October 1, 2009

Dr. Gary Banks
ORD Docket
Environmental Protection Agency
Mailcode 28221T
1200 Pennsylvania Avenue, NW
Washington DC 20460

SUBJECT: COMMENTS ON US EPA WHITE PAPER, "USING PROBABILISTIC METHODS TO ENHANCE THE ROLE OF RISK ANALYSIS IN DECISION-MAKING WITH CASE STUDY EXAMPLES"

Dear Dr. Banks:

The United States Nuclear Regulatory Commission (NRC) has reviewed and is providing comments on the United States Environmental Protection Agency's (EPA's) White Paper "Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision-Making With Case Study Examples" made available for public comment via *Federal Register* notice (74 FR 41695) dated August 18, 2009. The NRC supports the use of risk-informed and performance-based regulation. A key tenet of this regulatory philosophy is the use of risk-insights (that may be generated from probabilistic analysis) and other information to focus more licensee and regulatory attention on those issues most important to health and safety. The Commission's commitment to risk-informed regulation was formalized in a Policy Statement (60 FR 42622) issued on August 16, 1995, to expand the use of probabilistic risk assessment (PRA) "in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." The NRC continues to develop guidance, fund research, develop tools, and collect data to support the use of PRA in agency decision-making and appreciates the efforts of and challenges faced by EPA in similarly advancing the use of probabilistic risk assessment in its regulatory matters.

The NRC looks forward to continuing to review EPA documentation and sharing information related to use of PRA as both agencies continue to develop the tools and informational resources needed to support and advance the use of PRA methods and analysis to inform agency decision making.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding our comments, please feel free to contact me at 301-415-6663 or Christepher.Mckenney@nrc.gov.

Sincerely,

/RA/

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Comments on the U.S. Environmental Protection Agency's White Paper "Using Probabilistic Methods to Enhance the Role of Risk Analysis in Decision-Making with Case Study Examples"

General

1. Given the large range of decisions that could be made across the Environmental Protection Agency (EPA) offices and programs, it would be helpful to include in introductory chapters a general description of the types of decisions that are being made at EPA that could benefit from a Probabilistic Risk Assessment (PRA) (e.g., to perform cost-benefit analyses for rulemaking; to compare alternatives for remediation; to evaluate compliance against regulatory standards; or to optimize sample collection) and to discuss whether PRA may be more or less suited for these various applications (see last bullet on the bottom of page 21). A similar situation exists for NRC, the agency recognizes that the state of the art in PRA methods is more advanced and/or more amenable to certain regulatory programs (e.g., nuclear reactors and high-level waste disposal). Thus, when the Commission issued its Policy Statement on PRA in 1995, it expected that the transition to a risk-informed regulatory framework across all regulatory programs would be incremental and that the extent to which PRA would be used in various regulatory programs variable.

2. There appears to be a lack of specificity regarding how statistical measures of uncertainty should be considered in making decisions (e.g., evaluating compliance against a regulatory limit). While lack of specification provides more flexibility to the regulator and regulated, it could also lead to the inequitable treatment of risk information from site to site and undermine confidence in agency decision making. For example, the U.S. Nuclear Regulatory Commission (NRC) guidance advocates use of the peak of the mean dose generated from probabilistic risk assessment for decommissioning dose modeling analyses, as well as consideration of the 95th percentile dose for low-level waste disposal facilities when evaluating compliance with regulatory criteria (NRC, 2000; and NRC, 2006). Having recommended metrics in guidance makes it easier for the decision maker and the regulated community to more consistently apply risk information obtained from PRA, providing stability in the regulatory process.

The NRC recognizes differences in the manner in which EPA and NRC regulate (e.g., use of a risk range versus use of a specific dose criterion) which may lead to significant differences in the way PRA is used to make certain decisions. In fact, in several instances the White Paper implies that there is some flexibility in establishing a metric and variability between programs with respect to the usefulness of PRA and how the results are to be interpreted.

