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COMMENTS FROM REVIEW OF NRC OVERALL REVIEW STRATEGY  
FOR THE HIGH-LEVEL WASTE REPOSITORY PROGRAM

The comments below result from the Center for Nuclear Waste Regulatory Analyses (Center) review of the NRC Overall Review Strategy for the High-Level Waste Repository Program (ORS) dated May 12, 1992. Except where thought appropriate for the purposes of clarification, no editorial comments are included herein.

1. Page one, second paragraph, second sentence: In order to emphasize the relationship of the ORS with other program activities, this sentence could be replaced with, "The Overall Review Strategy and its complementary Regulatory Strategy provide a consistent policy basis for the NRC High-Level Waste (HLW) Program for licensing a repository. ORS defines planning for reviews, review capability development, and research to support the annual Five-Year Plan and budget preparation."
2. Page one, third paragraph, eighth line: In order to clarify the intent of this sentence, it is recommended that the wording which starts with "... as areas where..." be replaced with "... to provide direction for DOE's program and License Application (LA) preparation".
3. Page one, section 1.2: The Center recommends placing the acronym "NRC" at the beginning of the first sentence to clarify that only the NRC's programmatic requirements are dealt with in this document.
4. Page one, last paragraph, fourth sentence: In order to provide a more specific link between the Office of Nuclear Materials Safety and Safeguards (NMSS) and the Office of Regulatory Research (RES), it is suggested that this sentence be replaced with, "Programs included in the Five-Year Plan are the NMSS High-Level Nuclear Waste Repository Program and the RES HLW Research Program. Research Program requirements are defined through the development of Research User Needs."
5. Page two, general comment: The text on page two seems unclear with respect to Figure 1. Specific examples are listed below.
  - a. Page two, first paragraph: This paragraph refers to five activities which are conducted during the present five year planning period and to three licensing activities which are depicted in Figure 1. An examination of Figure 1 does not make it clear which five activities or which three licensing activities are being referred to.
  - b. Page two, paragraph two, twelfth line: This line refers to the "... development of requirements and guidance activity" from Figure 1. This activity is not specifically shown in Figure 1.
  - c. Page two, paragraph three, seventh line: This line addresses "... five program activities" from Figure 1. An examination of Figure 1 does not reveal which activities are the five program activities referred to.

Section 1.2 and Figure 1 should be reconciled.

- 6. Page two, paragraph two: This paragraph mentions SECY-88-285. The Center recommends referencing, in the text or in a footnote, the follow-on SECY's which are now part of the NRC's Regulatory Strategy.
- 7. Page three, section 2.0: This section could be expanded to include brief mention of the use of staff positions and staff technical positions.
- 8. Page four, section 2.2: In order to assist in the definition of interfaces, it is suggested that the following be added after the last sentence: "Other regulations which will influence the design of the HLW repository are 10 CFR Parts 71 and 72. These regulations influence the design of the repository through the natural interfaces between the transportation and interim storage facilities and the repository, particularly with regard to the design requirements of 10 CFR Part 60."
- 9. Page four, section 2.3: This paragraph could be revised to include mention of staff positions and staff technical positions.
- 10. General comment, page five and elsewhere: Throughout the text of the ORS, LA and Pre-LA Reviews are mentioned frequently. In all cases, reviews associated with the LA are addressed before reviews associated with the Pre-LA phase. The Center recommends placing discussion of Pre-LA activities before those of the LA phase to reflect the order in which these activities will be carried out.
- 11. Page five, section 2.4: The Center has several suggestions for modifying this section as delineated below:
  - a. Major assumption 1), first sentence: Add the phrase "in preliminary form" between the words "therefore available" and "for the staff's" to reflect the true nature of this information.
  - b. Major assumption 2): Continuing submission of performance assessment results during the three-year LA preparation period could be a major distraction to DOE, since this will be a period of intensive effort associated with documenting site characterization and analysis. It is suggested that the validity of this assumption be reconsidered.
  - c. Major assumption 3): The Center considers that this assumption should not be included in the ORS. It is difficult to define "success" and "resolution" in this regard, and the ORS should take into account the likelihood that "resolution" may not occur.
  - d. Major assumption 4): It is suggested that the ORS should not rely on this assumption, since it may not be reasonable to expect any other parties to take part in resolution of issues.

