

Peer Reviewer Comments on the EPA Probabilistic Risk Assessment Documents

Scott Ferson	Annette Guiseppi-Elie	Dale Hattis	Igor Linkow	John Toll
<p>1a. Have the papers provided a balanced view of the usefulness of PRA in decision-making, and if not, describe how it is unbalanced?</p>				
<p>References to Frey (22 papers in the Bibliography) is too much; improve writing style (e.g., prose, list seriality, consistency in formatting and punctuation).</p>	<p>Too much on human health and exposure issues; include a section on ecological assessments and toxicity parameters (e.g., upcoming changes to the IRIS process to reflect that toxicity criteria should not be treated as single point estimates). Did not adequately address the utility of PRA to communicate results. PRA tools incorporate variability and uncertainty; Section 3.3 identifies both of these areas as needing more guidance.</p>	<p>Update with the latest recommendations from the NRC 2009 (e.g., redefinition of RfD, facilitate inclusion of traditional threshold-type toxicity effects in benefits estimates for regulatory impact analysis) and update references since 2008, include some of my references. Note that all PRA techniques are not off-the-shelf tools ready for prime time. Both variability and uncertainty contain model and scenario ‘errors’; many PRA tools are ready to be used but these need further refinement. Description of how PRA can be integrated into Agency decisions is weak. Illustration of case study work (Appendix 4) very limited in main body of document. More emphasis is needed linking PRA with specific decisions.</p>	<p>In the managers’ document, too much emphasis on regulatory decisions, while real decisions involve alternative courses of action. Page 3 in the managers’ document refers to alternatives but no discussion is provided. There has been little progress over the past 20 years on dealing with uncertainty in quantitative environmental risk analysis.</p>	<p>Too much attention on PRA principles, while how PRA can affect decision making is weak. Documents do not provide a balanced view of the usefulness of PRA in decision making. Highlight that probabilities are conditional. Place greater emphasis on the costs of ignoring uncertainty.</p>
<p>RESPONSE</p>				
<p>The papers’ references since 2008 have been updated. Relevant editorial changes were made to the papers.</p>	<p>Relevant changes about ecological assessments, and variability and uncertainty have been made in the papers. For example, a table comparing human health risk assessment (HHRA) and ecological risk assessment (ERA) has been</p>	<p>The papers’ references since 2008 have been updated. Case studies are referenced in the main body of the papers. More information was added about how PRA can be integrated into Agency decisions.</p>	<p>The managers’ paper title has been revised as “Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions,” and the assessors’ paper as the</p>	<p>Relevant sections in both papers, such as “When is Probabilistic Risk Analysis Applicable or Useful,” and “When Should One Consider Using PRA?” have been revised.</p>

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	added.		“Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies.” The text and tone in both papers have been changed to indicate that they are reference, not guidance documents.	
<p>1b. Are there additional advantages or disadvantages of using PRA that were not identified and should be included? Please provide a description of any additional advantages or disadvantages you have identified.</p>				
<p>A significant PRA disadvantage not mentioned is that it requires assumptions about stochastic dependence among all of the distributional inputs. Middle paragraph, page 2, managers’ document, discusses PRA advantages informing about specific segments of the population at risk. Yet, it neglects to discuss the variability or uncertainty associated with these impacts. PRA must avoid the ensemble problem.</p>	<p>One PRA advantage not explicitly identified is the potential to be used for comparing across multiple stressors. A key advantage is the use of probabilistic tools for communication. However, if communication is an objective, then this needs to be identified early in the project and an appropriate plan developed to ensure success.</p>	<p>The main disadvantage not fully articulated is variability and uncertainty.</p>	<p>No comment.</p>	<p>Using PRA can lead to wasteful expenditures without tight project controls to keep analysts focused on uncertainties. There is no guarantee that PRA will be considered by regulatory decision makers. PRA is incompatible with one-off decision processes. For example, if parties are seeking a final remedy rather than an interim remedy, and want to minimize long-term monitoring expenses, then a PRA might not be appropriate. PRA can be used to obfuscate risk management decisions.</p>
<p>RESPONSE</p>				
<p>Relevant changes about dependence, variability and</p>	<p>Relevant changes about multiple stressors and the</p>	<p>Relevant changes about variability and uncertainty were made in the</p>	<p>No response necessary.</p>	<p>Additional information on the challenges facing EPA with</p>

