants out of one or more of the zones.

For estimating both ecological and human health risks, the EPA either used monitored data to determine contaminant source terms or estimated them using models and judgment. With regard to the monitored data, it may be necessary for EPA to determine how abnormal operating conditions may have affected the data, but the Subcommittee does not feel that EPA needs to modify the data because the effects of these conditions are already reflected in the data. With regard to the estimated source terms, it is important that the impacts of abnormal operating conditions be analyzed and incorporated into the estimates of risk. This is the focus of the recommendations presented here in response to charge question #2.

It is challenging to develop and integrate probabilistic analysis of the potential impacts of transient events into an analysis designed to produce a risk result. This might have discouraged EPA from covering transient events in the risk assessments. Nevertheless, in the long term, EPA needs to undertake rational analyses of transient events and include them into the risk assessments.

In the meantime, EPA could still assess the history and prospects of significant impacts of abnormal operational conditions on releases and emissions from impoundments. The data already developed in Tier II of the EPA Study provide a basis for assessing the current and potential impacts of transient events on human health and the environment in various regions of the United States. Such an analysis would rely on the impoundment location and monitored data, augmented with additional data from studies of other types of impoundments, such as those in the mining and agricultural sectors. First, impoundment performance information would provide the basis to assess the pattern of failures. Then statistical analyses could elucidate whether impoundments with similar locational, design and operational characteristics do pose and/or could pose significant risks to public health and the environment. The Subcommittee suggests this type of analysis would provide an adequate national level risk assessment.

If and when appropriate and sufficient amounts of data become available for probabilistic model analyses, such analyses would provide a better understanding of the risks associated with abnormal operating conditions. Until then, the results of the study's Tier III assessments should be de-emphasized in drawing conclusions about risks because they do not include the risk associated with the abnormal operating conditions. However, the results of Tier III analyses where necessary and appropriate should be used to support conclusions that are primarily based on Tier II analyses.

The following sections provide more detailed assessments on the extent to which EPA addressed transient events in its risk analyses. The Subcommittee also recommends ways to address transient events in risk assessments when/if the context and intended purpose of the relevant program warrants more detailed quantitative risk assessments.

3.2.1.1 Types of Abnormal Operating Conditions and the Necessity to Address Them.

For the design categories, locations and management systems of the impoundments described in this study, the Subcommittee has determined that the abnormal operating conditions described below should be considered in the analysis of risks associated with the performance of impoundments.

3.2.1.1.1 Changes in wastewater characteristics.

Wastewater that enters an impoundment may undergo major changes in characteristics due to accidental spills or changes in production practices. Possible manifestations of these changes are changes in pH (that could still be within the acceptable range for non-hazardous wastes), and release of chelating agents or fine particulates. Metals can be solubilized as a result of pH changes, with a consequent decrease in their breakthrough times as they travel through the liner of an impoundment. Direct chemical attack of liner materials under aggressive pH conditions is also a possibility. The release of chelating agents can also lead to an increase in the concentration of metals in the effluent and possibly, increased breakthrough of metals through the liner. Fine particulates settle very slowly in aqueous media and can mobilize contaminants through adsorption and/or ion exchange mechanisms into the effluent. These phenomena are not addressed in the modeling effort described in the report (USEPA, 2001), but the risks associated with these phenomena should be accounted for and appropriate safety factors incorporated in the predictive methodologies, if necessary.

3.2.1.1.2 Storm events

The OSW report (USEPA, 2001) stated that most surface impoundments receive stormwater, and that about 25% of all facilities have experienced overtopping events. Increased flow of water into an impoundment due to a storm event can, in addition to causing the release of poorly managed wastewater, scour the sludge zone of the impoundment and discharge elevated concentrations of contaminants from the sludge zone. High storm loadings can also result in partial or total release of impoundment contents. For example, an intense storm can wash out previously settled contaminants from the sludge zone. The Subcommittee recommends that watershed modeling approaches that incorporate high-impact storms of appropriate return periods be integrated into the methodology to address risks associated with stormwater influx into impoundments. EPA should also collect empirical information from the regions on surface impoundment failures during the past 10-20 years. Some case-histories may be available on impoundment failures due to storms in the Central and Western regions for the mining industry and in the Southeast region for the agricultural industry. Such information may be useful for calibrating facility failure and contaminant transport models.

3.2.1.1.3 Structural failure due to seismic events

Seismic events such as earthquakes can threaten the structural integrity of impoundments. A confining berm or dyke could fail due to ground shaking in earthquake-prone regions. Such failures would cause an immediate release of contaminants into the subsurface or over land. The Subcommittee has noticed the absence of seismic considerations in Table 4.4. An assessment of the design and geographic distribution of impoundments vis-à-vis earthquake zones is necessary to establish the risk of catastrophic failures within the timeframes of concern. This is particularly important because the period of coverage of the risk analysis is as long as 10,000 years.

3.2.1.2 Adequacy of the Methodology used to Analyze Risks Posed by Surface Impoundments

Except for not addressing abnormal operating conditions, EPA has done an excellent job of linking numerous factors to estimate both human health and ecological risks posed by surface impoundments. The Subcommittee particularly notes that EPA gathered, disaggregated and analyzed data on several impoundment characteristics to establish how impoundments have performed during and after their service lives.

However, adequate data may not be available for detailed quantitative assessments of all relevant scenarios using EPA's approach. Other informative analyses are possible that do not focus on developing an exclusively quantitative risk profile. Therefore, the Subcommittee suggests that EPA adopt a more empirical analysis of data and develop conclusions on national risk profiles based mostly on the Tier I and II analyses.

Abnormal operating conditions influence the magnitudes of the contaminant source concentration terms. Source term concentration estimates need to be reasonably accurate because they are input data to models used for contaminant migration and risk assessment. Indeed EPA acknowledges the criticality of source terms by stating (USEPA, 2001, page C-13), "one of the most sensitive parameters in risk modeling is the source concentration term. Frequently, this term is associated with a high level of uncertainty because (1) the data on concentration may not be sufficient to characterize the variability due to changing waste streams, impoundment conditions, and other characteristics; and (2) the analytical methods may be insufficient to quantify the concentration term ". In the second paragraph of Appendix page C-93 of the report (USEPA, 2001), EPA further states that " the release of contaminants into the subsurface constitutes the source term for the groundwater fate and transport model. Because the modeled subsurface fate and transport processes are the same for each waste management scenario, the conceptual differences between different waste management scenarios are reflected solely in how the model source term is characterized."

The Subcommittee agrees with EPA on the importance of source term characterization. Therefore, the Subcommittee suggests it would be useful for EPA to assess and report on how the selected risk assessment framework covers the effects of abnormal operating conditions on contaminant source terms and hence risk estimates. Such factors should be considered in drawing conclusions about risks in cases that warrant conventional risk assessments.

Except for the case of changes in wastewater characteristics, the Subcommittee does not advocate a generic modification of contaminant concentration source terms to accommodate the impacts of transient events in the risk assessments. Instead, the analysis should be done on a region-by-region basis because specific regions of the United States have transient events of significant magnitudes at elevated frequencies. As examples, earthquakes are prevalent in the West Coast and Central USA, while storms/floods are more frequent in the Southeast and Midwest. These high hazard zones overlap areas with high concentrations of impoundments. on the following page, Figure 1 (designated as Figure 2-2 on page 2.4 of OSW's report) shows that there are 1035 impoundments in the West Coast, 434 in Alaska and 601 in Hawaii where seismic events are relatively frequent; and 4103 impoundments in the Southeast where annual precipitation and storm frequencies are relatively high.

EPA used EPACMTP model to perform contaminant fate and transport analysis for risk modeling; the model is reasonably adequate provided input data are appropriate. The mathematical architecture of this model was previously reviewed by the SAB. The model is appropriate for use in performing fate and transport analyses but not for generating a contaminant release source term from multi-component constructed facilities like surface impoundments. The
Subcommittee notes that contaminant source term concentrations need to be determined either through the use of monitoring data or predictions of contaminant release rates/events using containment system failure/liner permeation models, for input into the risk models. As indicated by EPA in Figure 2 (designated as Figure 3.1 on page 3.3 of OSW's report[3]), the release scenarios
that are considered to impact upon source terms are volatilization / dispersion, leaching and erosion/run off. Analyses are likely to show that for some impoundments located in the regions mentioned in the preceding paragraph, this suite of release scenarios is incomplete. Furthermore, EPACMTP does not model the impacts of transient events and this should be stated under “model simplifications” on page 3-18 of the report (USEPA, 2001).

Page 3-18 of the report (USEPA, 2001) states that “the risk to receptors for the groundwater pathway was evaluated over a time period of 10,000 years”. This timeframe is long enough for the occurrence of very high–impact storms and seismic events at least in the active regions identified. Furthermore, most components of surface impoundments would have deteriorated to ineffective levels of performance within 200 years unless they are maintained or re-built. This does not imply that the service life of impoundments is 200 years. The actual service life depends on facility design, facility location, operational conditions including the impact of transient events, and the types of wastes impounded. Although contaminant arrival at reception locations can trail releases from facilities by several decades, it is necessary to conduct a general assessment of the need to account for the presence of liners in scenarios where long exposure time frames are considered.

[3] One of the SAB Executive Committee Members suggested to make the following changes on the figure:

1. Change the title to "Conceptual model of the potential relationships between chemical stressors from active surface impoundments and human and ecological receptors."
2. Switch "Plants" and "Animals" boxes, add a dotted arrow that connects between the arrow (between "Airborne Vapors" and ""Soil") and "Animals" pointing toward "Animals," do the same for "Plants," add a dotted arrow between "Aquatic Organism" and "Animals" pointing toward "Animals," and add a dotted arrow between "Animals" and "Plants" pointing toward "Animals."

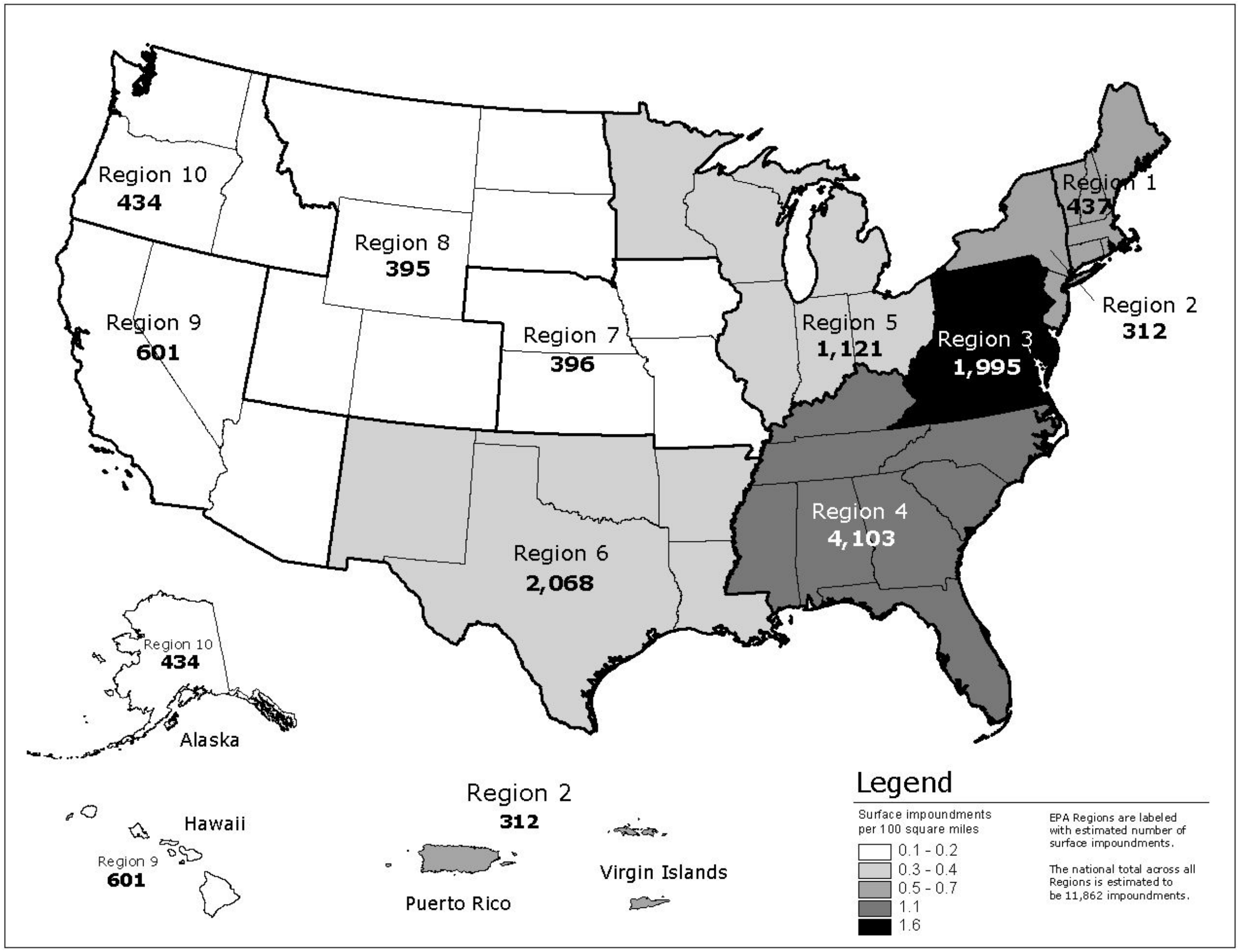

Figure 1. Regional distribution of surface impoundments.

