



Department of Energy
Washington, DC 20585

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NOV 18 1987

Mr. Robert Browning, Director
Division of High-Level Waste Management
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Browning:

This letter transmits DOE comments on the "Generic Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (September 1987 draft). The comments, both general and specific, are based upon extensive review of the subject document.

Previously, DOE had provided comments in November 1986 on the July 1986 draft of this Generic Technical Position (GTP). On August 25, 1987, DOE provided oral comments on a revised draft that NRC issued in July 1987. The forum was a public meeting arranged by the NRC staff to discuss the resolution of public comments received on the revised draft GTP. At that meeting, the NRC staff asked that DOE not submit written comments since the GTP was going to be reissued to address the concerns raised at the meeting. The current draft was subsequently issued in September 1987. Both the NRC and DOE briefed the ACRS Waste Management Subcommittee on October 16 regarding their respective views on this draft GTP.

As a result of the above interactions, a number of our original concerns have been adequately resolved. However, we continue to have substantive concerns regarding the content of this GTP, as well as reservations about its utility to the DOE program, as discussed below.

In reaching our conclusions, we have reviewed the guidance to determine the extent to which it facilitates protection of the public health and safety and the environment. This is in keeping with DOE's statutory safety and environmental responsibilities. We have also examined the guidance for its programmatic utility. That examination encompassed both content and format, and also considered relationships to other guidance that the staff has provided; and, of course, to the regulations inspiring the guidance in the first place. The overriding consideration has been whether adoption and implementation of this guidance in the



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DOE program will better assist DOE in meeting its regulatory obligations to NRC. Since the guidance will become, for all practical purposes, a surrogate for the requirements about which the guidance was created, it is important that the guidance be consistent with regulatory intent, that it be unambiguous, and that it be relatively straightforward to use. In the particular instance before us now--the GTP on Items and Activities in the HLW Geologic Repository Program Subject to QA Requirements--the guidance does not meet these criteria.

Our primary concerns with this GTP are summarized below. Further detailed discussion of our concerns is contained in the attachment to this letter.

- o The guidance reflects questionable interpretations of regulatory requirements. For example, the discussion of retrievability implies requirements that go beyond what is found in Part 60; the design basis accident dose limit is based on an incorrect interpretation of the rulemaking record.
- o The bases for staff positions are not always provided. One example of this is the unnecessarily conservative treatment of accident sequences to be considered in analysis.
- o At times, the GTP confusingly overlaps existing guidance. For example, the GTP calls for information to be included in DOE's Site Characterization Plans that is either already covered in Regulatory Guide 4.17 and DOE's SCP Annotated Outline (OGR/B-5) or goes beyond such guidance.
- o The GTP is an assortment of miscellaneous guidance only indirectly related to quality assurance. Moreover, the topics encompass a broad spectrum of technical areas that would be better addressed through separate guidance or other vehicles. These topics include: design basis accident dose limit, probability cutoff for accident sequences, retrievability, system redundancy, and probabilistic risk assessment techniques.

- o The GTP contains rather elementary and unnecessary discussions of certain topics, resulting in certain incorrect implications. For example, the discussion of PRA techniques implies a heavy reliance on PRA over other methods, which is inconsistent with Commission practice for other nuclear facilities; the treatment of system redundancy implies inflexibility in the use of other means of increasing system reliability.
- o Redundant presentation of the same material is provided, at times inconsistently. In particular, Section 4 (Staff Positions) covers the same material as Section 5 (Discussion), thereby leading to confusion and additional effort in review and implementation.
- o The comment and comment response record is not comprehensive and changes in successive versions of the GTP don't always represent a logical outgrowth of the record. For example, comments and commitments made at the August 25 meeting have not been documented in a comment response record for that meeting nor fully reflected in the September 30 draft.

These general concerns exemplify our overall concern regarding the GTP development process, which we expressed to you in my July 15, 1987 letter on productive interactions between our two agencies. We would be happy to discuss these concerns with you and your staff in the near future, with respect to both the overall process and this particular GTP.

If you have any questions regarding these comments, please contact me or Ed Regnier of my staff (586-4959).