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uncertainty, and the ensemble problem were made in the papers.	importance of communication were made in the papers.	papers. The papers' references were updated.		regard to PRA and the need for a methodical approach to decision analysis has been added to the papers.
<p>1c. Are there criteria or considerations that were not adequately addressed for determining whether or not probabilistic methods may be useful to characterize uncertainty and variability and support EPA decision making? If so, please describe such considerations.</p>				
<p>The documents misrepresented why there is confusion about how much data PRA requires. The amount of data needed is not a "controversy" but rather a function of the probabilistic approach; different approaches (e.g., Monte Carlo, probability bounding) require different amounts of data. These differences should be spelled out for risk managers.</p> <p>The subjectivist interpretation of probability needs to be addressed. When a subjectivist interpretation of probability is allowed, or when a probability-bounding approach is employed, then one can do an assessment with whatever data that happens to be convenient. This was not given attention in the documents. Cite recent EPA documents on expert elicitation.</p>	<p>Documents appear to be adequate in identifying the technical merits and utility of PRA to address uncertainty and variability for decision making. These arguments have been known and articulated by the Agency and others for well over 10 years. PRA techniques encourage the use of all available data, and this is a point that the documents may emphasize better.</p>	<p>There is not adequate presentation of how uncertainty and variability ideas factor into risk management choices under different scenarios. The most helpful introduction to these issues is a series of my papers.</p>	<p>The greatest possible effectiveness of governmental agencies in using limited resources is to achieve health and safety goals ("Do the very best you can") and be guided by the principle of "first, do no harm" from medical ethics. An implicit decision analysis of the costs of PRA versus its benefits has to be made to decide if PRA is worth pursuing.</p>	<p>The previous comments address this charge question. Paraphrasing: 'Parties should consider whether the decision process is one-off (i.e., building step-wise toward a final decision) or iterative and adaptive. If it's one-off, then PRA should be used with caution. If it's the latter, then PRA should be mandatory.' Decision makers should be prepared to bring in external peer reviewers if and when it becomes apparent that PRA is being used to obfuscate decisions. Responsible parties should be wary about investing in PRA until they receive reasonable assurances that the PRA will be appropriately considered by regulatory decision makers. No one should engage in PRA unless and until the PRA is designed to assess confidence in decisions (as opposed to uncertainty in underlying processes and data).</p>

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RESPONSE				
References such as the EPA Expert Elicitation Task Force White Paper and others have been added to the papers.	Descriptions of PRA techniques and the use of all available data have been integrated into the papers.	Relevant changes about variability and uncertainty were made in the papers.	Changes in the papers have been made regarding the costs and benefits of conducting a PRA.	As described above, relevant changes have been made in the papers regarding the need to better understand the decision making process and when PRA can be effectively used.
1d. Considering risk managers are a major audience for these documents, especially for the “managers’ summary” document, what additional information should be included in the document to aid them in decisions regarding the application of PRA?				
<p>After Figure 3, page 7, add figures depicting a cumulative distribution function, a complementary cumulative distribution, and a density function together for comparison. There should likewise be some graphical illustrations to accompany many, if not all, of the case studies.</p> <p>The managers’ summary should also include highly abbreviated explanations of the controversy of subjectivism and the cost of elicitation. It is fair to let them know the trouble they take on as well as the benefits they enjoy from adopting PRA.</p>	<p>The information and discussion in the “managers’ summary” is better articulated and presented than in the main paper. I would suggest a “roadmap” figure (conceptual model or risk equation or ecological framework diagram) that can provide context for where and how these techniques fit into the risk assessment process. Even though the examples are in an Appendix, the illustrations are useful for in the main document to provide context. An explicit figure/discussion on the use of a tiered approach (in support of Section 2.11) would be helpful in the text (as opposed to the Appendix). Note that “tiered” approaches are not defined in either document. There is a definition of “levels,” which suggest the concept of tiered evaluations. I</p>	<p>As indicated in my response to question 1c above, there needs to be a full discussion of different implications of variability versus uncertainty for risk management choices, including relationships to different enabling statues, with their rather vague and diverse mandates for health and environmental protection.</p>	<p>An outline and more structure would help. Current documents include a list of questions in almost arbitrary order. These questions and answers should be structured in topical section. This structure would provide a way for managers to search for specific answers. A brief section on decision analysis and how it is interrelated with PRA should be added. Page 6 of the white paper is a good start, although too condensed for a reader with no background training to understand (decision analysis and value of information are mentioned in one paragraph without much explanation). One of the common problems mentioned in the white</p>	<p>I was dissatisfied with the managers’ summary because it reads like past documents that have been ineffectual. Managers would be better advised to go back to Finkel (1990) because it covered the same ground, plus presenting some really nice information about communicating uncertainty. EPA should consider rewriting the managers’ summary as a vision statement. It could start by articulating why PRA <i>should</i> be a good idea (as it does now), but it should also acknowledge that after 20 years PRA hasn’t lived up to its promise, describe barriers to widespread adoption, and identify institutional changes that could lead to fulfilling the promise of PRA (in, say, the next 10 years).</p>