- e. In order to more clearly indicate the need to consider program interfaces, a fifth assumption could be added to this section to state, "DOE will provide appropriate documentation of interfaces with other High-Level Waste program components (e.g., cask and MRS design) beginning during the pre-LA phase."
- f. The Center notes that several statements in section 3.2 appear to be assumptions which should be consolidated in section 2.4. These statements are as follows:
  - (1) Page seven, third paragraph, the first two sentences after the statement of the strategy title.
  - (2) Page seven, fourth paragraph, the first sentence after the statement of the strategy title.
  - (3) Page eight, fifth paragraph, the fifth sentence after the statement of the strategy title.
- 12. Page five, section 3.1, first paragraph: This paragraph addresses "a general objective" for all reviews. However, the text seems to actually present two objectives. The Center recommends rewording this paragraph to reflect that it deals with two objectives.
- 13. Page five, section 3.1, second paragraph, "LA Review Objectives": The Center recommends clarifying that the "findings" referred to in this paragraph are findings with respect to compliance with Part 60.
- 14. Page five, section 3.1, second paragraph, "LA Review Objectives": This paragraph could be expanded to include the complementary objectives to avoid either (1) allowing an unsafely sited repository to be built, or (2) failing to provide timely authorization of the construction of a safely sited repository.
- 15. Page six, section 3.2: For consistency of understanding, it is suggested that the term "compliance review" as used in LA review strategies 1), 3), and 4) be defined.
- 16. Page seven, third paragraph, third sentence (beginning "The staff..."): The Center recommends modifying this sentence to reflect the manner in which "incremental information" acquired during the pre-LA phase will be incorporated into the ORS. This information could lead NRC to a decision that there is no need for a detailed LA review; however, the refinement and evolution of this information could result in a change to such a decision.
- 17. Page eight, second paragraph: In order to clarify the source of technical uncertainties, it is suggested that a sentence be added after the first sentence of this paragraph which states, "These uncertainties will have been identified through the conduct of ongoing reviews, development of Research User Needs, IPA, and regulatory analyses."

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18. Page eight, third paragraph: The first sentence of this paragraph may provide an unnecessary dilution of the strategy. If it is left in, it is suggested that examples of the "staff concern" be provided. The second sentence of this paragraph may not be required, since the audit review step should serve to identify areas where DOE has failed to properly demonstrate compliance.
  19. Page eight, last paragraph, nineteenth line: The Center recommends the insertion of the words "ability to conduct" between the words "staff's" and "detailed review". This change would more clearly reflect the intent of support for staff's review of the LA.
  20. Page nine, under the header "Pre-LA Review Strategies": The titles given for strategies 1) and 6) do not match the titles of those strategies as listed further on in this section.
  21. Page nine, "Pre-LA Review Strategies": In order to support definition of interfaces and integration of reviews with other components of the HLW Program, it is recommended that an additional strategy be added to state, "8) Develop familiarity with documents and regulations related to other HLW program components."
  22. Page ten, second paragraph: This paragraph discusses pre-LA review objectives and states that these reviews should use "similar types of reviews and supporting investigations as in the LA review strategy". The paragraph implies that there will be a formal assignment of review types for the pre-LA reviews similar to that being done in the development of Compliance Determination Strategies. The Center recommends considering whether that is the staff's intent and clarifying this paragraph in that regard.
  23. Page eleven, first paragraph: This paragraph deals with "focused QA reviews and audits". The last sentence of this paragraph refers to site characterization. The QA review and audit program encompasses more than just site characterization (e.g., repository design, waste package testing, etc.). This paragraph could be reworded to address more completely the scope of the QA program.
  24. Page eleven, fourth paragraph: This paragraph seems to emphasize site characterization. The Center recommends considering whether this paragraph should be reworded to reflect the larger scope of DOE's issue resolution strategy and performance allocation process.
  25. Page twelve, third paragraph: In order to clarify NRC's policy on closure of issues during the Pre-LA phase, it is suggested that a new sentence be added after the existing second sentence which states, "New information may require an item to receive further consideration, causing it to be reopened."