- Page 6, Section 1.3, second paragraph, Statements are made that in the face of uncertainty decision-making is determined not only by science but by Agency policy and where not prohibited by statute, the relative costs and benefits of regulatory alternatives may be considered in making decisions. But it is not clear what policies and statutes may limit the utility of PRA or cost/benefit analysis. Examples could be provided.

- Page 7, Section 1.4, sixth bullet, a statement is made that a decision maker often asks, "What is the percentile of the population to be protected?" It is not clear if there are specific recommendations regarding who is to be protected in EPA guidance or regulations.

Enclosure

- Page 13, Section 2.2, bullet 4, Statements are made that PRA might be most useful "When significant equity issues are raised by inter-individual variability." However, it is again not clear what individuals are to be protected.

- Page 16, Section 2.8, States that binary decisions may be perceived to be more readily answered with deterministic analysis as opposed to PRA that present a range of uncertainty. This statement recognizes the difficulty in making decisions when a range of possible outcomes is presented but offers no specific details on how this information should be synthesized or interpreted to make a decision.

- Page 25, fourth paragraph, Discusses evaluation of central tendency and reasonable upper bounds of exposures, effects, and risk estimates, such that the estimates could be for an actual individual in the population of interest rather than a hypothetical Maximally Exposed Individual (MEI). This discussion seems to imply that there is some regulatory flexibility in evaluating risks to potential receptors (does not necessarily have to be the MEI) but introduces ambiguity in the regulatory and decision criteria that might be used in its stead.

- Page 32, "Resolution" definition, Discusses an example when an evaluation of upper-bound risks may necessitate a geographical-information-system-based modeling framework precise enough to model exposures to individual receptors. One might argue that the necessary level or scale of the analysis would be dictated by regulatory criteria (e.g., maximally exposed individual) and depending on the endpoint, one form of analysis may be more appropriate then another (i.e., deterministic bounding versus probabilistic analysis) and/or would dictate what metrics would be used if a PRA is selected. It is not clear to what extent regulatory criteria (and modeling objectives) are prescribed or if there is some flexibility in evaluating individual risk.

- Page 58, Case Study 4, second paragraph, Discusses use of the 95th percentile regulation for lower tiers that do not include percent crop treated to use of the 99.9th percentile for the more refined assessments which would include percent of crop treated information, but the basis for these percentiles is not provided and it is not clear if these percentiles are specified in regulation or guidance.

- Page 60, Case Study 5, first paragraph, Discusses results of deterministic analysis that exceeds regulatory benchmarks but does not indicate what these benchmarks are or provide information on whether these benchmarks constitute regulatory requirements. The "Results of the Analysis" section presents information on the central tendency individual and reasonable maximum exposure individual, but it is not clear if decisions are based on protection of one or both of these individuals and at what percentage of the PRA distribution of results are these individuals expected to be evaluated.

Although there are obvious differences in the manner in which various agencies regulate (and even intra-agency program differences), it would help to clarify if evaluation of specific PRA metrics are recommended in EPA guidance (e.g., percentile of the population to be protected; mean or 95th percentile of exposure distribution) when making certain regulatory decisions (e.g., making cost-benefit decisions, or decisions regarding regulatory compliance); if certain

constraints (agency policy or statute) limit the use of PRA in EPA decision making; and if there is some flexibility in applying specific metrics to certain problems.

3. It appears that the focus of most of the PRA case studies presented in the EPA White Paper is on a subset of the components of an environmental risk assessment. Consideration of uncertainty and variability in all aspects of the assessment (i.e., initiating events/release, fate and transport, exposure, and consequences) may reveal that the risk is dominated by certain components of the environmental risk assessment model that may not be immediately intuitive. Factors such as uncertainty in scenarios being evaluated; features, events and processes that may occur in the future; and fate and transport of contaminants in the environment may have relatively large uncertainties. While uncertainty in these components of the environmental risk assessment is recognized (see bulleted examples below), more emphasis appears to be placed on exposure and consequence modeling in the textual examples and Case Studies.