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	would suggest specifically adding the term to the glossaries.		paper (page 16) is the “lack of understanding of how to incorporate the results of probabilistic analyses into decision making and how to establish action levels based on the scope of the assessment.” This is of primary concern to the risk managers versus risk assessors and has not been addressed adequately.	
RESPONSE				
A cumulative distribution graphic was added to the managers’ summary. Information about the challenges of PRA is included in the papers.	Relevant changes about the framework diagram and the tiered approach were made in the managers’ summary.	Relevant changes about uncertainty and variability have been made in the papers. It is the intent of the papers to provide general reference and descriptive information about Agency PRA use, not imply that it is guidance.	A table of contents was developed for the managers’ summary. Information about decision analysis was added.	The title and tone of the managers’ summary has been changed to reflect its intent as a reference and not guidance.
2. Have the current documents adequately addressed the unique issues, if any, associated with the application of PRA to both human health effects and ecological risk? If not, what additional information/case studies should be presented specific to human or ecological risk assessment?				
The texts focus mostly on human health examples, but have attentively included a reasonable representation of ecological examples as well. The same is true for the case studies.	Both human health effects and ecological risk assessments are covered in the document, but consistent with current practice in these areas, the discussion and examples are limited. For human health effects, the trend is towards ranges (at a minimum) rather than single point estimates of “toxicity” (e.g., EPA proposal for toxicity criteria for trichloroethylene	Most of the current discussion is oriented to human health, and within human health to the exposure portions of the pathway to harm. There needs to be much more discussion of the issues involved and implications of the NRC (2009) proposed redefinition of the RfD, and the capability to estimate risks of adverse effects under alternative poly choices for population exposures both above	Appendix 4, Case Studies, is actually one of the best and most important portions of the document. Applications and wide use of PRA should be featured in the main body of the paper. To strengthen the case, I would recommend adding references to applications of PRA reported in open literature. Review papers	The document (specifically Case Study 13) identifies what I would consider the big three uncertainty issues in ecological risk assessment, namely: 1) deriving risk-based effect thresholds; 2) linking organism-level measurement endpoints and population-level assessment endpoints; and 3) accounting for the effects of landscape on exposure and risk,

