

## Comments on “Draft Plan for Using Risk-Informed Approaches in the Materials and Waste Arenas: Case Studies”

### Comment

1. Objective 1 is listed as producing a final version of the NMSS screening criteria. To be consistent with the Risk-Informed Regulation Implementation Plan (RIRIP), it would be better to state the objective as providing input to the final version of the Agency screening criteria. We are working toward an Agency-wide set of criteria and I believe the criteria developed by NMSS are a good model to use.
2. The draft screening criteria should be replaced with the criteria presented at the August 22, 2000, meeting with NMSS staff.
3. A fourth objective and success measure are suggested for the case studies:
  - Objective 4: Identify methods, data and guidance needed to implement a risk-informed regulatory approach
  - Success Measure: Develop the risk-informed regulatory approach sufficient to define the methods, data and guidance needed and the feasibility of developing them.
4. Does the scope of the 8 identified case study areas include assessing how risk information could improve NRC's own internal process (e.g., inspection, enforcement, review of operating experience) or just requirements on licensees? To ensure consistency, both should be included. Also, assessing requirements on licensees should include rules, R.G. s, SRPs.
5. The scope of the case studies should be expanded to include and test the entire risk-informed framework (e.g., defense-in-depth), not just Safety Goals.
6. No mention is made of the schedule for the case studies. Target dates should be provided.

### Response

It is more appropriate to say that we are attempting to establish a risk-informed framework for the nuclear materials and waste arenas, rather than for NMSS only. The Plan has been revised accordingly (e.g., the term “NMSS” has generally been replaced with “materials and waste arenas”). Regarding the comment, Objective 1 has been revised as follows: “Produce a final screening criteria for the materials and waste arenas.” The screening criteria would be for agency-wide applications in these arenas.

The Plan has been revised as recommended.

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Objective 2 of the case studies is to “Illustrate how the application of risk information has improved or could improve a particular area of the NMSS regulatory process.” This includes potential improvements on our own internal processes.

The purpose of the case studies scope has been expanded so that case studies would also be used “to check for and test any existing risk-informed framework (e.g., defense-in-depth) in the materials and waste arenas.”

Target dates are not provided in the Plan. The schedule for the case studies is provided in the NMSS Operating Plan.

7. Are the results of all 8 case studies to be summarized in one commission paper, or individual papers?
8. What is the role of other offices (e.g., RES, OGC) in the case studies?
9. The NMSS safety goals should be separate items for study, not mixed into this plan, especially since safety goals have proven difficult for us to nail down in the past. Mixing them in with this study might cause a lack of focus on finally getting them defined for use in our work.
10. The measures of success are listed on page three, however, they read just like the objectives stated on page two. The measures should be the yardstick you use to determine if the objectives have been met - for example, look at the safety goals in Attachment 3 [to the August 18, 2000, memorandum from L. Kokajko] and the associated objectives (measures) for those goals.
11. Specific licensees should not be mentioned in the list of case studies. On page 5, V. H - delete 3M.
12. The plan should discuss how case studies are going to be selected. Are volunteers being requested? If so, will that be part of the public meeting? Or do you have a specific list of licensees that you want to review? Is the contractor going to select?
13. The approach seems to be rather confusing. For example the objective appears to be to define case studies which will be screened using screening criteria, which are determined using the objectives for defining the case studies. The "plan" should be reviewed for clarity by the authors. The plan doesn't seem all that well thought out or delineated.

The vehicle for reporting the results of the case studies is to be determined. We anticipate completing 4 case studies in FY2001. A Commission paper may be appropriate at the completion of the first 4 case studies, followed by another Commission paper when all case studies are complete. Also, we plan to brief the Commission in April 2001 on the status of activities to date; the communication vehicle for this has not been defined.

Input and support from other offices would be requested as necessary.

Development of the safety goals is one of the objectives of the case studies and, therefore, needs to be discussed in the Plan. However, we recognize that a separate plan may need to be developed to study, finalize, and implement the safety goals that result from the case studies.

Attachment 3, as referenced in the comment, presents the reactor safety goals. At this point, we do not have sufficient information to establish quantitative objectives (measures) similar to the quantitative objectives for the reactor safety goals.

The Plan has been revised as recommended.

The case study areas that have been selected are identified in the Plan. The order in which the case studies will be conducted will be determined, in part, by: (1) the availability of information and resources, (2) what may have already been accomplished in a given case-study area, and (3) what we perceive can be accomplished in given case study area.

The Plan has been reviewed for clarity. The evolution of the screening criteria and case study approach and their relationship are described in the "Background" and "Purpose" sections of the Plan.