Sincerely,



James P. Knight, Director
Siting, Licensing and Quality
Assurance Division
Office of Civilian Radioactive
Waste Management

Enclosure

cc:

O. Merrill, NRC-ACRS

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DOE Comments on the NRC Generic Technical Position
on Items and Activities in the High-Level Waste Geologic
Repository Program Subject to Quality Assurance Requirements
(September 1987 Draft)

General Comments

1. The GTP continues to call out an interim design basis accident (DBA) dose limit of 0.5 rem. A specific value for the accident dose limit is not necessary in this GTP. Consistent with Part 60 requirements, DOE is using 0.5 rem as the threshold in determining what structures, systems, and components are important to safety. However, 10 CFR Part 60 does not specify any DBA dose limit and DOE disagrees with the NRC staff interpretation of the Part 60 rulemaking record. The rulemaking record does not support an interpretation that 0.5 rem is the value to be used as the DBA dose limit (i.e., the cutoff for determining undue risk to the health and safety of the public). Using 0.5 rem as the DBA dose limit would be inconsistent with NRC regulations/guidance and past Commission practice pertaining to other nuclear facilities. DOE will be submitting a petition for rulemaking to establish a specific DBA dose limit to be directly included in Part 60. DOE recommends that all discussion of a specific value for the DBA dose limit be deleted from this GTP.
2. The July 1987 draft of this GTP contained a probability cutoff of 10^{-8} /year for accident sequences to be considered in determining items important to safety. At the August 25 meeting, DOE commented that such a conservative cutoff was not necessary to assure adequate protection of public health and safety, and that justification should be provided for the value chosen. In the present draft (September 1987), the numerical cutoff has been deleted and replaced with a statement that those sequences leading to a high consequence should be considered even if the probability of occurrence is exceedingly small. This provides ambiguous guidance to DOE and suggests that there should be no probability cutoff for sequences to be considered. Again, DOE believes that consideration of all sequences, no matter how small their probability, is not necessary to assure adequate protection of public health and safety. DOE recommends that the NRC staff adopt language that captures what is necessary to assure adequate protection, that is not inconsistent with past Commission practice, and that will be directly usable by DOE without extensive further interpretation. DOE believes that this topic needs further development.
3. The guidance provided in this GTP regarding retrievability is not consistent with the retrievability requirements contained in Part 60. Also, the guidance is not clear and is open to varying interpretations. The Part 60 requirement is that the design of the geologic repository

operations area must not foreclose the retrievability option. However, DOE is not required to conduct or undertake a detailed design for a retrieval system, as the GTP implies. At the time of the License Application, it would not be necessary to provide such detailed information regarding retrieval of wastes, but only plans for retrieval and alternate storage. In addition to the level of detail, the guidance can be read to imply a requirement of partial retrieval coupled with preservation of the functional capability of the repository. Retrieval, in the context of Part 60, would be exercised only if the repository were found to be unsuitable for disposal of radioactive wastes. Part 60 does not require the repository to be functional after retrieval. DOE also believes that the goal of not precluding the retrieval option need not require that items related to potential retrieval operations be on the Q-List and receive Subpart G quality assurance treatment. DOE believes that the subject of retrievability would be better addressed through some other vehicle and should be deleted from this GTP.

4. The GTP defines the Q-List to include structures, systems, and components important to safety, barriers important to waste isolation, and related activities. As we have commented in the past, items on the Q-List are subject to specific design requirements of 10 CFR 60. Therefore, only engineered structures, systems, components, and barriers (i.e., items over which DOE has design control) should be on the Q-List. Activities related to these Q-Listed items are already identified in 10 CFR Part 50 Appendix B and will be controlled accordingly, but would not need to be placed on the Q-List. With respect to natural barriers important to waste isolation, the quality of these barriers is not within the design control of DOE and, therefore, should not be on the Q-List. The activities related to the characterization/evaluation of those natural barriers important to waste isolation, or site-related activities that could affect the performance of these barriers, would not be placed on the Q-List but would be included on a "Quality Activities List" and conducted under the Subpart G QA program. The GTP should be revised to reflect this when discussing Q-List content. This is consistent with the agreement made by the NRC staff at the August 25 meeting.
5. DOE has objected in the past to the global inclusion of all site characterization activities, as well as barriers that may contribute to waste isolation, under the Subpart G QA program. In addition to those activities not related to safety or waste isolation, there are a number of site characterization activities that could, based on technical considerations, be considered non-QA-level-1 (e.g., certain supporting, scoping, or regional activities). With respect to barriers important to waste isolation, DOE's position is that only those barriers that will be relied upon to meet the postclosure requirements of Part 60 should be considered important to waste isolation. Also, it is inappropriate for the GTP to prescribe what barriers the NRC staff considers to be important to waste isolation. It is DOE's responsibility to determine these items, which would be based on the results of the performance allocation process, as supported by site characterization data and performance assessments. The NRC staff has tried to address these