- Page 23, bullet four, States that "There may be mismatches in the temporal and spatial resolution of each model, which confound the ability to propagate variability, and uncertainty from one model to another," recognizing the challenges of integration, and coupling of models.

- Page 27, Section A.3.1, "Structural Uncertainty in Scenarios" Section, Discusses important components of environmental risk assessment models (e.g., source definition, transport, exposure routes, etc.) that constitute forms of structural uncertainty but states that there are no formalized methodologies for dealing with uncertainty and variability (and that qualitative approaches to addressing these uncertainties are common).

- Page 27, Section A.3.1, "Coupled Models," Discusses components of an environmental risk assessment model that have varying spatial and temporal scales that are difficult to integrate and can introduce a significant source of structural uncertainty but presents no clear path on how this uncertainty can be addressed.

- Page 60, Case Study 5, "Probabilistic Analysis" Section, last sentence, Discusses the use of mathematical models of environmental fate, transport, and bioaccumulation of polychlorinated biphenyls (PCBs) in the Hudson River to forecast changes in PCB concentrations over time. However, it is not clear that uncertainty in PCB concentrations were propagated over time and how the uncertainty in PCB concentrations compares to uncertainty in angling duration and other exposure factors which appear to be the focus of the Case Study.

If sensitivity of model results to uncertainty and variability inherent in all aspects of environmental risk assessment modeling is not adequately studied, sensitivity analysis results may be misleading and PRA results of limited utility. Because the nature EPA decision making may differ markedly from other agencies (due to, for example, programmatic differences in risk assessment methods or end points evaluated), the apparent emphasis on certain aspects of environmental risk assessment modeling may be warranted. Additional discussion regarding the relative uncertainties expected to be introduced by various components of the environmental risk assessment model for various EPA applications and/or an explanation on why emphasis seems to be placed in particular areas of the risk assessment would be beneficial.

4. In many cases, in order to adequately perform PRA to inform decision making, sufficient resources are needed to (i) analyze and synthesize data into forms that are of use to a risk analyst and (ii) create an infrastructure to more efficiently implement PRAs. In fact, these limitations and challenges to the use of PRA are recognized by EPA. For example, it was noted in the EPA Policy for Use of Probabilistic Analysis in Risk Assessment (1997) that additional study was needed to evaluate uncertainty in dose response for human health risk assessments. The White Paper discusses the upfront increase in resources needed to perform PRA (bottom of page 16), but recognizes the longer-term benefit of development of standardized approaches and/or methods that can lead to the routine incorporation of PRA in Agency matters.

The NRC has faced similar challenges in developing a framework and tools to increase the use of PRA in its regulatory programs. For example, NRC contracted Sandia National Laboratories and Argonne National Laboratory to provide probabilistic capabilities in the DandD and RESRAD decommissioning codes, respectively, including development of associated parameter distributions in the late 1990s (SNL, 1999; ANL, 2000).

A summary listing or examples of the types of data that are routinely collected or are planned to be collected and analyzed by the EPA for inclusion in environmental risk assessments; and the types of tools and other resources that are currently being developed to aid in implementation of PRA analyses in the future would be beneficial.

5. A stated goal of the EPA White Paper is to explain how EPA can achieve a broader use of probabilistic methods and address uncertainty and variability by capitalizing on the wide array of *tools* and methods that comprise PRA. However, while significant information is provided on methods that comprise PRA, less information is provided on the tools of PRA (e.g., off-the shelf software for performing PRA or EPA sponsored codes specifically designed to execute probabilistic analysis). While this omission may have been intentional, it would be helpful if additional examples of “off-the shelf” software and additional details on other tools being used to perform these types of analyses is included.