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	<p>[EPA 2001; EPA/600/P-01/002A)]. However, given a choice of a range, assessors tend to default to the conservative end of the range. A specific discussion on this aspect is warranted. A case study to illustrate would likewise be useful. On the discussion on ecological risk, a specific discussion question that addresses “stressors” and the role of PRA in variability and uncertainty for these parameters (which are often more so than for human health) is warranted. The following may be a useful reference for case studies: Landis, W. G. 2005. Regional Scale Ecological Risk Assessment Using the Relative Risk Model. CRC Press, Boca Raton, pg. 286. Edited Book.</p>	<p>and below current and redefined RfDs.</p>	<p>(e.g., Lester et al., 2006) may be especially valuable to illustrate a wide use of PRA in the field.</p>	<p>but it’s not possible to adequately address those issues in the format of the current documents. On the human health side, I think it’s important, as I mentioned in my response to charge question 1(a), to help readers recognize that not all uncertainties should be analyzed in a PRA. The example I used is that exposure variability in a human population doesn’t necessarily belong in a PRA if the decision’s already been made to base risk management choices on risk to a relatively highly exposed subpopulation. In that case, for example, ingestion rate might better be treated as a decision variable than as a random variable.</p>
RESPONSE				
<p>No response necessary.</p>	<p>The Landis 2005 reference has been incorporated into the papers and a description about the similarities, and differences between HHRA and ERA has been added.</p>	<p>Relevant changes about RfDs and RfCs based on the NRC 2009 recommendations were made in the documents.</p>	<p>The case studies have been incorporated into the main body of the documents, and a reference to Lester et al., 2006, has been included.</p>	<p>A description about the similarities and differences between HHRA and ERA has been added to the documents.</p>

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<p>3a. Please comment on the completeness of the discussion of the tiered approach for decision making regarding the application of PRA. What, if any, additional refinements to the tiered approach outlined in the document can you recommend to further support management decisions regarding use of PRA?</p>				
<p>The discussion about the tiered approach is standard, but perhaps a bit shallow. The use of probabilistic methods mostly in higher tiers is explained. In fact, there is not strict limitation of PRA to higher tiers, and the counterexamples might be interesting too.</p>	<p>I agree with the positions taken on using a tiered approach. In the manager’s summary, the concept is appropriately articulated. The discussion could be enhanced with the use of a graphic to illustrate the concept. I would suggest a discussion on using all available data. Also, while starting as simple as possible to make the decision is appropriate, this should not preclude the use of a “higher” tier as a starting point if the data are available and the “stake” suggests such.</p>	<p>More generally, I think that current tiering approaches have led to: (1) neglect of even very basic analysis of uncertainty and variability when it would be efficient to do so in early stages of screening-type analyses; often it seems that 80 percent of the work on a risk issue has been done before probabilistic analysis is even started; and (2) neglect of the potential of structured probabilistic studies to help calibrate the screening procedures used at early stages of relatively data-poor choices. At the moment it seems that these screening procedures are mostly designed by seat-of-the-pants, what-seems-reasonable techniques. This can lead to implicit unexamined policy choices that are never effectively analyzed for management review. Usual conception of tiers is wrong; in fact PRA is more not less valuable for more data poor situations.</p>	<p>The document does not “describe various stages and aspects of an assessment or decision process in which probabilistic assessment tools may add value.” It repeats description of the tiered process introduced in the RAGS PRA document. A decision process needs to be introduced. The decisions should relate to actual EPA decisions (e.g., remedy selection) versus the risk assessment process (e.g., move from Tier 1 to Tier 2 assessment). The risk assessment process should be related explicitly to manager needs and not be considered in isolation, as it is done now. In addition, I recommend adding references to examples illustrating the use of these possible risk assessment approaches in the case studies of the white paper in specific decision contexts.</p>	<p>The concept of tiering is important and the discussion that’s presented is appropriate. It should be expanded though to make it easier for risk managers to set aside COC-receptor combinations that aren’t driving risks. We run into situations in (ecological) risk assessments where PRA is indicated for the risk driver(s), but we’re carrying along other COC-receptor combinations that really should be set aside until after we’ve decided what to do about the risk driver(s), at which point the effectiveness of the remedy for the non-risk drivers would be assessed. In our experience, risk managers can be uncomfortable with this approach, and we end up spending disproportionate effort on parallel treatment of non-risk drivers.</p>