concerns in the September 1987 draft GTP, but only with partial success. In sum, the conservatism being advocated by the NRC staff is related more to management of programmatic risk than to safety per se; thus, its value as regulatory guidance is questionable.

6. The GTP imposes new requirements for redundancy above what Part 60 requires. Moreover, DOE does not agree that redundancy of a function or of a component provides assurance that a dose limit will not be exceeded. Redundancy does reduce the probability of a given accident sequence occurring. However, DOE is responsible for determining the appropriate measures needed and employing these measures. Redundancy is but one of the methods available to increase system reliability. Flexibility to use other approaches should be maintained. DOE recommends that discussion of this topic, which is only indirectly related to quality assurance, should be deleted from this GTP and possibly covered under separate guidance.
7. DOE has commented in the past regarding the extent to which the NRC staff appears to be relying on probabilistic risk assessment (PRA) in identifying structures, systems, and components important to safety. While the staff has made changes to the wording, the GTP discussion continues to imply heavy reliance on PRA over other methods, which clearly goes beyond Commission policy on the use of PRA in other areas (i.e., primarily as a design aid). DOE cannot accept such inconsistency with past Commission practice, since it may incur undue programmatic risk during licensing if it were to rely so heavily on PRA, as the GTP seems to require. Rather, DOE will rely on a suite of widely used and accepted techniques, and rely on PRA where Commission practice and prudent judgment indicate its value. DOE recommends that, while the GTP can identify PRA as a potential analysis method, discussions of the method be deleted. This would not detract from the GTP, since the discussion is elementary in nature and can be found in past NRC publications and the general literature.
8. In several places, the GTP addresses items already covered under other guidance documents (e.g., the information to be included in DOE's Site Characterization Plans). The contents of the SCP have already been identified in Regulatory Guide 4.17 and DOE's SCP Annotated Outline (OGR/B-5). Discussion of such material is outside the scope of this GTP, and creates a potential for confusion, particularly when it goes beyond what is already in existing guidance. Therefore, this material should be deleted from the GTP. If NRC believes that further guidance regarding the contents of the SCP is needed, then R.G. 4.17 should be revised.
9. Section 4 (Staff Positions) and Section 5 (Discussion) provide redundant presentation of the same material, and at times are inconsistent. This leads to confusion in the guidance provided, and necessitates significant additional effort in review and eventual implementation. DOE recommends that Section 5 be deleted and that Section 4 be augmented with any appropriate material from Section 5. In our Specific Comments we have

provided comments on the Section 5 material, indicating material we consider appropriate for retention or deletion, as the case may be.

10. At times, the GTP uses language or expressions that are questionable (e.g., "first-of-a-kind facility" when referring to repository operations), imprecise (e.g., "shall" instead of "should") or vague (e.g., "single failure"). Such expressions should be avoided and vague terms defined to avoid varying interpretations. Also, in Section 3 (Definitions), the NRC lists some definitions repeated verbatim from Part 60 and others altered from those in Part 60, yet cites a Part 60 reference without distinguishing between the two. DOE recommends that the GTP should list all definitions that are Part 60 quotes in Appendix A of the GTP. Section 3 should list all new terms the staff wishes to define.
11. In various places, the GTP refers to the concept of demonstrating performance, something not required by Part 60. Rather, the finding required by Section 60.31 is one of reasonable assurance. Under this standard, demonstration is not required, especially for the postclosure period, where the measure is one of expected performance. Therefore, compliance should be based on "reasonable assurance of expected performance", well known to licensing proceedings, rather than an undefined demonstration requirement.

Specific CommentsSpecific Comments Related to General Comment 1:

- 1a. Section 4.2, Page 5 - A DBA dose limit of 0.5 rem is not appropriate and should not be included in this GTP. Delete the sentence starting with "For purposes of" on line 9 of the first paragraph. The footnote does not constitute guidance and should likewise be deleted.