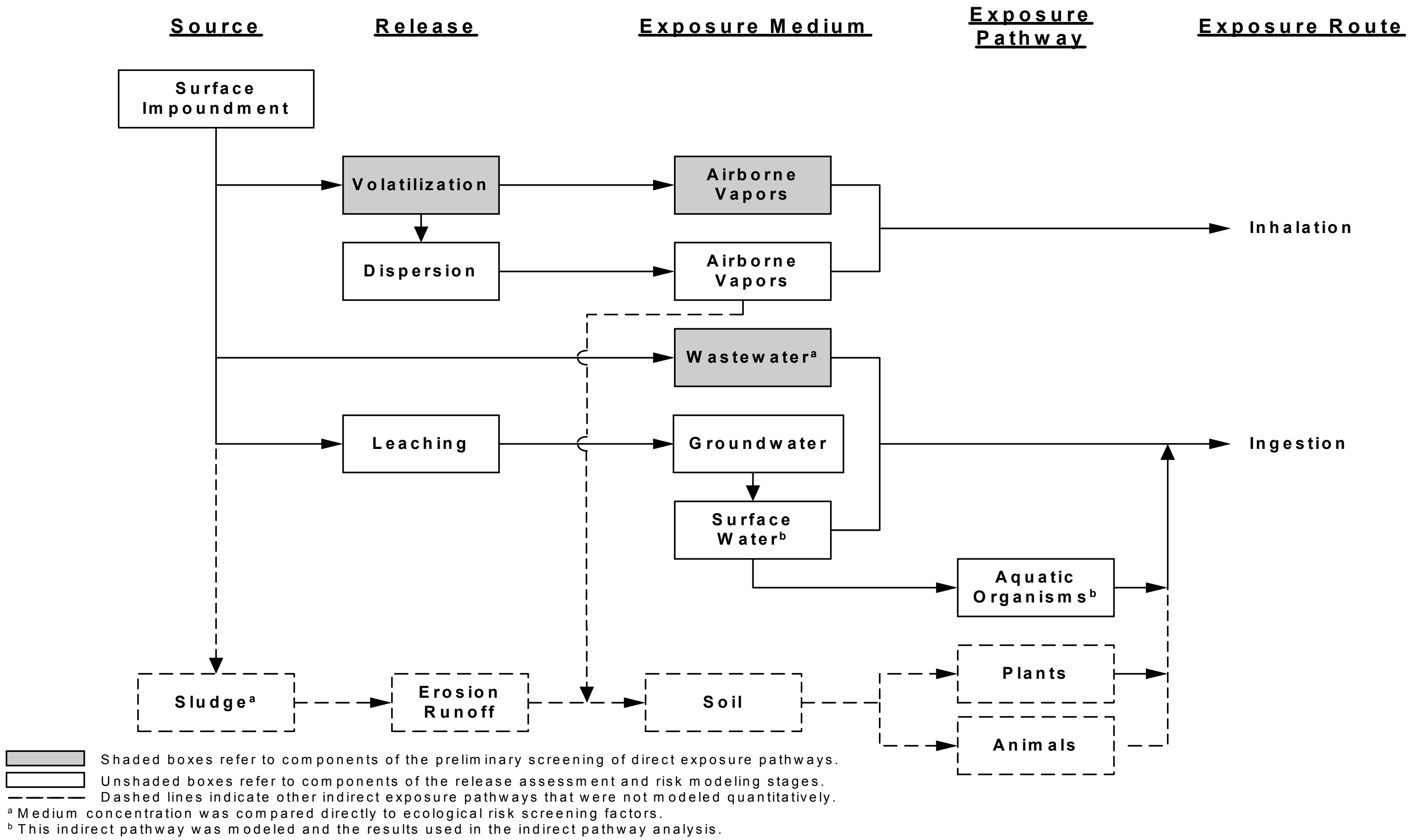

Figure 2. Exposure pathways for active surface impoundments considered for human and ecological receptors.

3.2.1.3 Data Needs for More Adequate Treatment of Abnormal Operating Conditions

EPA has collected a significant amount of valuable data on surface impoundments. On the assessments that it has conducted regarding the performance of impoundments, it has done a reasonably thorough job. To perform additional assessments, EPA should conduct additional analyses using the existing data with additional regional data, most of which can be collected from public agencies. For example, impoundment overtopping failures due to storms are known to have occurred in the Southeast region. Relevant information from that region may help in establishing the pattern of failures.

EPA has already collected facility design and contents data. It has also supplemented these data with synthetic data estimated using empirical information developed by several researchers. In the bottom paragraph of page 1-1 of the report (USEPA, 2001), EPA acknowledges that it performed a comprehensive census of agricultural, mining, industrial and municipal surface impoundments in the late 1970s and the early 1980s, including characterization of about 30,000 impoundments with respect to their geographic distribution, sizes, functions and potential for groundwater contamination. Unfortunately, EPA notes that these data were not used to support the analysis presented in the report (USEPA, 2001) because they were not available. The information to which reference is made above may be useful in determining the pattern of impoundment performance, especially if a significant number of the impoundments characterized are located in high hazard zones.

Hazard zonation information is needed. For a significant number of impoundments, EPA already has the information needed to address possible changes in wastewater characteristics. Where site-specific data are needed, EPA can use ranges of synthetic data drawn from the realm of experience in the magnitudes of transient events that have occurred/or are likely to occur in the region as well as the predominant geotechnical characteristics of sites in the region. In the case of overtopping due to storms, there may be useful information in the regions, especially in the Southeast region. Incidentally, EPA has collected and used relevant data in the report (USEPA, 2001) for a different purpose. In Section A.3.1.3 of page A-28 of the report (USEPA, 2001), EPA acknowledges that it used GIS to screen information on sites for the purpose of performing ecological risk modeling. The spatial relationships between each impoundment site and the following factors were considered: managed areas, landuse categories, permanently flooded woodlands, Bailey's ecoregions, fishable water bodies, soils and groundwater geology. Among the resources used for information were regional geologic maps, state soil survey maps and watershed maps. These data and resources need to be used again to analyze the potential impacts of storms/floods and seismic activities on contaminant source terms. Ground acceleration (seismic) maps of high seismic hazard zones are obtainable from the U.S. Geological Survey while flood frequency maps are available at the Federal Emergency Management Agency.

For detailed probabilistic treatment of the impact of transient events on risks posed by surface impoundments (which is not necessary to draw the conclusions sought in this study), event frequency maps alone are not adequate for use in predicting impoundment failures due to transient events. Such frequency maps are generally used to address geohazards risks that define the magnitudes and associated return periods of stressing events. The spectra of expected stresses within the period of consideration would then be used to analyze the reliability of the most common designs and expected (probable) releases. EPA needs to clarify how this analysis would be done for the operational service life of impoundments and for the balance of time within the 10,000-year period of concern. This type of analysis feeds into the exposure assessment and is quite commonly done in dam safety assessments. The focus of this category of analyses would be on specific designs of impoundments as required by Tier III risk assessment. Relevant methodologies can be included in a technical guidance or resource document. It is not necessary to implement such detailed quantitative assessments of a very small percentage of impoundments (with high uncertainties) as a basis for drawing conclusions on natural risk profiles.

3.2.1.4 Recommendations on Approaches to Incorporating Assessments of Abnormal Operating Conditions

As indicated in the introductory part of Section 3.2, EPA should analyze data at the Tier II level and collect more data, some from other regulatory programs that involve impoundments. EPA should base its conclusions on risks posed by abnormal operating conditions mostly on such data and their analyses.

The Tier III analyses may be used to provide technical guidance as well as groundtruthing of the Tier II results. A useful approach to incorporating the effects of transient events and changes in wastewater characteristics on risks posed by surface impoundments is the estimation of likely changes in the magnitude of the contaminant concentration source term. If the impoundment fails catastrophically in the high hazard zone or becomes ineffective due to aggressive wastewater characteristics, there should be an increase in contaminant source term concentrations for the relevant pathways.

For the Tier III analyses involving conventional quantitative risk assessment, the challenge for EPA is the development of a scheme for estimating the magnitude and rate of increases in source terms in response to these abnormal operating conditions. Some suggestions on the approaches that EPA may adopt to address the impacts of abnormal operating conditions on source terms are presented below for the Tier III assessment.

3.2.1.4.1 The Factor of Safety Approach

EPA may elect to apply empirical safety factors to source term concentrations in scenarios and zones of abnormal operating conditions; these are similar to the traditional approach used in structural design. Such factors, which would have the net effect of increasing the source term, should be directly proportional to the most probable intensity or magnitude of the event or phenomena within the timeframes and locations of interest. If available, historical data can be used to support the indexing system.

3.2.1.4.2 The Zero Containment Assumption

Under abnormal operating conditions that are of high intensity or frequency, EPA may assume that the containment system will not exist after certain specified service timeframes. For the groundwater transport pathway, this is tantamount to the assumption that the contaminant source term at locations immediately around the impoundment are the same as the concentrations of the target contaminants within the impoundment. This should be considered to be a conservative assumption.

3.2.1.4.3 Impoundment Degradation and Contaminant Release Modeling

This approach involves a more systemic analysis of the response of impoundment components to various levels of stress imposed by transient events or contaminant release/chemical attack by impoundment contents. Essentially, the analysis establishes a quantitative relationship between the degradation of major impoundment components and the magnitude of a transient event over time. With increase in the permeability or hole size/density of the impoundment liner following a transient event, contaminant release rates would be high. Appropriate models can then be used to estimate the growth in the source term in response to the slow or abrupt increase in contaminant release volume. Probabilistic analyses of potential damages cannot be avoided if this approach is adopted. Relevant issues have been described by Bass *et al.* (1985), Iman *et al.* (1990), Inyang and Tumay (1995), Inyang (1994), Peterson (1990) and Inyang *et al.* (1995)

3.3 Charge Question 3: Validity of Screening-Level Risk Characterizations

A screening-level risk assessment is generally intended to determine the scope of a definitive or higher-tier risk assessment by eliminating from further consideration of chemicals, receptors, and/or facilities that are clearly not associated with a potential risk. EPA presented results from two screening-level analyses to determine the potential for risk to human health from indirect pathways and to determine the potential for ecological risk from all pathways considered. Indirect pathways for human exposure and ecological exposure were not considered in a more definitive risk assessment.

To investigate the risk of potential indirect exposures to human receptors through pathways such as ingestion of crops, dairy products and fish that might be contaminated through runoff from closed impoundments, or air dispersion onto nearby farmlands, EPA conducted a screening level risk characterization. In contrast to a conventional risk assessment, this analysis consisted of categorizing and ranking exposure factors of potential concern for each facility in order to identify facilities where indirect pathways may be of potential concern.

In the first stage of the indirect screening, EPA reviewed the constituents reported in the surveys to identify a short list of bioaccumulative constituents for indirect exposure. The second stage of the screening analysis was to identify all facilities that reported managing these constituents and to screen these facilities according to their potential for indirect exposures. The criteria considered included size of the surface impoundment, distance from the impoundment to the nearest receptor, slope of the terrain in the vicinity of the site, and size of nearby water bodies. The rankings assigned to these facilities were based exclusively on an assessment of current site-conditions, including both impoundment status and environmental setting criteria in the vicinity of the facilities. A future closure scenario was also included in the analysis to address potential risks following impoundment closure.

Once the screening had been completed to identify facilities where indirect pathways were of potential concern, EPA generated national estimates of the proportion of facilities that could pose concerns due to indirect pathway exposures. The measures used were as follows:

a) *Potential Concern*. This risk metric is an indicator of the potential for completion of more than one indirect exposure pathway at the facility.

b) *Lower Concern*. This risk metric is an indicator of the potential for completion of one indirect exposure pathway at the facility and, therefore, of relatively lower concern.

c) *Least Concern*. This risk metric is an indicator of low potential to complete even one indirect exposure pathway at the facility.

Six percent of facilities fell into the potential concern category for indirect exposure. EPA found that the qualitative character of the indirect exposure pathway analysis led to several major areas of uncertainty that affected their interpretation of the results. EPA concluded this degree of uncertainty was acceptable for a first-pass assessment as to whether individual facilities have the potential for indirect exposure pathway risk. They found that the use of the screening methodology precludes drawing any conclusions regarding the potential magnitude of risk that these facilities could pose either now or in the future.

EPA conducted a screening-level risk characterization of potential ecological concerns. This assessment identified facilities where there could be ecological concerns provided there were direct contact and/or ingestion of surface impoundment contents by various ecological receptors, using conservative screening assumptions. Some aquatic and terrestrial organisms may dwell in or very near surface impoundments.

The ecological risk screening was similar to the first screening stage of the human health risk analysis, but did not go beyond that stage to consider actual exposures, and did not rely on fate and transport modeling. The assessment strategy was intended to represent only the potential for adverse ecological effects, not the actual risk posed to ecological receptors.

Potential risk was assessed for numerous birds, mammals, and amphibians as well as for soil, aquatic, and sediment communities (*e.g.*, earthworms, fish, and insect larvae). Aquatic and terrestrial plants were also assessed. EPA assigned receptors to each facility based on regional data sources and land use characteristics at each facility. The assessment compared chemical concentrations in surface impoundment water and sludge to concentrations that are considered protective. An additional element of the ecological screening analysis considered whether surface impoundments are located near sensitive ecosystems such as wetlands, wildlife refuges, or national forests.

In the final stage of the screening-level assessment EPA compared the number of each facility's risk exceedances to the median number of exceedances for all the facilities that did not screen out. Using this standard, facilities that exceeded screening levels were placed in two categories:

a) *Potential concern*. Facilities having at least the median number of exceedance for ecological receptors (*i.e.*, 38 or more exceedances).

b) *Lower concern*: Facilities having fewer than the median number of exceedances for ecological receptors.

In addition, a *least concern* category indicated risk below the screening threshold.

EPA found that a total of 34 chemicals exceeded the risk criteria for at least one receptor at one impoundment, and 54 of the more than 62 ecological receptors considered showed potential risk exceedances. These receptor taxa include mammals, birds, and plants, as well as soil, aquatic, and sediment communities. Ninety-two percent of facilities exceeded risk thresholds for at least one receptor at one impoundment. EPA found that the screening nature of the analysis led to several major areas of uncertainty that affect interpretation of the results.