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RESPONSE				
<p>Relevant changes about the tiered approach were made in the documents. The three tiers in the new figure that describes the tiered approach correspond to the three groups of EPA case studies that use PRA tools in the Appendix.</p>	<p>Relevant changes about the tiered approach were made in both documents, and a figure was added to illustrate the graduated hierarchical (tiered) approach.</p>	<p>More information about EPA’s experience with the use of PRA has been added to the documents, with an overview of the similarities and differences between HHRA and ERA.</p>	<p>References to the PRA case study examples and the tiered approach to risk assessments have been added to the documents. Information about the decision process was added.</p>	<p>Chemicals of concern (COC) are identified in the relevant EPA case studies, and details about HHRA and ERA are described and illustrated in the documents and case studies.</p>
3b. Please comment on the use of a tiered approach to when to use PRA considering management considerations of cost, time and resources.				
<p>Although I don’t disagree with the points made in the documents on the subject, it is possible to employ fully probabilistic methods in the context of screening. This can be done conveniently with probability bounding. Such a probability bounding approach has been used for both human health and ecological risk assessments at two Superfund sites (Housatonic in Massachusetts and Calcasieu in Louisiana).</p>	<p>Agree with the position on the use of cost, time and resources. However, I would add that the relevance of the decision is probably a key consideration. Recall the use of double-loop Monte Carlo simulations for the Hazardous Waste Identification Rule (i.e., for major regulatory decisions, the use of the appropriate techniques should take precedence [while balancing cost, time and resources] in getting the appropriate decision).</p>	<p>The usual consignment of PRA only to rare and highly data-rich situations is far from ideal. Because it can add information from other, parallel cases, PRA can actually be more helpful for data-poor situations. For extensive discussion, see section 3 of my recent conference paper: Air Toxics, report/conference paper by Abt Associates, Inc. to the U.S. Environmental Protection Agency under EP-W-05-022 WA 3-80, Final, March 2010.</p>	<p>The decision context needs to be introduced. It should be noted that even though the decision to use PRA could be based on the considerations listed above, a value of information approach needs to be implemented to address this issue (see risk assessors’ document, page 3, Section 1.4., paragraph 2)</p>	<p>The tiering concept is important. It’s not realistic to set hard and fast criteria for when to use PRA because it depends to great extent on project team dynamics, project process and schedule, and what’s at stake. The tiered approach should be refined to make it easier to opt into a PRA for risk drivers while opting out for other COC-receptor pairs.</p>
RESPONSE				
<p>EPA welcomes comments about probability bounding</p>	<p>No response necessary.</p>	<p>A reference to the Air Toxics paper was added to the reference section</p>	<p>Relevant changes about the decision context were made</p>	<p>The documents have been revised to relate the tiers of a</p>

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<p>and its applications. However, a full discussion about the use of probability bounding versus other probabilistic methods are the beyond the scope of the documents.</p>		<p>in the documents.</p>	<p>in the documents.</p>	<p>risk assessment to the three groups of EPA case studies to better understand the importance of risk drivers in determining when to use a PRA.</p>
<p>4a. Is each document written at the appropriate level of detail for the intended audience and length of document? Specifically, is too much or too little detail presented for the respective audiences? Please provide suggestions on how to address any such shortcomings.</p>				
<p>There is appropriate detail in the managers' summary document. However, in the white paper, more detail and maybe a figure or two about how PRAs actually work would be helpful in Appendix A. It is a bit of a disappointment to read 17–24 pages, finally be told to go look in Ang&Tang, Cullen&Frey, or Morgan&Henrion for any hint about what PRA is doing. The white paper, Section 2.5, is remarkably terse given the centrality of the question in the section header (especially considering the first paragraph more properly belongs in the previous section). This would be the section that deserves beefing up if any does. Would it be possible to list examples of how exactly a PRA</p>	<p>The manager's summary is clear and has the appropriate level of detail. I think that the use of graphics to highlight points is helpful. The use of a roadmap-type figure to further illustrate where the PRA fits in the process would be additive. This type of figure could also help with context and continuity in the documents. The main paper would benefit from review by a single technical editor. The style and structure of the discussion is not consistent. While the intent is clear, some of the discussion is not easily understood. I would highly recommend inclusion of graphics (along the lines of suggestions for the manager's summary) to aid in readability. While the question format works for the manager's summary, the style in the main paper is distracting. A more typical format (which could</p>	<p>The management paper in particular needs much more detail on how uncertainty and variability issues relate to the risk management criteria implemented by different EPA offices under different enabling statutes. Additionally, the technical definitions of uncertainty and variability need to be covered very early in the management summary. Without better developing these ideas, the whole effort to demystify PRA and inform the managers that this is important for their work is likely for naught.</p>	<p>The current documents repeat information already presented in previous EPA documents (e.g., PRA RAGS). Need to refocus these documents and present PRA within an EPA decision framework, and show that this is an established and validated tool. Not enough detail on how to incorporate PRA in the decisions (in both documents; i.e., the link between risk assessment and risk management). This is the main criticism for the two documents.</p>	<p>My issues with these documents have to do with scope, not length or level of detail. The papers focused on the mechanics of PRA from the perspectives of analysts and decision makers, but the mechanics of PRA are already well documented elsewhere. After 20 years, PRA hasn't lived up to its promise because it's inherently suited to iterative, adaptive management, whereas policies and regulations tend to artificially compartmentalize environmental problems and drive us toward one-off solutions that fit within the mandate of the governing rules. A second concern that we encounter in site-specific risk assessments is high uncertainty about whether and how a PRA will be used by decision makers, and those trying to influence decisions. These are</p>