<u>Specific</u>

6. Page 9, Section 1.7, second paragraph, A statement is made that deterministic risk assessments provide estimations of exposures and resulting risks that address uncertainty and variability in a qualitative manner. Deterministic analyses can, to a certain degree, study uncertainty and variability in model results in a quantitative fashion, although there are obvious limitations to this approach. For example, robust sensitivity analysis can be conducted and a conscious decision made to select a certain parameter value that is expected to represent central-tendency or pessimistic estimates of risk in a deterministic assessment. Statements in the text regarding the limitations of deterministic analysis and implications that these types of analyses are not science based should be checked and carefully worded (see also page 16, Section 2.8, statement that decisions should be based on the best available science). As discussed in the White Paper, in some cases deterministic analyses are adequate and while they may not necessarily reflect the best available science (because best available science is not warranted), they may still be technically defensible and scientific in their approaches.

7. Page 12, Section 2.1.1, While the 1997 EPA Policy on Probabilistic Analysis in Risk Assessment (EPA, 1997) states that additional study is needed to apply PRA to dose effects (and this policy does not appear to be superseded), several examples are included in this paragraph regarding use of PRA in this manner. Please clarify EPA's current policy and progress in this area.

8. Page 13, first paragraph on "Model Uncertainty" and page 23, Section 3.4, bullet 2, These sections of the White Paper provide information about model uncertainty and challenges faced in evaluating this type of uncertainty. It should be noted that while model uncertainty and abstraction are important components of uncertainty that should be evaluated, it would be preferable to spend adequate resources up front making sure that the models used to perform the risk assessment are appropriate for their intended application (e.g., that the appropriate level of complexity is captured in the models) and that uncertainty is propagated in the appropriately-selected model. However, in the case of complex systems that must necessarily be simplified and that are difficult to validate using existing data, use of multiple models or scenarios may be warranted and uncertainty in these models should be addressed. While evaluation of model uncertainty is an area in need of continued research, guidance is currently available on the treatment of model uncertainty that can be referenced in this section (e.g., see for example Meyer, 2004).

9. Page 13, Section 2.2, Suggest adding a bullet regarding the utility of PRA when model complexity makes it difficult to assess the conservatism of a particular selection of parameter values in a deterministic assessment.

10. Page 21, Section 3.1, Statements are made regarding the utility of PRA in evaluating various risk management strategies and alternatives; and that sensitivity analyses can be used to identify influential knowledge gaps. However, no information is provided on how probabilistic analyses are superior in these areas compared to deterministic analyses and/or when it might be appropriate to use deterministic analyses.

11. Page 24, second paragraph, last sentence, Provide an example of when it would be appropriate to refine an assessment objective depending on the availability of information. It would seem that the assessment objective would be based on some regulatory metric and not necessarily the availability of information. If insufficient information is available one might not be able to make a decision or might manage uncertainty with conservative assumptions.

12. Page 24, "Levels of Analysis" box, The text should clarify and provide a basis for the ordering of "levels of analysis" (e.g., why is expert elicitation listed last or sensitivity analysis [which can take on many forms] listed first?). The text should note that sensitivity analyses can be either deterministic or probabilistic. It is not clear why Monte Carlo analysis of variability is limited to exposure data and human health and ecological effect data. Define or provide examples of "decision uncertainty analysis" and "geospatial analysis" and provide a basis for where they fall in the ordering of analyses.

13. Page 25, third paragraph, "In such a situation, depending on the resource implications of risk management, it might be appropriate to proceed with a more refined, or higher level, analysis. If the cost of intervention is less than the cost of further analysis, then it may be appropriate to simply proceed to the risk management decision as a preventive measure that is

also expedient. In some deterministic assessments, for instance, for ecological risks, the assumptions are not well assured of conservatism and the estimated risks might be biased to appear lower than the unseen actual risk." The last sentence above introduces a separate thought and potential problem with respect to deterministic analyses that should be developed on its own (issue with deterministic analyses not clearly being conservative in the face of great uncertainty). Additionally, the thought that additional ecological modeling could be more costly then remediation (making remediation potentially a more attractive option) could be more clearly made in the example. Suggest rewording the sentence for clarity and/or providing a better example.