3.3.1 For the indirect human health and ecological screening-level analyses do the results point to areas of potential future research? If so, do you have recommendations on prioritizing future studies in these areas?

Areas of potential future research are described in Sect. 3.7. These include research related to the indirect human health and ecological pathways, as well as other areas of uncertainty in the Surface Impoundments Study.

3.3.2 Based on the screening-level estimates EPA developed for other indirect and ecological risks, did it appear that EPA overlooked potential problem areas?

In general, potential indirect pathways were not overlooked. However, a more comprehensive indirect pathway risk assessment would assess effects of transient events, such as overtopping events or liner failures; indoor routes of exposure, such as volatile chemicals in home shower water or dishwashers; land application of industrial sludges; and potential use of contaminated water to irrigate crops. Similarly, in evaluating the screening-level estimates for indirect risks, an exploration of the impact of chemical selection and presumptions of hazard and potency for certain chemicals is needed.

The Subcommittee is uncomfortable with the approach used to categorize facilities where indirect pathways are a potential concern. The use of simple ranking categories to produce three equal-sized bins for some pathways may underestimate (or overestimate) the actual risk. (For example a designation of level 1 for Surface Area may still pose significant risk.) Therefore, the final ranking heading "Potential Concern" suggests more certainty than warranted. (See further discussion of terminology in Sect. 3.3 of this report).

In general, potential problem areas related to ecological risk assessment were not overlooked. It would be useful to have more justification for the presumed negligible exposure of ecological receptors to air pollutants. If a more refined ecological risk assessment is performed, some consideration of the acute and chronic exposure implications of events, such as overtopping, flooding, dike failure, and liner failure, would be helpful.

EPA states that it overlooked threatened and endangered species (p. C-160) of the report (USEPA, 2001), but that is not really true. Given the conservative character of the screening ecological risk assessment, it should apply equally to most threatened and endangered and non-threatened individuals, unless there is reason to believe that these organisms are more sensitive than others. The only exception may be the amphibian and reptile populations for which reproductive data were not available.

In general, the terminology related to potential levels of risk was confusing, such that potential risks may have been overlooked in the conclusions of the study. In Sect. 3.3. of this report, the Subcommittee recommends a more objective approach to terminology related to potential risk.

3.3.3 Did EPA clearly describe and properly characterize the other indirect human health and ecological risk analyses?

Potential risks were appropriately analyzed in the screening-level analyses. For example, the suite of assessment endpoints and the criteria for their selection (USEPA, 2001, p. C-160) were a strength of the assessment. The assessment clearly identified the pathways that were not considered in the ecological risk assessment (dermal and inhalation), explained that risks to populations were inferred from risks to individuals, and described how risks to plant and invertebrate communities were inferred. However, results were not always presented clearly.

Several points of clarification would be helpful.

a) The biotransformation of mercury to methyl mercury, as well as other biophysical and photochemical transformations were not explicitly addressed in the risk assessment. This should be stated in the text.

b) Only chemicals that bioaccumulate were considered for the indirect exposure pathway. The report should describe how the bioaccumulation potential of a chemical compound was determined (USEPA, 2001, p. C-135).

c) Volatilization was considered only for the chemicals that "have the potential to volatilize." The report should state how this potential was determined

d) Cut-off points for volatilization (< 250 m, 250-500 m, >500 m) and particulate entrainment (>300m, 150-300 m, <150 m) were based on "significant changes" in the modeling results reviewed (USEPA, 2001, p. C-142). This threshold needs better definition.

e) The statement on p. 3-41 of the report (USEPA, 2001) "The ecological screening assessment is precautionary because it is based on direct ingestion or uptake of the surface impoundment influent" is somewhat misleading. A similar statement is made on p. C-162 of the report (USEPA, 2001). The risk assessment for vertebrates is based on dietary uptake of foods that have accumulated chemicals from the surface impoundments, and direct ingestion of sludge/soil and water from the surface impoundments. For plants and soil invertebrates, the risk assessment is based on direct contact with the sludge/soil. This information should be stated.

In general, the methodology for the ecological risk analysis was presented well, but results could be clearer, and the definition of terms could be improved in some cases. The use of the terms "potential concern" and "lower concern" is not easily understood. Although the terms are defined for the ecological risk assessment on p. 3-42 of the report (USEPA, 2001) and for the "other indirect pathways" assessment on p. 3-36 of the report (USEPA, 2001), their definitions are not intuitive or literal. All facilities with ecological risk exceedances are, in reality, of "potential concern." Similarly, all facilities with potential for completion of at least one indirect exposure pathway are of "potential concern," in contrast to the definition on p. 3-36 of the report (USEPA, 2001).

To help clarify the analysis, the Subcommittee recommends that the conclusions of the screening-level risk assessments be presented in one of two formats. One distinction would be between the percentage of facilities with "potential risk" and those with "risk below threshold of concern." If EPA desires to categorize further facilities presenting potential risk, the Subcommittee recommend that this be done in a literal manner (*e.g.*, "potential risk from 2 or more pathways") rather than using subjective adverb descriptors that appear to quantify risk more than the results allow.

The conclusion that "those constituents and impoundments do not pose significant risks to . . . the environment" (USEPA, 2001,Sect. 3.6, 2nd para) is not supported by the screening-level ecological risk assessment. Similarly, the conclusion that "Based only on this initial screening level analysis and using precautionary assumptions, no more than 29 percent of facilities nationally may pose potential concerns to ecological receptors that live near, or make direct use of, surface impoundments" (USEPA, 2001, top of p. 3-49) is not supported by the risk assessment if the reader uses the literal definition of "potential." In fact, those statements conflict with the statement on p. C-47 of the report (USEPA, 2001) that "the majority of facilities have some potential for adverse ecological effects." Facilities with less than 38 receptor exceedances across facilities still have potential for risk, according to this assessment. EPA will be able to clarify these points using the altered terminology related to potential risks recommended above.

One point that is not made very clearly is that almost all facilities (92%, Table 3-24 of the EPA's report) pass through the screening-level risk assessment (which is not consistent with the statement that "29 percent of facilities may have localized ecological impact during their operation or after closure," p. ES-6 of the EPA's report). Only 8% of facilities are eliminated from concern in the screening assessment. This makes the reader think that either 1) surface impoundments have a high potential for ecological risk or 2) exposure or effects assumptions were too conservative to be useful. The fact that the vast majority of surface impoundments pose potential ecological risk should be stated more clearly in the executive summary, perhaps with caveats that a definitive, quantitative assessment has not been performed.

Terms such as "facility risk," "surface impoundment risk" and "constituent risk," that are defined on p. C-177 of the report (USEPA, 2001) are not clear. For example, the Subcommittee believe that facility risk consists of the sum of hazard quotients of multiple chemicals across one receptor at one facility, but the role of chemical constituents in the definition is not discussed.

3.3.4 Summary

In summary, the methodologies for the screening-level risk characterizations were, for the most part, clearly presented. However, the Subcommittee recommends that EPA:

a) reevaluate the use of binning for ranking facilities that may represent a significant indirect exposure risk,

b) better define the technical terms used to differentiate risk levels above and below thresholds,

c) better characterize ecological exposure in the screening analysis or in a more detailed risk assessment, and

d) better characterize and ultimately reduce uncertainty in exposure (*e.g.*, chemical transformation) and effects through additional secondary data-gathering and research.

3.4 Charge Question 4: Use and Interpretation of Survey Data

3.4.1 Please comment on the appropriateness of the application of the EPA's data processing and analysis protocols for ensuring consistency in interpreting survey data on a specific constituent's presence in an impoundment, or that constituent's quantity.

EPA used data processing and analysis protocols to ensure consistency in interpreting survey data on a specific constituent's presence or quantity in an impoundment. Sections A.4.2.1 and A.4.2.2 in Appendix A to the report (USEPA, 2001) describe the various processes and protocols employed to interpret non-detect data reported with a detection limit, non-detect data reported without a detection limit, present but quantity unknown (PQU) data and missing sludge data.

Regarding the appropriateness of EPA's data processing and analytical analysis protocols and presentation techniques as they apply to the use of surrogate data, the Subcommittee found:

a) EPA designed a structured data process and structured protocols for dealing with surrogate data that consists of detection limit look-up tables, a decision tree for imputing non-reported quantities and an algorithm for calculating sludge concentrations. As described, this structured approach combined with the quality assurance step of double data-entry are appropriate for the incomplete survey data and will ensure that similar data gaps will be addressed in a consistent manner.

b) The consistency of outputs from these data processes and protocols and how EPA interprets survey information to generate the resulting surrogate datum can vary from contaminant to contaminant. For example, the detection limit look-up table for one contaminant lists a method detection limit while a quantitation limit is listed for another contaminant. Furthermore, the outputs from the data processes and protocols vary according to the proximity of a similar impoundment that has reported data. That is the surrogate concentration may be taken from a similar functioning impoundment at the same facility or a different facility with the same 2 digit industry group. For additional comments, please refer to the following specific Charge Question Sections 3.4.4 and 3.4.7.

3.4.2 Please comment on the appropriateness of the application of EPA's analysis methods and presentation techniques to distinguish and explain the various degrees of certainty in the findings.

The report (USEPA, 2001) clearly recognizes and discusses the reality of uncertainty when undertaking a nationwide study and when inferring from a limited database consisting of data of varying quality and completeness. EPA also used analysis methods and presentation techniques to help distinguish and explain the various degrees of uncertainty in the findings.

Regarding the appropriateness of the analysis methods and presentation techniques for uncertainty as they apply to the use of surrogate data, the Subcommittee found:

a) That the discussions of uncertainty are qualitative and lacking quantitative criteria and ranges of potential uncertainty. Qualitative statements are made about the quality of the modeling results as a function of the quality of the concentration data reported in the survey. For example, page 3-5 of the report (USEPA, 2001) states that, "EPA is most confident in those (concentration) data where respondents reported a value above a limit of detection and far less confident in other values, such as values less than detection limits." If concentrations were reported in the survey, then "... EPA considers these data to have a reasonable degree of certainty" (quote from page 3-6 of the report (USEPA, 2001)). These types of statements are necessary but not sufficient to describe and explain the various degrees of certainty.

b) Determining the sensitivity of risk estimates to concentration data would assist in evaluating the impact of surrogate data: The sensitivity of risk estimates to various assumed uncertainties in concentration data could be obtained using Monte Carlo simulations. The uncertainty in the concentration data would need to be characterized as carefully selected and realistic probability distributions that are used as input to the simulations. The results of the sensitivity analyses should indicate whether additional work is needed to reduce the uncertainty of survey concentration data in order to achieve suitably certain risk estimates. However, all these analyses could be performed only if a reference level of uncertainty of the risk estimates were established as a point of comparison; this was not done for this study.

3.4.3 Please comment on the degree of clarity of the risk results presentation, in the situations when surrogate data and detection limit data are employed.

The report (USEPA, 2001) gives risk results for two cases: 1) when the direct pathway releases and risks are estimated using contaminant concentration values reported in survey forms, and 2) when those release and risk estimates are based on surrogate and detection limit data. This distinction is made repeatedly within the report's executive summary, the body of the report, tables and appendices.

Regarding the clarity of the report (USEPA, 2001) in presenting risk results, when surrogate data and detection limit data were employed, the Subcommittee found:

a) For air, groundwater and surface water pathways the report (USEPA, 2001) consistently discriminates between the releases and risks estimated using contaminant concentration values reported in survey forms and those release and risk estimates based on surrogate and detection limit data. Release and risk results are presented separately for surrogate/detection limit waste concentrations. Conducting separate screening risk assessments for reported data and for surrogate/detection limit data is laudable.

b) The method used to obtain release and risk results when surrogate data and detection limit data were employed was clearly explained.

c) The clarity of the discrimination between reported and surrogate/detection limit data suffers from mislabeling of tables in the report (USEPA, 2001) (*e.g.*, Tables C.1-16 and C.1-17). The related text refers to "groundwater pathway", Table C.1-16 refers to "Groundwater to Surface Water pathway" and Table C.1.17 refers to "Surface Water Pathway".

d) For ecological risks, the report (USEPA, 2001) does <u>not</u> but should discriminate between the levels of concern estimated using contaminant concentration values reported in survey forms and those levels of concern risk estimates based on surrogate and detection limit data.

e) For ecological risk analysis, the report (USEPA, 2001) does <u>not</u> but should discriminate between the levels of concern estimated using sludge contaminant concentration values reported in survey forms and those levels of concern risk estimates based on calculated sludge data.

3.4.4 Is it likely that EPA's data imputation protocol, or "surrogate data protocol" for imputing waste composition data markedly affected the ultimate conclusions regarding potential risks? If so, in what direction did the protocol probably bias the conclusions?

EPA used a structured data imputation protocol when a survey respondent clearly indicated the presence of a particular chemical constituent in an impoundment, but did not indicate a corresponding quantity. EPA used the structured data protocol to impute a surrogate value according to a specific hierarchy of assumptions.

The theme of the imputation methodology is to find the most similar impoundment possible within the survey database that had data for the chemicals without values. The surrogate data protocol is summarized below.

a) A nearest neighbor imputation methodology was applied to develop surrogate concentration data where chemicals are expected to be present, but quantities are unknown. In cases where the presence of a chemical in an impoundment could be inferred, a value from a similar impoundment was used to represent a likely concentration. As detailed in the report (USEPA, 2001) surrogate concentrations were developed: "(1) where the respondent had checked the " PQU" flag, (2) where the respondent had entered a chemical but provided no value (and did not check PQU), and (3) where chemicals were reported in wastewater effluent (to infer presence within the impoundment)."

   The imputation methodology employed a decision framework that was programmed into a data processing system to implement the methodology. The process was designed to find the most similar impoundment possible within the survey database that had data for the chemicals without values. The factors considered in order of importance were impoundment location (same facility or similar facility), aeration or not and function (treatment or non-treatment only).