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| <p>14. It is unclear what is meant by "certain well decommissioning incidents" on page 4 Case Study Areas, item C. In all likelihood this means well <i>documented decommissioning projects</i>, but may mean cleaning up old wells. This should be clarified.</p>   | <p>The Plan has been revised to state "certain decommissioning incidents."</p>  |
| <p>15. Based on our discussion, the bulk of the work under this plan will be done by the Risk Group and its contractors. It is unclear how much staff effort will be required from staff not assigned to the Risk Group under the auspices of being designated as the "Division contact" See page 5, Case Study Structure, item B. Given the scope of the "questions" we believe that it could be a significant staff effort that has not been budgeted.</p> | <p>Noted.</p>   |
| <p>16. Regarding the intent of the case studies, one participant noted that reconsideration of prior regulatory decisions may be warranted, based on the results of the case studies, and that NMSS should be open to this possibility.</p>  | <p>Noted.</p>   |
| <p>17. Commenting on criterion 5, a participant suggested that information and analytical models of sufficient quality might always be obtained or developed at some cost. Therefore, he suggested that the criterion be reworded to state "reasonably developed."</p>   | <p>The Plan has been revised as recommended.</p>  |
| <p>18. Regarding criterion 7, a participant indicated a risk-informed approach may show that legislative constraints are not appropriate, and instead of accepting the legislative constraints as precluding the risk-informed approach, the risk-informed analysis should be used to support revision of the legislative basis.</p>   | <p>Noted.</p>   |
| <p>19. In general, it was noted that criteria 5 through 7 may be answered with a "maybe" rather than a "yes" or "no."</p>  | <p>Noted. If the answer to the criteria is "maybe," a judgment would need to be made as to whether that answer is closer to "yes" or "no" and, thus, either proceed or screen out the activity.</p> |
| <p>20. Regarding the case study outline, a participant advised that materials regulatory history is much more distributed than the reactor regulatory history, in that materials regulation is distributed across entities external to the Agency, such as the States. Therefore, individuals other than the Agency historian may need to be contacted. Also, he noted that taking a top-down approach may affect the development of safety goals.</p>       | <p>The Plan has been revised to include interviews with other appropriate individuals.</p>  |

21. The participants also discussed the schedule and vehicle for communicating the case study results to the Commission, as well as the content of the communication. A participant noted that an information paper is a good vehicle to communicate with the public. Stakeholders would be involved.
22. Given the diversity of the case study areas, it was stated that it is likely that numerous approaches to risk analysis would be used.
23. The quality of the analyses should depend on the decision that needs to be made. While reactor quality standards may be more uniform, quality across materials activities need not be equivalent. Assuming that only one level of analysis is appropriate is a commonly made mistake. In actuality, there are many types of analyses with varying associated costs. The stability of the analysis should be considered, focusing on the results, by asking whether a lesser quality study would yield the same result as a higher quality study.
24. Most of the discussion of the proposed case study structure focused on the involvement of stakeholders. Regarding licensees, in some cases there are a few, in other cases there may be thousands. Also, general license holders do not identify radiation safety officers for interactions. For the more ubiquitous licensed activities, greater staff effort may be required to have stakeholders involved in the case study process.
25. One participant asked whether stakeholders would be involved in the analysis stage of the case studies, or would they not be involved until the process is near completion. The availability of information for stakeholder review and consideration throughout the process is preferred. It was suggested that posting to the web throughout the process is useful.
26. One participant asked how the public's acceptability of the safety goals would be determined. Sometimes the more vocal members of the public do not reflect the views of the public at large. "Acceptability to the public" will depend on how the public is involved in the process and how the safety goals are presented to the public. A participant from the U.S. Department of Energy stressed the importance of proper risk communication and risk management. The public should be involved as well as informed throughout the process, to develop a partnership when the product is complete. The DOE participant invited the NRC's involvement in an interagency committee on risk communication and in an international risk symposium in November 2000.
- At the September 21 meeting, we indicated that the Commission would be briefed in April 2001 on the status of activities to date. The communication vehicle has not been defined; it could be an information paper, or it could be something more substantial. Similarly, the content has not yet been established; safety goals may or may not be included.
- Noted.
- Noted
- Noted. We recognize the diversity of stakeholders in the material and waste arenas and will make a concentrated effort to engage the various stakeholders.
- As we discussed in the meeting, stakeholders would be involved in all case studies early enough to have an impact; also, we would welcome information identified by industry and other stakeholders as early input to the case studies.
- Noted.

27. Participants commented that case studies may bridge areas of consideration, such as loss of control. Also, the nature of the stakeholders varies considerably across the case study areas. The specific cases studied should be typical, or representative, to be most useful. Noted.
28. Several participants commented on specific case study areas: Noted.
- a. Gas chromatographs - the case study could provide useful information to standardize the presently "inconsistent" regulations.
  - b. Fixed gauges - the potential for loss of control may complicate the risk analysis.
  - c. Spent fuel interim storage - would likely focus on dry cask storage licensed under Part 72.
  - d. Site decommissioning - case study may want to focus on reactor site decommissioning; recommended interfacing with the DOE Center for Risk Excellence regarding risk communication.
  - e. Part 76 gaseous diffusion plant (GDP) certification - NRC risk study in the 1980's supporting the development of GDP emergency plans may be a good reference.
  - f. Transportation - the risk assessment performed to approve the Trojan reactor vessel transport may be looked at.