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communicates a more 'robust representation of risks,' perhaps in examples across the spectrum of EPA's activities?	include some questions) with some call-out boxes to highlight topics is favored. Also, as suggested earlier, some continuity between the text and the examples would be useful.			the problems that these documents need to focus on if the objective is to promote the appropriate use of PRA.
RESPONSE				
Both documents have been revised, with Appendix A being modified and incorporated into the main body of the assessors' document.	Additional explanatory figures have been added to both documents, and more information is provided about the relationship between the text and case studies. The documents have been reviewed and modified by a technical editor.	Changes have been made to both documents regarding uncertainty and variability issues. As described earlier, the title and tone of the documents have been changed to indicate that the assessors' document is a "white paper" and the managers' documents addresses "frequently asked questions."	The documents have been changed to present PRA in the context of the phases of the risk assessment process and the tiered approach for risk assessment.	Both documents have been modified to more fully describe the risk assessment and risk management decision making, and where PRA fits within that process.
4b. Is the level of detail of information in the case studies adequate, or is more information needed? Please provide specific suggestions on how to improve the case studies, if you have any.				
Don't think the level of detail is adequate in the case studies. Some, especially two of the case studies, were hard to follow. They would be improved by graphical depictions of the difference that PRA made in the assessment, or the results it produced, as shown in case studies #5 and #10. It would be useful to have slightly fuller outlines of the models employed. For instance, in case study #1, how many	While not the same in each instance, the level of detail is appropriate. Links could be provided to the main references/documents. It would be helpful to link text and examples.	No comments.	The case studies are the best portions of the document; the level of detail in the case studies is just right to understand how the end probability distributions were obtained. However, what lacks is the "so what?" component. A probability distribution has been obtained, so what? In some cases, it has helped solve a specific decision problem. In some other cases, the information obtained can be	The case study summaries were most useful, and I'd like to see more of them, particularly for ecological PRAs. Enough information is presented to get the reader started if they want to learn more about a particular use of PRA. Completing the case studies would require far more detail than could reasonably be expected in these documents.

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inputs were there, out of which six were critical?			used for helping make a range of decisions. What are these decision problems? What are the alternative courses of action? How has this sophisticated PRA helped in making better decisions? Or how can it help in the future? Of all the case studies, only case studies 9 and 15 address this issue.	
RESPONSE				
A fuller characterization of the case studies is provided in both documents, with a description of how selective case studies are related.	Hyperlinks have been provided for the “Selected References” for each case study, and more descriptive information is provided in the documents about the case studies.	No response necessary.	More descriptive case study information is provided in the main text of both documents.	No response necessary.
4c. Please discuss whether, and how, the white paper could be improved to help the reader to better understand how PRA can help address and communicate variability and uncertainty.				
Again, I think pictures of outputs would serve that purpose.	Graphical representations (particularly in the main document) are needed.	I think some basic succinct phrases could help communicate. For example, “variability involves real differences among people or things in the real world that affect risks; uncertainty is mostly in your head, involving imperfection of our information about the values of parameters related to risks. We are, of course, generally uncertain about the amount of variability in parameters affecting risks.”	Given the availability of very thorough EPA RAGS PRA guidelines and multiple books and papers, it is important to focus the white paper and managers’ summary on specific concerns of the user community. I think the lack of PRA applications results from: (i) managers’ requirement to see PRA as	Would recommend against adding a primer on communicating variability and uncertainty; this is a topic that’s much better left to practitioners faced with real risk assessment problems. Case studies on successfully communicating variability and uncertainty would be a good way to improve the papers.