   Note that because detection limits were decided to be valid representations of concentrations in the impoundments, the detection limit values derived using the techniques described below were used for surrogates.

b) When the survey data did not include a sludge concentration and there was sludge within the impoundment, the sludge concentration was determined by employing "wastewater partition coefficients (Kdw) for metals and a soil organic carbon-water partition coefficient (Koc) for organic constituents, along with total suspended solids (TSS) data pulled from the study survey." This calculation was designed to account for contaminants associated with the suspended solids, because total wastewater concentrations not dissolved wastewater concentrations were reported in the survey data. TSS values were obtained directly from the surface impoundments survey database or estimated using other data available for the impoundment. If these were not available a default value was used. The other parameters needed to estimate the partition coefficients were taken from the literature.

Regarding whether the surrogate data protocol for imputing waste composition biased conclusions regarding risk and the direction of any detected bias, the Subcommittee found:

a) The surrogate data protocol allows for a risk assessment to be conducted when data inputs are incomplete and provides a consistent procedure for selecting surrogate values.

b) The use of the surrogate data protocol tends to increase the number of risk exceedance impoundments and appears to have a conservative bias in the perspective of protecting human health, when compared to risk assessments performed solely on survey data. A comparison of the risk analysis results indicates that the total number of facilities that exceed risk criteria or may exceed risk criteria approximately doubles when surrogate/DL concentrations are used in addition to reported concentrations.

c) The surrogate data protocol does not identify the impact on the estimated risks from using the surrogate concentrations versus the "true" concentrations. This impact might have been estimated if acceptable distributions of "true" concentrations could have been specified based on measurements from the other impoundments that had no non-detect data.

d) The surrogate data protocol uses best available data, but there are no criteria set up to evaluate if "the best available data" meet the quality of data required for the project. The required quality of the risk estimates was not specified, which makes it difficult to specify the quality of data required. For example, if there was a need to estimate risks within say an uncertainty factor of 10, and if uncertainties on model parameters other than concentrations were established, then it could be determined what levels of uncertainty in the concentrations would still permit achieving the factor of 10 criteria. Trial and error and sensitivity analyses might have provided some guidance as to whether the surrogate data protocol was sufficient.

e) It may be useful for EPA to evaluate information on the range of surrogate data values available for a given constituent at a given impoundment. If the range of values is small, then the uncertainty in specifying a surrogate value is somewhat reduced. If the range were large, then using the maximum surrogate values would be more conservative than otherwise. Without an evaluation of this range information, the degree of conservativeness in risk assessments that results from using the maximum of those values cannot be assessed.

f) The report (USEPA, 2001) does not offer any information as to how the use of the surrogate data protocol biases ecological risks or risks resulting from indirect pathways.

g) The charge question cannot be answered properly without performing a sensitivity analysis. This might be done as follows: Select a subset of facilities with impoundments that did not require surrogate data. Remove the quantitative values to create impoundments that require surrogate data. Apply the imputation methodology to these sites and follow through with the risk assessment process using the surrogate data. Determine whether the conclusions of the risk assessment are changed from those obtained before the original quantitative chemical values were removed. Rather than use actual impoundments, one could also set up a computer study to do this investigation. This simulation study could be set up to mimic as closely as possible the characteristics and types of facilities actually encountered in the survey. The effect on risk assessment conclusions could be determined for various amounts of non-detects and non-quantitative responses on survey forms.

3.4.5 Should EPA have used any other approaches for qualifying or presenting surrogate data?

As discussed above, the report (USEPA, 2001) discriminates between the direct pathway release and risk estimates based on contaminant concentration values reported in survey forms and those release and risk estimates based on surrogate and detection limit data. This distinction is made repeatedly within the report's executive summary, the body of the report, tables and in its appendices.

Regarding whether EPA should have used other approaches for qualifying and presenting surrogate data, the Subcommittee found:

a) The presentation and qualifying approaches were reasonable and intuitive and readers, who have a range of technical expertise, should understand the source of releases and risk estimates.

b) It is not an unreasonable approach to attempt to impute a value from a similar impoundment or facility. The maximum of all surrogate data values for a given constituent was used in the survey database for risk assessment (page A-36 and A-37) of the report (USEPA, 2001). That approach is obviously different than selecting a random value from the set of surrogate values obtained for the constituent. The selection of a maximum rather than a random value could tend to increase the risk estimate. If a random rather than a maximum surrogate value was used, then the risk estimate could be either increased or decreased depending on the surrogate value used. It appears that EPA chose to be conservative and select a maximum surrogate value, which would only tend to increase the risk. But there should be some mechanism for assessing the added uncertainty in risk estimates from using that approach. This might be accomplished by specifying a subjective probability distribution of the maximum surrogate values for use in a Monte Carlo uncertainty analysis of risk. Of course, this distribution would be different than the distribution that would apply to a randomly selected surrogate value. Specifying a distribution for the surrogate values would have permitted an assessment of the effect of surrogate uncertainty on risk uncertainty.

c) For indirect exposure pathways and for ecological risks the report (USEPA, 2001) does not report separately the levels of concern estimated using contaminant concentration values reported in survey forms and those levels of concern based on surrogate and detection limit data.

3.4.6 Was using the assumption that a chemical could be present up to the detection limit, when it was reported as being present below a detection limit, a reasonable concentration to choose for risk screening purposes?

For purposes of release and risk assessments, survey values, reported as below detection limits, were not entered into the database as non-detects but entered at the associated detection level concentration. If a contaminant was reported as non-detect without an associated concentration value, a look-up table was employed to select a concentration.

Pages 3-4 and 3-5 of the report (USEPA, 2001) explain that many different reporting conventions for detection limits were used. Very low and very high detection limits were reported. EPA is far less confident in risk assessment results for situations where detection limits are used in place of actual data values. Hence, EPA presented the risk results separately according to whether the risks were calculated using concentrations reported in the facility surveys or calculated using surrogates and detection limit concentrations. EPA states (page 3-6) that risk results based on reported concentrations have greater certainty than those when detection limits were substituted for unreported concentrations.

Much has been written about the treatment of censored/non-detect data, including guidance offered by EPA (EPA QA/G-9). Treatment of detection limit data is typically managed by one of two general methods: substitution or statistical methods. For the substitution method, the typical approach is to substitute concentrations of zero, concentrations of half the detection limit or concentrations at the detection limit for non-detect data. The choice of the substituted concentration is a function of objectives and decision errors of concern. The statistical method can be used when there are multiple data points for the population being characterized. For example, censured concentration distributions below a detection limit can be estimated from non-censured data above the detection limit, or statistical parameters such as averages can be adjusted to account for censored portions of the population.

Regarding EPA's assumption that a chemical could be present up to the detection limit, when it was reported as being below a detection limit, the Subcommittee found:

a) It is reasonable to use the detection limit in place of the non-detect reported value for purposes of a screening risk assessment. This conservative approach to screening is also compatible with the approach recommended in the *Science*

Advisory Board's Review of the Office of Solid Waste's Proposed Surface Impoundment Study (1998). Of course, this approach will tend to bias high the estimates of risk. However, this consequence as indicated in the SAB's 1998 report is acceptable and even desirable for a screening risk assessment.

b) A member of the public asked in response to a Subcommittee telephone conference call as to whether the assumption that a contaminant could be present at a concentration up to the detection limit is reasonable when the contaminant was not expected to be present at the facility. The Subcommittee's response to this expansion to the charge is that the answer would depend on the certainty with which it is believed that the constituent is not expected at the facility. Very high certainty would suggest reporting a detection level concentration is not appropriate. Lower certainty regarding the absence of the contaminant would suggest reporting a detection level concentration is appropriate for a screening assessment. The Subcommittee was not charged to address this question, and other than the preceding response is not prepared to address this question on a contaminant by contaminant basis.

3.4.7 Did the EPA-generated default detection limit protocol provide reasonable approximations of likely detection limits encountered in the field by the facilities, when the detection limits were not reported in the laboratory analysis?

For purposes of release and risk assessments, survey values, reported as below detection limits, were not entered into the database as non-detects but entered at the associated detection level concentration. If a contaminant was reported as non-detect without an associated concentration value, a look-up table was employed to select a concentration. These lookup tables were based on the wastewater analytical methods for wastewater and SW-846 EPA 8000 series were used for organics in sludge. Detection limits for metals in sludges and for other contaminants in wastewater or sludge that lacked a detection limit, available in a commonly used analytical method, were extracted from the detection limits that existed in the survey database. If an air contaminant was reported as non-detect without an associated concentration value, the detection limit concentration was extracted from a look-up table based on EPA air methods. Detection limits for air contaminants not included in EPA methods were based on best professional judgment.

All look-up table detection limits were multiplied by a factor of 10 to account for potential interferences.

Regarding whether the default detection limit protocol provided reasonable approximations of likely detection limits encountered in the field, the Subcommittee found:

a) EPA should provide further information regarding the "look-up" tables of default detection limits to document whether such look-up values can be assumed to be upper limits on actual concentration values.

b) The detection-limit look up tables incorporated concentration values that were associated with a variety of detection limit [method detection limits (MDL), instrument detection limit (IDL)] and reporting limits [minimum levels (ML), estimated quantitation limits (EQLs)]. The concentrations associated with these different detection and reporting conventions can be significantly different for the same contaminant (*e.g.*, EQLs concentrations as defined in RCRA guidance can be as much as 10 times higher than the MDL for the same compound and for some methods the difference between the EQLs and IDLs could be even greater). The contaminants (wastewater metals) for which IDLs were employed, did not suffer from a significant discrepancy as compared to MDLs, because the referenced method incorporated IDLs from a dated document based on older and less sensitive instruments and did not account for the concentration factors that are incorporated into some sample preparative steps. The use of reporting limits (ML and EQLs) instead of detection limits resulted in more conservative estimates from the perspective of protection of human health and the environment.

c) EPA increased detection limits by a factor of 10 to account for interferences. Commonly an analytical interference can require that the sample be diluted prior to analysis, likewise high concentrations of analytes, that are not of concern, can decrease the effectiveness of preparative concentration steps that lower method detection limits. The safety factor of 10 should be sufficient for most wastewaters. EPA, recognizing the limitation detailed on page 3-4 of the report (USEPA, 2001), should consult the Office of Water and compare look-up detection limits for sludge contaminants to those in the survey database in an attempt to determine if the sludge detection limits are sufficiently conservative.

3.4.8 Do the results that are based on imputed/detection limit data suggest that further analysis is needed?

For background, please refer to the beginning of Section 3.4.7.

Regarding whether the risk results based on imputed/detection limit data suggest further analysis is needed, the Subcommittee found:

a) An indication that further analysis is required is when performance criteria set up before conducting the study are not achieved. The Subcommittee is unaware that EPA developed such performance criteria.

b) EPA should attempt to groundtruth look-up detection limit concentrations by comparisons to the field sampling data and detection limits reported in the survey data.

c) The SAB's earlier report (USEPA, 1998) made a recommendation to "analyze the sensitivity of the model estimates for the high and low ends of the anticipated parameter distributions". Since the EPA found in this report the release and risk estimates to be sensitive to the combination of surrogate/detection limit substitutions, it would be valuable to determine the sensitivity of the model outputs for the direct pathways due solely to the detection limit substitution protocol. This sensitivity analysis could be as simple as running the model with concentrations of zero and half the detection level concentrations to determine if the release and risk estimates vary significantly from the more conservative substitution of concentrations at the detection limit. Further sensitivity analyses could be performed to determine the effect on screening risk assessment results if the look-up table detection limit values, themselves, are changed to be larger or smaller than actually used.

d) Because the report (USEPA, 2001) did not document the impact of surrogate data/detection limit data versus survey data on ecological and indirect pathway risks, it would be advisable to perform these sensitivity analyses as well as determining the sensitivity to alternative detection limit concentrations as discussed in the previous bullet.

3.5 Charge Question 5: Analysis and Interpretation of Field Sampling Data

3.5.1 What is the SAB's view on EPA's conclusions about the accuracy of the reported survey data on chemical constituent concentrations/quantities?

The introduction to Appendix E of the report (USEPA, 2001) indicates that EPA conducted field sampling at a subset of 12 authoritatively selected facilities and subsequently analyzed the collected samples "to supplement other data sources, provide "ground-truth" and fill gaps in data obtained via EPA's *Survey of Surface Impoundments*". Appendix E later identifies the original objectives as:

Objective 1: Determine whether the waste characterization data provided by the facilities in their survey responses and the corresponding sample analysis results from EPA's sampling program are in reasonable agreement and within the range of values expected (*i.e.*, do EPA data "verify" the survey data).

Objective 2: Determine whether the field sampling and analysis program confirms the presence of constituents reported by the facilities and determine the extent to which the field data identify gaps in the industry-supplied data.

The *Quality Assurance Project Plan for Surface Impoundment Study Field Sampling and Analysis Program*, Revised April 18, 2000 (USEPA, 2000), known as a QAPP, captured an expanded list of objectives in the following decision statements, which are similar to those in DQO Development document (Attachment A to the QAPP):

a) Determine, using EPA field monitoring data as a "spot-check" and using process knowledge, whether or not facility-supplied data are reasonable and within the range of values expected or whether the data should be questioned and the discrepancy investigated.

b) Determine whether or not there are gaps in the industry supplied data and whether those gaps should be filled by conducting field sampling and analysis, or by other means (such as requesting additional information/clarification from the facility).

c) Determine, using actual field monitoring data (both submitted by facilities and generated by EPA), whether or not the multimedia models provide accurate output.

The field teams collected samples of impoundment influent and effluent, wastewater from within the impoundment, sludges, leachate and groundwater. According to the QAPP, these samples were collected using judgmental sampling, which relies upon professional judgment to select a sample that represents the target population. The resulting analytical data are discussed in the body of the report (USEPA, 2001) as well as in Appendices C and E and attachments to Appendix E.

All EPA collected data were subjected to data validation and if the data were generated under non-compliant analytical conditions, the associated data were qualified.