- 26. Page thirteen, third paragraph, first sentence: This sentence discusses ORS implementation of 10 CFR 60.18. The Center notes that there are many aspects of 10 CFR 60.18 which are not actually implemented by the ORS and suggests that this sentence be reworded to reduce the scope of the statement.
- 27. Page fourteen: Insert a discussion of Pre-LA Review Strategy 8) to state "Develop knowledge of documents and regulations related to other HLW program components. This knowledge will support the definition of program interfaces and the conduct of integrated reviews. This strategy will require close coordination with NMSS divisions with responsibilities in these other program areas."
- 28. Page fourteen, section 4.0: In order to promote clarity and to avoid overuse of the term "strategy" in this document, the Center suggests that the title of this section be changed to "APPROACHES AND SCHEDULES".
- 29. Page fourteen, section 4.0: In order to provide conciseness, the Center recommends combining strategies 1) and 2) by inserting the words "Using the principles of systems engineering" at the beginning of strategy 1) and deleting strategy 2).
- 30. Page fourteen, section 4.0, strategy 5): The Center recommends expanding this strategy to include "exploratory" as well as "confirmatory" research, since both types are important components of safety-related research.
- 31. Page fourteen, section 4.0: The description of the strategies at the beginning of this section ends with reference to Figure 3 and schedules addressed therein. This reference should be to Figure 2.
- 32. Page fifteen, first paragraph, last sentence: This sentence refers to schedules presented in Figure 3. These schedules are actually presented in Figure 2.
- 33. Page fifteen, paragraph two, third line: Recommend replacing the words "disciplined and documented" with the words "formal, systematic, and documented" to more accurately reflect the purpose of the Systematic Regulatory Analysis process.
- 34. Page sixteen, first paragraph, first line: Recommend addition of the word "Relational" between the words "Architecture" and "Data" and combining the words "Data" and "Base" into one word. These changes will accurately reflect the title of the relational database.
- 35. Page seventeen, second paragraph: The schedules referred to in this paragraph for Figure 3 are actually in Figure 2.
- 36. Page seventeen, paragraph 3: The Center recommends expansion of the title and text of this paragraph to include discussion of "exploratory" research, since such research is an important component of safety-related research.

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37. Page twenty, Figure 1: The Center recommends revising this figure to more clearly reflect the text of section 1.2.
  38. Page twenty-three, Table 1: This table does not indicate the role which the Format and Content Regulatory Guide has with respect to the ORS. It also does not reflect development of research needs.
  39. Page A-1, section 1.0 (1): This paragraph, in addressing the scope of 10 CFR Part 60, leaves out regulatory scope beyond that of construction authorization. The Center recommends revising this paragraph to reflect that 10 CFR Part 60 provides regulation for all phases of repository operations, even though NRC staff's current focus is on pre-LA and LA concerns.
  40. Page A-3, subparagraph (8), tenth line: The phrase beginning "... except that..." could be interpreted to mean that the Commission may make a unilateral decision to extend the decision period. The Center suggests that this be clarified consistent with NWPA, (Section 114)(d).
  41. Page A-3, section 2.1, second sentence: This sentence seems to imply that the decision to authorize construction has already been made. In order to clarify, the Center recommends deleting the words "order to" in the third line and replacing them with the words "determining whether to".
  42. Page A-4, first and second paragraphs: These two paragraphs refer to "secondary" findings. Direction provided to the Structural Task Force was that these findings were to be called "staff" findings. The Center recommends that the term be made consistent with guidance to the Structural Task Force.
  43. Appendix C: This appendix presents the Performance Assessment Strategy. It is recognized that this strategy was written in 1991 and is being repeated verbatim here. The Center recommends considering whether this strategy should be updated for inclusion in the ORS, since some portions of it may be out of date. For example, the Performance Assessment Strategy refers to the License Application Review Strategy.