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			<p>validated and easily applied methodology; and (ii) needs to clearly integrate PRA in specific decision contexts. Unfortunately, both the white paper and managers' summary in its current form just summarize previously published documents and do not address these potential concerns. We need to stop presenting PRA as a "new approach" and compare it with "current practice" (e.g., p. 2 of manager's summary). PRA is not new; it should be presented as a robust and established tool with multiple applications done already and with many new coming in the pipeline. The very last appendix (Appendix D) should be a Key Focus of presentation. Even though relevance of PRA to decision making is highlighted in multiple places in the report, including the title, the document does very little in linking PRA with decision making.</p>	
RESPONSE				
<p>Although no 'picture of outputs' is provided, the format of the white paper has been revised to more fully</p>	<p>More graphs and figures have been added to the white paper.</p>	<p>Relevant changes about variability and uncertainty were made in the white paper.</p>	<p>The white paper is not meant to provide regulatory guidance for decision making; its intent is to</p>	<p>Information about the case studies has been integrated into the main body of the white paper.</p>

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describe issues related to the methodology for PRA and how various probability-based techniques can drive a range of possible outputs.			provide general reference and descriptive information about Agency PRA use.	
<p>4d. Are the citations and references sufficient, or are there critical references which need to be added? If so, please provide those citations and their relevance to the papers.</p>				
<p>The citations are relatively few and, as mentioned above, unbalanced. I don't think any reference is 'critical,' but many might be helpful. I thought, for instance, Vick (2002) and Bernardini and Tonon (2010) would be useful. Some reference about dependence/correlation issues would also be appropriate. Our old report (Ferson et al. 2004) might work, but there are others too, such as perhaps one of Roger Cooke's papers. References: Vick, S.G. 2002. Degrees of Belief: Subjective Probability and Engineering Judgment. ASCE Press. Bernardini, A., and F. Tonon. 2010. Bounding Uncertainty in Civil Engineering: Theoretical Background. Springer. Ferson, S., R. Nelsen, J. Hajagos, D. Berleant, J. Zhang, W.T. Tucker, L. Ginzburg and W.L. Oberkamp. 2004.</p>	<p>While the text is short on citations, the reference lists seem adequate. A few other references are included in the comments on relative risk models.</p>	<p>As mentioned earlier, the references badly need updating to include nearly 2 years of additional material (more recent than 2008). Above in my response to charge question #1, I have cited some papers of mine that could be helpful.</p>	<p>The reference list is not adequate. Dr. Frey co-authored more than half of the cited papers. Even though he is one of the undisputed leaders in the field, a substantial body of work has been done by others and should be represented. Significant gaps include publications on application case studies which are crucial in convincing managers that PRA has been validated by now.</p>	<p>I've cited seven documents, six of which (i.e., all except Morgan and Henrion [1990]) weren't cited in the reports. The comments where they are cited provide the relevance to the papers. Literature cited: Dakins ME, Toll JE, Small MJ, Brand KP. 1996. Risk-based environmental remediation: Bayesian Monte Carlo analysis and the expected value of sample information. Risk Anal 16(1):67-79. Finkel AM. 1990. Confronting uncertainty in risk management: a guide for decision-makers. Center for Risk Management, Resources for the Future, Washington, D.C.</p>

Peer Reviewer Comments on the EPA Probabilistic Risk Assessment Documents

Scott Ferson	Annette Guiseppi-Elie	Dale Hattis	Igor Linkow	John Toll
Dependence in Probabilistic Modeling, Dempster-Shafer Theory, and Probability Bounds Analysis. Sandia National Laboratories, SAND20043072, Albuquerque, NM. www.ramas.com/depend.pdf				
RESPONSE				
Relevant changes about references were made in the papers.	Relevant changes about references were made in the papers.	Relevant changes about references were made in the papers.	Relevant changes about references were made in the papers.	Relevant changes about references were made in the papers.