To evaluate whether the sampling program contaminant concentrations were within reasonable agreement with the survey data, EPA compared its measured values with those reported by the facility using several statistical approaches and concluded that "there is a pattern of agreement between the waste characterization data provided in the surveys and EPA's sample analysis results for the corresponding impoundments, sample locations and parameters of interest" and that "there is no reason to question the concentration data provided in the facility survey".

Regarding EPA's conclusions about the accuracy of the reported survey data on chemical constituent concentration/quantities, the Subcommittee found:

a) The Subcommittee, not knowing the representativeness of collected samples nor the true constituent concentrations in the various media sampled at the 12 facilities, is unable to authoritatively determine the accuracy of the sampling data. However, EPA's use of a structured planning process such as the DQO process, and subjecting the sampling data to data validation are significant steps in respectively assuring and documenting the analytical quality of the data.

b) The DQO process planning effort, which was conducted to support the development of the QAPP, is documented in an appendix to the QAPP. The DQOs specified in the first 4 steps of the DQO process provided in the plan are generally well done, but step 6 ("Specify Limits on Decision Errors) is less satisfactory in that it provides no quantitative basis for determining the number of samples from selected facilities that should be collected. Furthermore, on pages 17 and 18 of the DQO report, the plan called for basing the number of samples for each facility entirely on practical considerations such as budget and schedule, rather than more appropriately basing the number of samples on the quality of the information needed to achieve the purposes of the field sampling program (*i.e.*, validating models, completing the risk analyses, and verifying facility-supplied survey data).

c) The selection of facilities for subsequent sampling by EPA was approximately proportional stratified sampling, *i.e.*, roughly 5 to 10% of the facilities in each of the Standard Industrial Classification (SIC) groups (strata) chosen for sampling. Using proportional stratified sampling is a reasonable approach, although the expected variability in data to be obtained and the representativeness of those data for the population of facilities should have been considered in determining the number of facilities. Nine of the seventeen major SIC groups had no facilities selected for sampling. There was no discussion in the report (USEPA, 2001) on the sensitivity of the conclusions due to not sampling the 9 SIC groups.

d) Because the actual field samples collected by EPA were not randomly collected, and because the Subcommittee does not know if the judgmentally collected samples are representative of the media present at the 215 facilities that submitted survey data, the Subcommittee is unable to use the sampling data to authoritatively evaluate the accuracy of the survey data. However, because 88% of the 151 contaminant data pairs are within an order of magnitude of each other and because 78% of the time, when there is a difference, the difference is not measurably significant or the survey datum is the higher concentration an argument can be made that the survey data, although positively biased compared to the sampling data, is likely suitable for the study's conservative purpose.

e) EPA should attempt to more clearly justify its rationale for its conclusion that "there is no reason to question the concentration data provided in the facility survey" (USEPA, 2001, p. 2-10) EPA should make an effort to explain its conclusion in a more quantitative manner rather than basing it solely on the argument that the data are acceptable because they are typically higher and thus yielding a more conservative risk estimate. EPA expertise regarding the spatial and temporal heterogeneity of wastewaters and impoundment wastes, sampling conditions and the accuracy of analytical methods should be employed to further explore the bias and range of values when comparing sampling data to survey data. For example, if EPA's sampling was performed during times of elevated temperatures, one may expect a negative bias in volatile organic concentrations in waters versus a 3-year averaged survey datum.

f) EPA is encouraged to use the sampling data to evaluate the surrogate data protocol (*i.e.*, use the look-up tables for ND and use the nearest neighbor imputation to see how the imputed data match that which was measured in the field.) EPA may have performed this evaluation because the report (USEPA, 2001, p. 3-11) mentions the important QA role of the sampling data when discussing the "EPA Surrogate Data Protocol". If this evaluation has been performed, the outcome should be more clearly presented.

g) During the DQO planning process a decision was made to allow for the use of performance-based analytical methods in lieu of existing analytical methods that have been successfully applied to these matrices. This decision placed additional burden on EPA to review the applicability of any non-routine analytical method that was employed and comparability of the resulting data.

h) DQOs for the field sampling were not consistently presented in the tiered documents (*i.e.*, DQO Development document, QAPP, SAP and Appendix E).

3.5.2 What is the SAB's view on EPA's conclusion on the potential incomplete reporting of chemical constituents present?

The EPA's second objective for field sampling was to determine whether the field sampling and analysis program confirms the presence of constituents reported by the facilities and determine the extent to which the field data identify gaps in the industry-supplied data.

For the second objective EPA compared the number of constituents reported by each facility for each sample location, to constituents in the related samples collected by EPA and counted the number of constituents that were detected in both and those additional constituents detected solely in EPA-collected samples.

EPA found that field sampling typically confirmed the presence of constituents reported by the facilities. They also found that the field sampling confirmed the presence of a number of additional constituents not reported by the facilities.

Regarding EPA's conclusions on the potential incomplete reporting of chemical constituents, the Subcommittee found:

a) EPA is correct in concluding that the facility reporting is incomplete.

b) On page E-17 (bottom) of Appendix E of the report (USEPA, 2001) it states that quantitation of additional constituents provides supplemental data for possible use in the uncertainty analysis of the study, but it is not clear if this was actually done.

c) Regarding explanations as to why the facilities did not report the presence of certain constituents, EPA is encouraged to identify and evaluate local, State and Federal requirements for each of the 12 facilities to determine if the facilities were responsible for detecting the unreported constituents at the concentration levels reported at in the field samples.

3.5.3 Would the SAB recommend alternate approaches, in order to obtain the best possible information regarding the exact chemical constituents present, given the same budget and time constraints?

In its DQO Development Document, EPA concluded that, "Due to funding and other practical constraints (*e.g.*, mobilizing field teams to multiple sites) . . . the field sampling must be limited in scope". Such budget and time constraints are typical for data collection activities. Such data collection activities are best designed using a structured planning process, such as the Data Quality Objective Process used by EPA, so that an optimized sampling and analytical design will maximize the return on consumed resources and increase the chances of achieving objectives.

Regarding EPA's request for recommendations under the same budget and time constraints, the Subcommittee found:

a) The Subcommittee is not familiar with the details of the "budget and time constraints" that EPA had to operate under, therefore it is not possible for the Subcommittee to respond to this question as worded. The Subcommittee recognizes that the realities of constraints can limit data gathering, decrease information and increase uncertainty in data-based decisions. The Subcommittee believes that EPA did a responsible job of documenting the constraints and their logic for choosing judgmental sampling, grouping of facilities and single sampling visits.

b) It would have been advantageous if the survey questions could have been structured such that more complete and sufficient information on concentrations was obtained. For example, it would have been helpful if EPA decreased the flexibility it allowed in the reporting of chemical concentrations and non-detect values (*e.g.*, request upfront, that those responding to the survey use a specified format for non-detect values and that the use of "PQU" data be discouraged).

c) More thought should have been given to how the survey and EPA-measured data would be statistically compared and the requirements of that comparison, such as comparability of the survey and EPA-measured data.

3.6. Charge Question 6: Handling of Groundwater Source Term

EPA evaluated the risk to human health posed by chemical constituents migrating from surface impoundments via the groundwater pathway. A groundwater solute fate and transport model, EPACMTP, was used for this purpose. The EPACMTP model considers transport in both the vadose and saturated zones. Fate and transport processes included in the model are advection, hydrodynamic dispersion, equilibrium sorption, and rate-limited chemical hydrolysis. Human health impacts from ingestion of contaminated groundwater and surface water, and from ingestion of fish from contaminated surface waters, were considered in the risk assessments conducted. Exposure scenarios considered in the risk modeling were ingestion of water from a well downgradient of a leaking surface impoundment, ingestion of surface water that receives impoundment-contaminated groundwater, and ingestion of fish residing in the contaminated surface water.

The mass rate of release of chemical constituents in liquid from the surface impoundment into the subsurface constitutes the source term for the groundwater solute fate and transport model. The properties that define the source term for a particular chemical constituent or group of constituents are:

a) surface area of the impoundment;

b) leachate flux from the impoundment, *i.e.*, flow of water leaking out of the bottom and sides of the impoundment per unit of impoundment surface area;

c) concentration of constituent or group of constituents in the leachate; and

d) duration of the leachate infiltration.

Charge #6 is focused on item c), the concentration of chemical constituents in the leachate.

Concentrations of chemical constituents in leachate were requested by EPA in the national survey of surface impoundments. Relatively few facilities (12) in the survey sample reported leachate data, however, implying that there is little monitoring of the presence and abundance of chemical constituents in the groundwater beneath and near to surface impoundments. While leachate data reported were sparse, nearly all facilities that provided any data on impoundment liquid constituents gave data for impoundment wastewater composition.

In performing the risk modeling for the groundwater pathway, EPA preferred to use a consistent approach for the groundwater source term for the various sites and scenarios considered. The original intent was to use leachate data for the groundwater source term. The limited data on leachate composition, however, forced EPA to reconsider this approach. EPA decided to use impoundment wastewater composition data instead of leachate data.

The core issue relevant to Charge 6 is the use by EPA of wastewater composition as the source area water composition for the groundwater exposure/risk modeling. EPA contends that wastewater composition will reasonably approximate leachate composition for impoundments containing little or no sludge. EPA has some concern, however, that in impoundments containing some sludge, the concentrations of some constituents could be considerably different in the pore water of the sludge than in the impoundment wastewater. EPA's comparison of some field data on sludges with the corresponding wastewater composition, indicated to EPA that the decision to use wastewater concentration may have underestimated the contaminant mass for some chemical constituents.

3.6.1 Would the SAB recommend another approach for representing the groundwater source term, for example, performing a bounding analysis, using the sludge data, where available, to represent an upper bound of the groundwater source term, and using wastewater data as the lower bound, for those chemical constituents for which this situation may be an issue?

In response to the above question, the SAB supports EPA approach of using impoundment wastewater composition to define the groundwater source term for steady-state impoundment operation, and does not recommend a bounding analysis using available sludge data. The available sludge data are inadequate in the scope of constituents and conditions represented, and calculating leachate concentrations from sludge concentrations would necessitate assumptions that would lead to substantial uncertainty in the estimates obtained. The use of impoundment wastewater composition to represent impoundment leachate composition is a reasonable, conservative approach for steady-state impoundment operation given the limited submittal of leachate data by survey respondents. Quantitative leachate data were acquired in the survey for 44 impoundments located at 12 facilities[4]. For the three facilities that reported both leachate and wastewater composition data, the ratio of leachate to wastewater concentrations generally ranged from 0.01 to 1.0, but in a few cases were as low as 0.0001. In no cases did leachate exceed wastewater concentrations. While the available data are quite limited, to be sure, they support the use of wastewater composition as a conservative approach.

The weakness of EPA's approach to defining the groundwater source term -- using the impoundment wastewater composition to represent the composition of leachate leaking from the

[4] Summary provided to David Dzombak by Rebecca Cuthbertson on December 21, 2001.

impoundment - is that the concentrations of some constituents entering the groundwater may be significantly different from the concentrations in the impoundment wastewater. These differences may arise due to reactions in the sludge on the bottom of the impoundment, or to reactions that occur in the course of transport through the impoundment liner or barrier material. Moreover, the nature of such reactions may change over time, as changes in wastewater and sludge composition may lead to changes in the type and solubility of sludge constituents. Because the source area concentration directly influences the calculated exposure concentration of a constituent at receptor locations, it clearly would be best to use leachate data rather than an approximation of leachate data.

Defining the groundwater source term as the impoundment wastewater composition is reasonable in a number of respects, however. It enables consistency in the risk modeling across all the locations in the survey sample. The wastewater compositions will only approximate the impoundment leachate concentrations, but the related uncertainty is likely not greater than the uncertainty that would be involved with estimating the modification of impoundment wastewater constituent concentrations as a result of movement through the sludge, liner, and barrier material. In addition, EPA's approach appears to be nonconservative. That is to say, the concentrations of some constituents will be overestimated by considering the impoundment wastewater as representative of the leachate. In fact, as discussed above the limited available leachate data uniformly are less than or equal to the corresponding wastewater composition data. It will certainly not be the case that concentrations of all constituents are underestimated. For example, the wastewater composition data used appear to be total analysis data, reflecting analyte present in suspended solids as well as in the aqueous phase. The TSS fraction may not be transportable through the unsaturated and saturated zones. In addition, some of the surface impoundment analytes of concern, identified in the facility survey, tend to sorb strongly to earthen materials, and would be unlikely to migrate far past an earth material liner. Benzo(a)pyrene and benzo(a)anthracene, listed in Table 3-15 of the report (USEPA, 2001), are examples. Fluoride and arsenic, two primary analytes of concern (Tables 3-8 and 3-15 of the report), can also sorb strongly to earthen materials such as oxide minerals under some chemical conditions, though they also can be completely dissolved under other conditions.

The use of impoundment wastewater composition to represent impoundment leachate composition is a reasonable approach given that the survey respondents provided limited leachate data. While reactions in the sludge layers, liners, and barrier materials of impoundments will modify concentrations of some constituents, estimating these modifications for a large number of sites would yield results with substantial uncertainty. Significant data collection would be needed to reduce this uncertainty, and if additional data collection were to be undertaken, it would make most sense to put resources into acquiring more leachate data, which are directly relevant. It would be very difficult to work in a rationale, defendable manner from sludge data alone. There would be issues of the representativeness of the data, considering that only small quantities of sludge are employed in any single sludge analysis, and also a range of issues related to selection of an appropriate partitioning model.

3.6.2 Compared to other sources of uncertainty in the groundwater and groundwater to surface water pathway analyses, how large a source of uncertainty does the decision to use wastewater composition data appear to introduce into the overall study conclusions?