14. Page 31, Appendix B: Glossary, Suggest adding PRA-related terms to the glossary that are used but not well-defined in the text of the White Paper: (i) dose response, (ii) target population, (iii) hazard identification, (iv) reference dose, (v) hazard index, (vi) decision uncertainty, (vii) geospatial analysis.

15. Page 34, "Sensitivity Analysis" definition, Suggest listing the different types of sensitivity analysis and sensitivity analysis techniques.

16. Page 53, Case Study 1, Explains how sensitivity analysis was used to determine key variables for population exposure variability to arsenic in chromated copper arsenate pressure-treated wood. The study found that data needed to be collected on the amount of dislodgeable residue that is transferred from the wood surface to a child's hand upon contact and the amount of dislodgeable residue that exists on the wood surface. It would seem that these parameters would change over time as the integrity of the pressure treated wood diminished. This would be an example of a scenario or structural model uncertainty that might be the most risk significant aspect of the exposure modeling, but if not considered, would not be evaluated as part of the PRA (see general comment 3 above).

17. Page 62, Figure 1, It is not clear why this plot which shows the uncertainty in risk estimates to discrete population percentiles (representing inter-individual variability) is not an example of a 2D Monte Carlo analysis (appears to be [albeit a more discrete] version of a 2D Monte Carlo analysis result similar to what is presented in Figure 2 on page 26). On the other hand, the figure on page 73 does not seem to clearly present results of a 2D Monte Carlo analysis related to ozone exposure with only uncertainty in model inputs apparently being presented. Suggest including more illustrative examples of the characteristics of 2D Monte Carlo analysis in the Case Study examples.

<u>Editorial</u>

1. Check consistency of the use of the hyphen in decision-maker, decision-making throughout the document. The Chicago Manual of Style indicates that decision making is the noun and decision-making is the adjective. While there are probably multiple correct uses, the document should be consistent in its application.

2. The reference Cullen and Frey 1999, is used more heavily than any of the other references throughout the document although there are many other references. It might be appropriate but the heavy reliance on this particular reference was noticeable.

3. Page 5, 1st paragraph, “One can use probability (chance) to quantify the frequency of occurrence or the degree of belief in information.” This statement can be clarified to avoid an incorrect interpretation. Probability is not equivalent to frequency. Probability is a value between 0 and 1. Frequency can be greater than 1.

4. Page 6, last paragraph, A statement is made that “Increased uncertainty can make it more difficult to …” perform a cost-benefit analysis. Suggest re-writing for clarity (i.e., what is the increase in uncertainty in relation to?).

5. Page 14, Suggest deleting the dates that introduce the listed items as the dates are already included in the references at the end of the bullets.

6. Page 14, Section 2.4, second paragraph, Introduce the acronym SAB used on the following page.

7. Page 15, Section 2.7, Check bullets to ensure parallelism in punctuation and sentence structure.

8. Page 27, Section A.3, This paragraph is redundant with the second paragraph on page 25.

9. Page 32, first paragraph, last sentence, Suggest providing a better example then “logistic models” which has not been defined and may not be obvious to a reader.

10. Page 32, “Resolution” definition, Check sentence stating “If the grid size selected is too small…,” should this be “large” not “small” or should reference to the scale be small (as opposed to grid size).

11. Page 34, “Uncertainty” definition, Delete last sentence which appears to be a reviewer comment.

12. Page 53, first paragraph, first sentence, Should the reference to Group 2 assessment be Group 3 Assessment (for Case Study 9—see Page 51).

13. Page 57, Should Case Study 9 actually be Case Study 5 (see Page 51).

14. Page 63, title caption, Should be “report” not “reprot.”

References

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Meyer, P.D., et. al., 2004. "Combined Estimation of Hydrogeologic Conceptual Model and Parameter Uncertainty," NUREG/CR-6843, Pacific Northwest National Laboratory and University of Arizona, March, 2004.

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