Quantification and consideration of the uncertainty in the source area constituent concentrations likely would not change significantly the main conclusions from the quantitative risk estimation for the groundwater pathway (Section 3.2.3.1 of the EPA report) and groundwater-to-surface water pathway (Section 3.3.2.1 of the EPA report). These conclusions were as follows: 1) very few facilities exceeded acceptable risk criteria with respect to groundwater and surface water ingestion, and ingestion of aquatic organisms from affected surface waters; 2) a significant portion of the facilities that exceed acceptable risk criteria were for the groundwater-to-surface water pathway were "zero discharge" facilities; and 3) the highest risks for the groundwater and groundwater-to-surface water pathways were for impoundments without liners. The numbers of sites that serve as the basis for these conclusions may change somewhat with quantitative consideration of uncertainty in source area concentrations, but the overall conclusions would likely remain the same. Given the uncertainty in other risk model components, *e.g.*, the magnitude of leakage from the impoundments, the simplified hydrogeological conditions assumed for the groundwater transport modeling, and the simplified exposure scenarios, the uncertainty in the source area constituent concentrations is likely to be relatively small.

Even if more accurate source area constituent concentrations were obtained from a new leachate data collection effort, the major conclusions of the risk modeling analysis with respect to the groundwater pathway would likely remain the same. Consider, for example, the major conclusion presented on page 3-16 of the report (USEPA, 2001): "the highest risks for the groundwater pathway on an impoundment basis correlate strongly with the absence of a liner." This conclusion would not change if the source area constituent concentrations were higher or lower. Moreover, EPA risk analysis indicated that "very few facilities-- less than 1 percent" exceeded risk criteria for analytes of concern in groundwater, considering both direct consumption of groundwater as well as indirect human exposure through surface water impacted by groundwater (pages 3-15 and 3-28 of the report (USEPA, 2001)). This indicates that it would be hard to justify a new leachate data collection effort in an attempt to refine estimates of low risk. It would be useful to demonstrate systematically that the main conclusions from the groundwater pathway risk analysis would not be changed if source area constituent concentrations were higher, *e.g.*, by an order of magnitude as an estimated upper bound. A sensitivity analysis could be performed to examine the effects of increases in constituent source concentrations. It seems unlikely that differences in the source area concentrations in the range of an order of magnitude (a conservative upper bound based on the available leachate and wastewater composition data) will change the main conclusions reached in the study.

3.7 Recommended Future Research Topics

The Subcommittee has identified several areas of future research that could improve the estimation of human-health and ecological risks associated with surface impoundments. Research areas should be prioritized based on their relative impact on the reduction of uncertainty for estimating the risks. Therefore, it would be helpful to conduct sensitivity analyses to identify sensitive parameters. For these parameters, a higher priority should be given to those that have not been considered in estimating the risks or do not have sufficient data. The research recommendations include those relevant to Charge Question 3a, Section 3.3.1, concerning the improvement of the screening-level indirect and ecological risk assessments.

3.7.1 Performance of Surface Impoundments

a) Evaluation of the long-term performance of liner systems.

b) Evaluation of lessons learned from the operation of surface impoundments in the mining and agricultural industries, which were not included in the report (USEPA, 2001).

c) Development of historical and empirical data on surface-impoundment failures due to transient events (natural and man-made), including frequency of and area affected by overtopping and seismic events.

d) Transfer of the findings of the report (USEPA, 2001) to the development of technical guidance for designing and operating surface impoundments.

3.7.2 Human Health and Ecological Risks (Including Bioaccumulation)

a) Development of health risk indices of the chemicals whose cancer potency values and non-cancer reference doses or concentrations are not available.

b) Biological sampling (*e.g.*, fish and others) of high-risk facilities for persistent constituents after determining a dominant indirect pathway(s).

c) Investigation of toxicity of chemicals from sludge/soil from surface impoundments to ecological receptors. It is apparent that toxicity data and exposure factors were only available for 35 of 256 chemicals (USEPA, 2001, p. C-179).

d) Assessment of potential magnitude of residual risk of chemicals not selected for assessment.

e) Evaluation of interactions of chemicals in determining toxicity of chemicals from surface impoundments.

f) Investigation of chronic toxicity to amphibians and reptiles.

g) Further development of scaling factors for interspecies toxicity extrapolation. See Sample and Arenal (1999) for recent factors.

3.7.3 Fate and Transport (Air/Groundwater/Soil/Sludge)

a) Experimental study on the fate and transport of chemicals in and around aqueous surface impoundments and in soil/sludge from dried out and/or abandoned surface impoundments (so that chemical concentrations in nearby wetlands can be predicted, or concentrations in soils associated with overtopping events can be predicted).

b) Incorporation (and validation) of additional processes (*e.g.*, biotransformation and others) into groundwater transport models to conduct multi-site evaluation and reduce uncertainty associated with the models.

c) Experimental study on the resuspension and subsequent dry deposition of particles from surface impoundments.

d) Investigation of volatilization and subsequent near-field dispersion of SVOCs and VOCs from water bodies.

e) Investigation of volatilization of chemicals from home shower water.

3.7.4 Fate and Transport (Uptake and Bioaccumulation)

a) Experimental study of uptake of chemicals from sludge/soil from surface impoundments, including SVOCs and VOCs from air by plants and SVOCs and VOCs from contaminated soil by plants. See Efroymson *et al.* (2001) for a compilation of data (and regressions) on plant uptake of 8 inorganic chemicals from various contaminated soils.

b) Measurement of tissue levels of persistent or bioaccumulative chemicals (*e.g.*, dioxin, methyl mercury) in human and wildlife foods, such as fish, near surface impoundments.

c) Investigation of the interactions of chemicals in determining bioaccumulation of chemicals from surface impoundments.

3.7.5 Risk Assessment Methodologies (Model Development and Validation)

a) Evaluation of 3MRA, originally intended for use in this study (USEPA, 2001, p. C-2) or another multimedia model for use in assessing risks from surface impoundments.

b) Incorporation of a probabilistic approach into the quantitative risk assessment of air-human risk pathways by making use of the progress made in this area especially within EPA. (The Subcommittee understands that it would be difficult to develop distributions on human health effects [*e.g.*, cancer potency]).

c) Development of probability distributions for those significant parameters used in CHEMDAT8.

d) Evaluation of the role of model uncertainty as part of the total uncertainty in risk results.

e) A study of sensitivity of the risk and hazard measures to alternative assumptions regarding hazard and potency.

f) A study of sensitivity of the risk to presumptions regarding biophysical and photochemical conversions.

3.7.7 Risk Mitigation Measures

a) The study of methods to discourage biota from colonizing surface impoundments.

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APPENDIX A: CHARGE QUESTIONS POSED BY US EPA

The following was prepared by the US EPA Office of Solid Waste as part of charge questions that were posed to the Subcommittee.

1. Validity of General Methodology and Approach

This study (USEPA, 2001) was a classic risk assessment for use in reviewing waste management practices at nonhazardous waste surface impoundments. It relied on primary data collected for the specific purpose of answering the study questions. The study's technical objective was to assess risks posed by the waste management practices described in the statute and consent decree. The study population consisted of facilities with three different types of Clean Water Act regulatory status: direct, zero, and indirect dischargers.[1] For direct and zero dischargers, the study design was a randomized two-phase sample of facilities, with all eligible impoundments selected at the second-phase sample facilities. A questionnaire was used to collect basic information regarding each facility and surface impoundment in the second-phase sample. Publicly available data were also collected, and a limited field sampling effort at some facilities was conducted. These data were used to develop a risk analysis to evaluate the nature and extent of human health and ecological impacts posed by these surface impoundments.[2]

The policy questions posed in the legislation and the consent decree were:
"to characterize the risks to human health or the environment associated with [managing decharacterized wastes in Clean Water Act treatment systems]" and to "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." (RCRA Section 3004(g)(10))

and

The Administrator shall...perform [a] stud[y] on gaps in the hazardous waste characteristics and relevant Clean Air Act ("CAA") controls, and the resulting potential risks to human health, posed by the inhalation of gaseous and non-gaseous air emissions from wastes managed in...surface impoundments (excluding those impoundments receiving decharacterized

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1 The legislation specified these three Clean Water Act categories, and thus defined the study population.

2 For indirect dischargers, the design was a purposive sample, with all eligible impoundments selected at the sampled facilities, collection of primary survey data, analysis of those survey data, and comparison with direct and zero discharger results.

wastewaters that EPA is obliged to study pursuant to Section 3004(g)(10) of RCRA, 42 U.S.C. S 6924(g)(10))....[3]

In offering an overall review of the study EPA asks the SAB to keep these general questions in mind:

a) Does the SAB believe that the general methodology, EPA chose for developing its risk analysis, was appropriate for the policy questions posed in the statute and consent decree?

b) Regarding the overall study implementation, from design through sample selection, data collection and analysis, what areas of strength does the SAB see in the overall methodology, and what areas of potential improvement or additional analysis does the SAB recommend?

c) Did EPA adequately characterize the risks? Are the risk analysis and findings transparent? That is, are they explicit in:

describing the assessment approach, assumptions, extrapolations and use of models

describing plausible alternative assumptions

identifying data gaps

distinguishing science from policy

describing uncertainty, and

describing the relative strength of the assessment?

d) Please provide an SAB's assessment of the accuracy of EPA's overall study conclusions regarding risks to human health and the environment. Were the conclusions either false-positive or false-negative (finding risks of greater or lesser magnitude than the risks that likely exist)?

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[3] Civ. No. 89-0958, *Environmental Defense Fund, Inc. vs. Whitman et al.* June 12, 1997.

2. Need to Consider Abnormal Operating Conditions

Regarding the releases that result from abnormal operating conditions, such as overtopping, or dike/berm failures, EPA asked survey respondents about the frequency, duration and magnitude of these kinds of events.[4] EPA presented the findings in Chapter 2 of the report (USEPA, 2001), page 2-26, but did not attempt to incorporate this information into the risk assessment or otherwise perform failure modeling, due to concerns about the high non-response rate on this particular survey question, as well as possible memory effects (recall and reporting of more recent events).

a) In light of the findings of the report, should EPA perform a more detailed evaluation of abnormal operating events, would the data collected point to additional studies or research to provide more detail about this issue? If so, what methods or approaches would the SAB recommend regarding collecting more reliable data, and modeling the probability and impacts of such events?

3. Validity of Screening-Level Risk Characterizations

For most pathways of potential concern, EPA conducted conventional risk assessments using well-developed and peer reviewed modeling tools. These analyses resulted in formal estimates of risks or exceedances of health thresholds and were conducted for the direct ingestion of groundwater, direct inhalation and the examination of groundwater to surface water impacts on human health ambient water criteria.

For a variety of potential indirect exposures to human receptors, EPA conducted a screening level risk characterization. These included potential exposures through indirect pathways such as ingestion of crops, dairy products and fish that might be contaminated through a variety of transport mechanisms such as runoff from closed impoundments, or air dispersion onto nearby farmlands. This analysis consisted of a categorizing and ranking of exposure factors of potential concern for each facility in order to identify facilities where indirect pathways may be of potential concern, rather than a conventional risk assessment.[5]

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[4] See Attachment A-1, Survey of Surface Impoundments question C25 (Industrial Surface Impoundments in the United States, 2001).

[5] EPA's methodology and results for describing the human health risks potentially posed by indirect pathways, other than the groundwater to surface water pathway, is described in the report in section 3.4 and Appendix C, beginning on page C-135 (Industrial Surface Impoundments in the United States, 2001).

Similarly, EPA conducted a screening level risk characterization of potential ecological concerns. This assessment identified facilities where there could be ecological concerns provided there were direct contact and ingestion of surface impoundment contents by various ecological receptors, using conservative screening assumptions.[6]

The reasons EPA conducted screening level risk characterizations for indirect pathways and for potential ecological risks were that the available data and available modeling tools were less complete and less certain, and EPA wanted to present results in a manner commensurate with the level of certainty in the available data.

a) For the indirect human health and ecological screening-level analyses, in the SAB's view, do the results point to areas of potential future research? If so, does SAB have recommendations on prioritizing future studies in these areas?

b) Based on the screening-level estimates EPA developed for other indirect and ecological risks, did it appear that EPA overlooked potential problem areas?

c) Did EPA clearly describe and properly characterize the other indirect human health and ecological risk analyses?

4. Use and Interpretation of Survey Data

EPA used various data processing and analysis protocols to ensure consistency in interpreting survey data on a specific constituent's presence in an impoundment, or that constituent's quantity. EPA used analysis methods and presentation techniques to help distinguish and explain the various degrees of certainty in the findings. Please comment on the appropriateness of the application of these data processing and analysis protocols, and on the degree of clarity of the risk results presentation, in the situations described below.

Surrogate data.[7] In this situation, the survey respondent clearly indicated the presence of a particular chemical constituent in an impoundment, but did not indicate a corresponding quantity. EPA used the surrogate data protocol described in Appendix A to impute a value according to a specific hierarchy of assumptions. In the risk results, EPA presented findings of risks that were computed based on these surrogate values separately from findings of risks above

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6 The methodology and results for describing the potential ecological risks is described in the report in section 3.5 and Appendix C, beginning on page C-159 (Industrial Surface Impoundments in the United States, 2001).

7 See pages A-36 to A-38 of Appendix A, Study Design and Survey Data Collection and Processing (Industrial Surface Impoundments in the United States, 2001).

the relevant threshold level that were computed based on reported survey values for chemical constituent quantities.

a) Is it likely that EPA's data imputation protocol, or "surrogate data protocol" for imputing waste composition data markedly affected the ultimate conclusions regarding potential risks? If so, in what direction did the protocol probably bias the conclusions?

b) Should EPA have used any other approaches for qualifying or presenting the data?

Detection limits.[8] There were various situations in which the specific chemical constituents were clearly indicated, but the quantities were unknown because the only information reported was that the chemical was not detected in a laboratory analysis. In the first such situation, the survey respondents provided the pertinent detection limits, and EPA's data processing and analysis protocols called for using the reported detection limit as the actual quantity present in the impoundment, for the purpose of performing the screening or risk assessment. In the second situation, the survey respondents provided the chemical's identity and some kind of indication that the chemical was present below some sort of detection limit, but the exact detection limit was not stated. Typically, the survey response included "ND" or "BDL";EPA interpreted these responses as "nondetect" or "below detection limit." In this second situation, the data processing and analysis protocols called for using an EPA-generated default detection limit for the chemical constituent in question, and assuming that the constituent was present at that detection limit. In either of these situations, EPA kept findings of risks above the relevant threshold level that were computed based on these detection limit values separate from findings of risks above the relevant threshold level that were computed based on reported survey values for chemical constituent quantities.

c) Was using the assumption that a chemical could be present up to the detection limit, when it was reported as being present below a detection limit, a reasonable concentration to choose for risk screening purposes? Was this assumption reasonable in cases where the constituent was not expected to be present at the facility?

d) Did EPA-generated default detection limit protocol provide reasonable approximations of likely detection limits encountered in the field by the facilities, when the detection limits were not reported in the laboratory analysis?

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[8] See pages A-35 and A-36 of Appendix A, Study Design and Survey Data Collection and Processing (Industrial Surface Impoundments in the United States, 2001).

e) Do the results that are based on imputed/detection limit data suggest that further analysis is needed?

5. Analysis and Interpretation of Field Sampling Data

Based on a comparison of EPA field sampling results with the corresponding reported survey values for chemical concentrations/quantities, EPA concluded that the survey respondents generally did not systematically under report the quantities of chemical constituents present in the impoundments.[9]

a) Although there are limitations of performing the comparison of survey and field sampling waste composition data, what is the SAB's view on EPA's conclusions about the accuracy of the reported survey data on chemical constituent concentrations/quantities?

Based on a comparison of EPA field sampling results with the corresponding reported survey information on chemical constituents present in the impoundments, EPA concluded that there may have been incomplete reporting of the entire suite of chemical constituents present in the impoundments.[10]

b) What is the SAB's view on EPA's conclusion on the potential incomplete reporting of chemical constituents present?

c) Would the SAB recommend alternate approaches, in order to obtain the best possible information regarding the exact chemical constituents present, given the same budget and time constraints?

6. Handling of Groundwater Source Term

In order to estimate potential risks posed by the groundwater and the groundwater to surface water pathways, EPA needed to represent the impoundment and its contents in a modeled

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[9] See Attachment E-1 for a table showing the reported survey values and corresponding field sampling measurement results (Industrial Surface Impoundments in the United States, 2001).

[10] See Attachment E-2 for a table listing the facilities, impoundments and chemical constituents found in the field sampling but not reported on the survey (Industrial Surface Impoundments in the United States, 2001).

system, in which the contaminants that enter the groundwater transport pathway are represented as a mass flux of contaminants from the impoundment into the groundwater system. This mass flux is the groundwater source term, and EPA needed data on the identity and quantity of chemical constituents entering the groundwater system in order to model it properly.

The survey requested data on chemical constituents and their quantities in leachate from the impoundments. Leachate is the portion of the waste that is managed in a waste management unit, but leaks ("leaches") out of the bottom or sides of a land-based waste management unit. Facilities that collect leachate from their impoundments were able to report on chemical constituent presence/quantities in leachate, but relatively few facilities in the study sample appear to collect their impoundments' leachate. Thus, relatively few facilities answered the questions on leachate composition. However, virtually all the facilities that supplied waste composition data at all supplied it for wastewater composition.

To perform the data analysis, EPA needed to take a step-wise, efficient approach, beginning with screening thousands of impoundment/chemical combinations and ultimately modeling some. For these purposes EPA used the wastewater concentration. In impoundments containing little or no sludge, using wastewater composition data would be a reasonable approximation for the mass flux into groundwater. However, in impoundments containing some sludge, it is reasonable to expect that the concentrations of some constituents present in the pore water of the sludge could be considerably different than the concentrations present in the impoundment wastewater. These concentrations would resemble the leachate composition more than the wastewater. A comparison of some of the field sampling data on sludges with the corresponding wastewater composition, indicates that, for certain chemical constituents, the decision to use wastewater concentration may have underestimated the contaminant mass by more than an order of magnitude.

a) Would the SAB recommend another approach for representing the groundwater source term, for example, performing a bounding analysis, using the sludge data, where available, to represent an upper bound of the groundwater source term, and using wastewater data as the lower bound, for those chemical constituents for which this situation may be an issue?

b) Compared to other sources of uncertainty in the groundwater and groundwater to surface water pathway analyses, how large a source of uncertainty does the decision to use wastewater composition data appear to introduce into the overall study conclusions?

APPENDIX B: ROSTERS AND BIOS FOR THE SUBCOMMITTEE

FY 2002 Executive Committee Roster

FY 2002 Environmental Engineering Committee Roster

FY2001-02 Surface Impoundments Subcommittee Roster

Bios for the Subcommittee

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Research Strategies Advisory Committee

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Also Member: Radiation Advisory Committee

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Also Member: Environmental Economics Advisory Committee

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Also Member: Ecological Processes and Effects Committee

SCIENCE ADVISORY BOARD STAFF

Ms Betty Fortune, Office Assistant, 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-4534, Fax: 202-501-0323, (fortune.betty@epa.gov)

Ms. Diana Pozun, Program Specialist, 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-4544, Fax: 202-501-0323, (pozun.diana@epa.gov)

U.S. Environmental Protection Agency
Science Advisory Board
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Dr. Domenico Grasso, Rosemary Bradford Hewlett Professor and Chair, Picker Engineering Program, Smith College, Northampton, MA
Also Member: Executive Committee

SAB MEMBERS
Dr. H. Barry Dellinger, Patrick F. Taylor Chair , Department of Chemistry, Louisiana State University, Baton Rouge, LA

Dr. Hilary Inyang, Duke Energy Distinguished Professor and Director, Global Institute for Energy and Environmental Studies, University of North Carolina at Charlotte, Charlotte, NC
Also Member: Research Strategies Advisory Committee

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Dr. Byung Kim, Staff Technical Specialist, Ford Motor Company, Dearborn, MI

Dr. John P. Maney, President, Environmental Measurements Assessment, Gloucester, MA

Dr. Michael J. McFarland, Associate Professor, Department of Civil and Environmental Engineering, Utah State University, Logan, UT

Dr. Bruce E. Rittmann, John Evans Professor of Environmental Engineering, Department of Civil Engineering, Northwestern University, Evanston, IL

Dr. Thomas Theis, Director of the Institute for Environmental Science and Policy, University of Illinois at Chicago, Chicago, IL

Dr. Valerie Thomas, Research Scientist, Center for Energy and Environmental Studies, Princeton Environmental Institute, Princeton University, Princeton, NJ

U.S. Environmental Protection Agency
Science Advisory Board
Environmental Engineering Committee
Surface Impoundments Study Subcommittee *

CHAIR

Dr. Byung Kim, Staff Technical Specialist, Ford Motor Company, Dearborn, MI

EEC MEMBERS

Dr. Hilary Inyang, Duke Energy Distinguished Professor and Director, Global Institute for Energy and Environmental Studies, University of North Carolina at Charlotte, Charlotte, NC
Also Member: Research Strategies Advisory Committee

Dr. Michael Kavanaugh, Vice President, Malcolm Pirnie Inc, Emeryville, CA

Dr. John P. Maney, President, Environmental Measurements Assessment, Gloucester, MA

Dr. Michael J. McFarland, Associate Professor, Department of Civil and Environmental Engineering, Utah State University, Logan, UT

OTHER SAB MEMBERS

Dr. Lauren Zeise, Chief, Reproductive and Cancer Haz. Assessment Section, California Environmental Protection Agency, Oakland, CA
Also Member: Research Strategies Advisory Committee

CONSULTANTS

Dr. David Dzombak, Professor, Department of Civil and Environmental Engineering,, Carnegie-Mellon University, Pittsburgh, PA

Dr. Rebecca A. Efroymson, Research Staff Member, Environmental Sciences Division, MS 6036, Oak Ridge National Laboratory, Oak Ridge, TN

Dr. Richard O. Gilbert, Staff Scientist, Battelle Memorial Institute, Washington, DC

Dr. Thomas Holsen, Professor, Department of Civil and Environmental Engineering, Clarkson University, Potsdam, NY

Dr. Makram Suidan, Professor, Department of Civil and Environmental Engineering , College of Engineering, University of Cincinnati, Cincinnati, OH

SCIENCE ADVISORY BOARD STAFF

Ms. Kathleen White, Designated Federal Officer, 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-4559, Fax: 202-501-0582, (white.kathleen@epa.gov)

Ms. Mary Winston, Management Assistant, 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-4538, Fax: 202-501-0256, (winston.mary@epa.gov)

* Members of this SAB Panel consist of
a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.
b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.
c. Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board.
d. Federal Experts: The SAB charter precludes Federal employees from being Members of the Board. "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.

BIOS FOR THE SUBCOMMITTEE

Dr. David A. Dzombak, received his Ph.D. in Civil-Environmental Engineering from the Massachusetts Institute of Technology. He is a Professor of Civil and Environmental Engineering at Carnegie Mellon University, a registered Professional Engineer in Pennsylvania, and a Diplomate of the American Academy of Environmental Engineers. The emphasis of his research is on water and soil quality engineering, especially the fate and transport of chemicals in subsurface systems and sediments, wastewater treatment, *in situ* and *ex situ* soil/sediment treatment, hazardous waste site remediation, and abandoned mine drainage remediation. Dr. Dzombak has served on the National Research Council Committee on Bioavailability of Contaminants in Soils and Sediments, and on various research review panels for the Department of Defense, Environmental Protection Agency, National Institute of Environmental Health Sciences, and National Science Foundation. He has also served on the Board of Directors and as an Officer of the Association of Environmental Engineering and Science Professors; as chair of committees for the American Academy of Environmental Engineers, American Society of Civil Engineers, and Water Environment Federation; and on advisory committees for various community and local government organizations, and for the Commonwealth of Pennsylvania.

Dr. Rebecca A. Efroymson is a Research Staff Member in the Environmental Sciences Division, Oak Ridge National Laboratory, U.S.A. She has a Ph.D. in Environmental Toxicology from Cornell University. Her research experience includes the development of frameworks, toxicity benchmarks and models for ecological risk assessment, with emphases on contaminated soils, air pollutants, plants, microorganisms, and soil invertebrates. She has led and provided technical support for ecological risk assessments of contaminated burial grounds, streams, ponds, and watersheds for U. S. Department of Energy facilities in Oak Ridge, TN. She has contributed ecological components to an EPA multimedia model for air pollutants. She is developing improved tools and methods for ecological risk assessment at petroleum-contaminated sites, including landscape ecological approaches. She has led an ecological risk assessment for land application of sewage sludge in forests and arid ecosystems. She has developed an ecological risk assessment framework for military aircraft overflights (*e.g.*, impacts of noise) and contributed to a broader risk assessment framework for military training and testing activities. Prior to working in Oak Ridge, she was an American Association for the Advancement of Science Diplomacy Fellow at the U. S. Agency for International Development, where she was involved in comparative risk assessment and pollution prevention programs. She also has research experience related to the biodegradation of hydrocarbons.

Dr. Richard O. Gilbert received his Ph.D in Biomathematics from the University of Washington, Seattle, Washington. He is a Staff Scientist in the Statistical and Quantitative Sciences Group at Battelle, Pacific Northwest Division in Richland, Washington. Dr. Gilbert is currently located at the Battelle Washington Office in Washington D.C. He has 32 years experience at Battelle in the statistical design and analysis of environmental studies to assess radionuclide and chemical contamination and cleanup in environmental media, with emphasis on the Nevada Test Site and other Department of Energy sites. He is perhaps most well known for his often-cited reference book *Statistical Methods for Environmental Pollution Monitoring* published in 1987. Dr. Gilbert's recent activities include contributing to the development of EPA guidance documents and teaching short courses on the Data Quality Objectives planning process and environmental statistical design and analysis methods, developing statistical designs for the detection of unexploded ordnance at Department of Defense sites, and assisting with the development of the *Visual Sample Plan* software that helps environmental professionals determine the right number and location of environmental samples. Dr. Gilbert has also managed and conducted Monte Carlo uncertainty and sensitivity analyses of environmental models, with particular emphasis on reconstructing doses received by the public from Iodine-131 emissions from the Hanford Site in Washington State in the 1945-1963 time period. Dr. Gilbert has served as a consultant to EPA Science Advisory Board (SAB) on the Drinking Water Committee, the Statistical Consultation Subcommittee of the Environmental Engineering Committee, and Surface Impoundments Subcommittee of the Environmental Engineering Committee. He has also served as a member of the Health Physics Society's N13.31 Working Group that is writing the American National Standards Institute (ANSI) Standard *Assessment of Radiation Doses Resulting from Plutonium and Americium from Soil.* Dr. Gilbert is a Fellow of the American Statistical Association (ASA) and an elected member of the International Statistics Institute. He was also elected Chair of the Environmental Statistics Section of the ASA in 1995 and was awarded the Distinguished Achievement Award from the Section.

Dr. Thomas M. Holsen, received his Ph.D. in Civil Engineering from the University of California at Berkeley. He is a Professor of Civil and Environmental Engineering at Clarkson University. His research interests include the transport, transformations and fate of hydrophobic organic chemicals, metals, and ions in the atmosphere. Recently he was responsible for determining the importance of dry deposition during the Lake Michigan Mass Balance Study and is currently investigating the transport and deposition of pollutants in New York State, to the Hudson River Estuary and to the Chesapeake Bay. He was a reviewer of several congressionally mandated reports on the importance of atmospheric deposition to the Great Waters and recently testified at a Congressional briefing on the persistent organic chemicals negotiations. He has published extensively on the absolute and relative importance of atmospheric deposition of toxic substances in and their cycling within several large ecosystems. He regularly teaches a graduate course on the transport of pollutants in the environment. He has over 65 publications and has successfully supervised research projects from industrial sources and State and Federal Agencies.

Dr. Hilary I. Inyang is the Duke Energy Distinguished Professor of Environmental Engineering and Science, Professor of Earth Science and Director of the Global Institute for Energy and Environmental Systems at the University of North Carolina-Charlotte. He holds a Ph.D. in geotechnical engineering and materials, with a minor in mineral resources, from Iowa State University. Prior to his current position, he was University Professor, Dupont Young Professor and Director of the Center for Environmental Engineering, Science and Technology

(CEEST) at the University of Massachusetts, Lowell. His research and allied professional activities have focused on waste containment systems, contaminant leachability, soil/contaminant physico-chemical interactions, natural disaster mitigation techniques, rock fragmentation techniques for energy installations and underground space, and energy / environmental policy. His projects have been sponsored by federal agencies such as US. Department of Defense, U.S. Environmental Protection Agency, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, Federal Highway Administration and the United States Agency for International Development. He has authored/co-authored several research articles, book chapters, federal design manuals and the textbook Geoenvironmental Engineering:principles and applications, published by Marcel Dekker. He is an associate editor / editorial board member of eight refereed international journals and contributing editor of three books, including the United Nations Encyclopedia of Life Support Systems (Environmental Monitoring Section). From 1997 to 2001, Dr. Inyang served as the chair of the Environmental Engineering Committee of USEPA's Science Advisory Board. He is a member of the National Advisory Council on Environmental Policy and Technology (Effluent Guidelines Committee) and has served on more than sixty international, national and state science/engineering panels and committees. He is currently the elected president of the newly-formed International Society of Environmental Geotechnology and has co-chaired several international conferences in the US, Brazil, China, Canada and Japan since 1995. Dr. Inyang is a former AAAS/USEPA Environmental Science and Engineering Fellow, National Research Council Young Investigator (1997) and Eisenhower Fellow of the World Affairs Council (1992/93).

Dr. Michael C. Kavanaugh is Vice President and the National Science and Technology Leader for Malcolm Pirnie, Inc. He is a chemical and environmental engineer with over 27 years of consulting experience. He has provided a broad range of consulting engineering services to private and public sector clients both in the U.S. as well as western Europe and parts of Asia. His areas of expertise include hazardous waste management, site remediation, strategic environmental management, risk analysis, water quality, water treatment, industrial and municipal wastewater treatment and technology evaluations including patent reviews. Dr. Kavanaugh has extensive litigation experience, and has been a designated expert in his areas of expertise in numerous cases. He has also been selected to serve as a neutral technical mediator or arbitrator on several large litigation cases. Dr. Kavanaugh has been project engineer, project manager, principal-in-charge, technical director or technical reviewer on over 200 projects covering a broad range of environmental issues. Dr. Kavanaugh has prepared over 35 peer reviewed technical publications, edited two books, and has made over 100 presentations to technical audiences as well as public groups. Dr. Kavanaugh was the Chair of the Water Science and Technology Board of the National Research Council from 1989 to 1991. During this time, the Board managed or developed over 15 projects related to all aspects of water resources management. From 1994 to 2000, he chaired the Board on Radioactive Waste Management, a Board responsible for evaluating the Nation's strategies for management of radioactive waste. He recently served on the Board of Scientific Counselors, advising the Assistant Administrator of the Office of Research and Development in EPA. He is currently on the Editorial Advisory

Board for the Environmental Science and Technology Journal, published by the American Chemical Society. He was elected to the National Academy of Engineering in 1998.

Dr. Kavanaugh has a B.S. and a M.S. in Chemical Engineering from Stanford and the University of California, Berkeley, respectively. He received his PhD in Civil/Environmental Engineering from UC Berkeley in 1974. He is a registered professional engineer in several states and is a Diplomate of the American Academy of Environmental Engineers, a designation that requires regular confirmation of professional standing.

Dr. Byung R. Kim received his Ph.D. in Environmental Engineering from the University of Illinois, Urbana, IL. He is now Staff Technical Specialist in the Chemistry and Environmental Science Department of Ford Research Laboratory, Dearborn, MI and is a professional engineer. His current research interest is in understanding various manufacturing emission issues (physical/chemical/biological waste treatment processes and the overall environmental impact of manufacturing processes). He also has worked on the adsorption of organics on activated carbon and water quality modeling. He has served on EPA SAB Environmental Engineering Committee and was Editor of the Journal of Environmental Engineering, American Society of Civil Engineers (ASCE). He served on the advisory board for the National Institute of Environmental Health Superfund Basic Research Program at the University of Cincinnati. He received a Richard R. Torrens Award for editorial leadership from ASCE and two Willem Rudolfs Medals from Water Environment Federation on his publications.

Dr. John P. Maney received his Ph.D. in Analytical Chemistry from the University of Rhode Island, Kingston, Rhode Island. Dr. Maney has over 30 years experience in analytical chemistry and over 20 years experience in environmental sampling, environmental analysis and data quality issues. He has directed and founded environmental testing laboratories, managed numerous government contracts and subcontracts, which have addressed among other issues, analytical method development, analytical method validation, hazardous waste sampling, and authoring of guidance. Dr. Maney has chaired and participated in the consensus standard process for USEPA/ASTM accelerated standards regarding sampling, subsampling and data quality. For the last 11 years he has been president of Environmental Measurements Assessment (EMA), a consulting company that focuses on sampling, analytical and quality issues.

Dr. Michael J. McFarland received his bachelors' degree in Engineering and Applied Science from Yale University, his masters' degree in Chemical Engineering from Cornell University and his Ph.D. in Agricultural Engineering from Cornell University. Dr. McFarland is currently an associate professor in the Department of Civil and Environmental Engineering at Utah State University where his research interests are focused in the areas of air quality management, industrial waste management and pollution prevention. Dr. McFarland has served on numerous federal, state and local environmental engineering and public health advisory committees for the US Dept. of Defense, US Environmental Protection Agency, US Dept. of Energy, National Science Foundation, Utah Dept. of Environmental Quality and Cache County, Utah. Dr. McFarland has authored or coauthored over fifty publications in the field of environmental engineering including engineering textbooks, workbooks, journal articles and conference proceedings. Dr. McFarland is a registered professional engineer in the State of Utah and currently holds Grade IV operator certifications for both wastewater and water treatment. Dr. McFarland is a member of the American Academy of Environmental Engineers (AAEE), the Water Environment Federation (WEF), the Society for Risk Analysis, National Biosolids Partnership and the Association of Environmental Engineering and Science Professors (AEESP).

Dr. Makram T. Suidan, received his Ph.D. in Environmental Engineering from the University of Illinois. He is now the Herman Schneider Professor of Environmental Engineering and Director of the Environmental Engineering and Science Program at the University of Cincinnati. Dr. Suidan's principal research interests are in the areas of physical, chemical and biological treatment of hazardous wastes, anaerobic and aerobic biological treatment of municipal and industrial wastes, applications of membrane technology to biological treatment systems, biological treatment of gas phase pollutants, and bioremediation of spilled oil and hydrocarbons. Much of his work focuses on the development of unit processes for the treatment of difficult to handle wastewaters. For example, major effort in Dr. Suidan's laboratory is directed towards the development of low-cost ex-situ processes for the biological treatment of gasoline oxygenates. These processes rely on membrane technology to harvest difficult to grow microorganisms. Dr. Suidan has authoree and co-authored over 170 refereed journal articles and over 160 conference proceedings. Dr. Suidan was the 1996 Association of Environmental Engineering and Professors Distinguished Lecturer and is the recipient of many honors and awards for his research. He was editor in chief for the Journal of Environmental Engineering, ASCE and Chair of the Science Advisory Committee for one of EPA Hazardous Substances Research Centers. He has served on a number of panels for the NSF, EPA, and DOE.

Dr. Lauren Zeise is Chief of Reproductive and Cancer Hazard Assessment within the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. She has served in that position since 1991. She first came to state service in 1988. In that position she oversees a variety of the state's cancer, reproductive and ecological risk assessment activities.

Her group evaluates and provides advice on cancer, reproductive and ecological risks posed by environmental contaminants, and develops policy guidance for conducting such assessments. The group also conducts scientific evaluations mandated by Proposition 65 and evaluates the risks from use of drugs, cosmetics, gasoline and other products. It is also developing the state's guidance on evaluating risks stemming from the exposure of children, infants and fetuses to cancer-causing substances. She chaired the California's Comparative Risk Project Human Health Committee, and oversaw the external review of the State's risk assessment practices, policies and guidelines. She has authored over 200 reports on environmental health risks for the State of California.

Dr. Zeise has been involved in the evaluation and review of a variety of risk assessment issues. She has served on various committees of the EPA's Science Advisory Board (SAB), National

Institute of Medicine, National Research Council (NRC), National Toxicology Program Board of Scientific Counselors, and the former Office of Technology Assessment. Currently she serves on the SAB Research Strategies Advisory Committee, NRC Committee on Air Quality Management in the United States, NRC Committee on Toxicology, IOM Committee on Assessment of Wartime Exposure to Herbicides in Vietnam and EPA FQPA Science Review Board. She is a member and fellow of the Society of Risk Analysis and is on the editorial board for the Society's journal. The National Cancer Institute Smoking and Tobacco Smoke Monograph *Health Effects of Environmental Tobacco Smoke* was conceived and developed under her editorial direction. She is coauthor of the recently released International Agency for Research on Cancer monograph *Quantitative Estimation and Prediction of Cancer Risk*. Her research has focused on cancer risk assessment methodology and applications including her doctoral research. She received her doctorate from Harvard University in 1984.

APPENDIX C: SUMMARY OF ELEMENTS OF EPA QUALITY SYSTEM

The Agency's quality **policy** is consistent with ANSI/ASQC E-4 and is defined in EPA Order 5360.1 CHG 1 (1998), the Quality Manual and the organizational components designed for policy implementation as described by the Agency's **Quality System** (EPA QA/G-0). The quality system provides the framework for planning, implementing, and assessing work performed by the organization for carrying out required quality assurance and quality control.

EPA has a comprehensive system of tools for managing its data collection and use activities to assure data quality. The **management tools** used in the organizational level of EPA Quality System include Quality Management Plans and Management System Reviews. The **technical tools** used in the project level of EPA Quality System include the Data Quality Objectives Process, Quality Assurance Project Plans, Standard Operating Procedures, Technical Assessments, and Data Quality Assessment.

At the management level, the **Quality System** requires that organizations prepare **Quality Management Plan** (QMP). The QMP provides an overview of responsibilities and lines of authority with regards to quality issues within an organization. Therefore, not only does ETV have a QMP, but the verification partners and subcontractors are required to develop and implement their own QMPs. The ETV program calls these documents **Quality and Management Plans.**

Organizations with **QMPs** review their own performance and develop **Quality Assurance Annual Report and Work Plans** (QAARWP) that provide information on the previous year's QA/QC activities and those planned for the current year. The QAARWP functions as an important management tool at the organizational level as well as at the Agency-wide level when QAARWP supplied information is compiled across organizations.

At longer multi-year intervals EPA conducts periodic **Management System Reviews** for organizations. An **MSR** consists of a site visit; a draft report that details findings and recommended corrective actions, consideration of the reviewed organization's formal response to the draft report and the authoring of a final report.

At the project level, the data life cycle of planning, implementation and assessment becomes important. The data life cycle begins with systematic planning. EPA recommends that this required planning be conducted using the **Data Quality Objectives (DQO) Process**. The DQO process includes seven steps:

1. State the problem
2. Identify the decision
3. Identify the inputs to the decision
4. Define the study boundaries

5. Develop a decision rule
6. Specify tolerable limits on decision errors
7. Optimize the design

The **Quality Assurance Project Plan (QAPP)** is the principal output of the **DQO** process and is the project-specific blueprint for obtaining data appropriate for decision-making. The QAPP translates the DQOs into performance specifications and QA/QC procedures for the data collectors. In the ETV program the **QAPPs** are known as **Test/QA plans**; these provide a second level of assurance that the technology verification test will be performed in a matter to generated objective and useful information of known quality.

The final step in the data life cycle is the **Data Quality Assessment (DQA)** which determines whether the acquired data meet the assumptions and objectives of the systematic planning process that resulted in their collection. In other words, the DQA determines whether the data are usable because they are of the quantity and quality required to support Agency decisions.

ACRONYMS & GLOSSARY

BDL: Below Detection Limit
CAA: Clean Air Act
CWA: Clean Water Act
DAF: Dilution Attenuation Factor
DQO: Data Quality Objectives
EDF: Environmental Defense Fund
EEC: Environmental Engineering Committee
EPA: Environmental Protection Agency
EPACMTP: EPA Composite Model Leachate Migration with Transformation Products
EQL: Estimated Quantitation Limit
HELP: Hydrologic Evaluation of Landfill Performance
HQ: Hazard Quotient
IDL: Instrument Detection Limit
ISCST: Industrial Source Complex Short Term
IWAIR: Industrial Waste Air Model
IWEM: Industrial Waste Exposure Model
LDPFA Land Disposal Program Flexibility Act
LDR: Land Disposal Restriction
MDL: Method Detection Limits
ML: Minimum Level
ND: Non Detect
OSW: Office of Solid Waste
PQU: Present but quantity unknown
QA: Quality Assurance
QAPP: Quality Assurance Project Plan
QC: Quality Control
RCRA: Resource Conservation and Recovery Act
SAB: Science Advisory Board
SIC: Standard Industrial Classification
TSS: Total Suspended Solids
Uncertainty: incompleteness of one's knowledge about an unknown quantity whose true value could be established if a perfect measuring device were available. For example, the dispersion factors used in ambient air quality and groundwater models are uncertain because of the simplifying assumptions that are typically used to describe the fate and transport of emitted pollutants.
Variability: temporal, spatial or inter-individual differences in the value of an input parameter. For example, the body weights or breathing rates for members of a population will span a range which can represented fairly accurately by a distribution. The degree of variability in any quantity is influenced directly by the averaging time, geographic area or other characteristics of the population under consideration.