Specific Comments Related to General Comment 2:

- 2a. Section 4.2, Page 5 - DOE does not agree that all potential accident sequences need to be considered in determining items important to safety, particularly if their probability of occurrence is "exceedingly small". This is not consistent with past Commission practice. The two sentences in the first paragraph beginning with "DOE should generate" should be replaced with language that captures what is necessary to assure adequate protection, that is not inconsistent with past Commission practice, and that will be directly usable by DOE without extensive further interpretation. Also, in the last sentence of this paragraph, delete "no matter what the probability of occurrence is."

Specific Comments Related to General Comment 3:

- 3a. Section 4.2, Page 6 - The guidance on the retrieval process goes beyond the Part 60 requirements and does not portray the NRC staff's intent, as clarified in the October 16, 1987 ACRS briefing. In order to better reflect this intent, paragraph (d) should be deleted and replaced with: "In the event that retrieval is necessary, DOE should, at that time, analyze the proposed retrieval process to identify items important to safety. Such items should be covered under a Subpart G QA program."
- 3b. Section 5.2, Page 14 - The discussion of retrieval implies that DOE must undertake a detailed design of a retrieval system now, which is inconsistent with Part 60 requirements. Paragraph (d) should be deleted.

Specific Comments Related to General Comment 4:

- 4a. Section 1.0, Page 1 - The Q-List, as envisioned by DOE, is a list of structures, systems, and components important to safety and engineered barriers important to waste isolation, and does not comprise the entire scope of the Subpart G QA program. In the last sentence of the first paragraph, substitute "structures, systems, and components important to safety and engineered barriers important to waste isolation" for "the items and activities important to safety or waste isolation". Later on in that sentence, substitute "lies within" for "comprises".

- 4b. Section 3.0, Page 3 - The definition of "Activities" needs to be clarified to properly and explicitly reflect the relationship between the Q-List and the Quality Activities List being proposed by DOE. The last two sentences of that definition should be deleted and replaced with the following: "For example, the pertinent requirements of 10 CFR Part 50 Appendix B apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including safety analyses and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-List. However, activities related to natural barriers important to waste isolation should be identified and listed on a Quality Activities List. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. For example, site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way need to be assessed for inclusion on the Quality Activities List."
- 4c. Section 3.0, Page 4 - The definition of "Q-List" needs to be revised to include only structures, systems, and components important to safety and engineered barriers important to waste isolation. In line 2 of the definition, add "and engineered" before "barriers". In line 3, delete "and related activities". This revised definition needs to be reflected throughout the GTP.
- 4d. Section 3.0, Page 4 - In order to define what would be included in the Quality Activities List proposed by DOE, add the following definition to this section: "Quality Activities List, as used in the geologic repository program, is a list of those activities conducted during site characterization, construction, operation, or closure that relate to the characterization or evaluation of natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR Part 60 Subpart G QA program, include data gathering, performance assessments, and those activities that could adversely affect a natural barrier's ability to isolate waste."
- 4e. Section 4.1, Page 4 - In order to properly reflect the revised definition of "activities", change the title of paragraph (a) to "Criteria for Q-List and Quality Activities List". Delete "and Activities" from the title of paragraph (b), as well as throughout the paragraph.
- 4f. Section 4.2, Page 5 - In order to properly reflect the revised definition of "activities", delete "and Activities" from the title of this section. Also, on line 8 of the first paragraph, insert "and are defined in 10 CFR Part 50 Appendix B" after "important to safety".

- 4g. Section 4.2, Page 6 - Activities related to items important to safety have already been identified in 10 CFR Part 50 Appendix B. In line 4 of paragraph (c), delete "and activities".
- 4h. Section 4.3, Page 7 - In order to consistently reflect the definitions of the Q-List and the Quality Activities List, the following changes should be made. At the end of line 3, add another sentence: "Those engineered barriers important to waste isolation should be placed on the Q-List." Also, on lines 3 and 4 of the first full paragraph, delete "a site and engineered barriers should be" and replace it with "natural barriers important to waste isolation, activities related to the actual performance assessments, and those activities that may adversely impact the waste isolation capabilities of these barriers should be identified on the Quality Activities List and".
- 4i. Section 4.4, Page 7 - The first sentence of paragraph (a) incorrectly paraphrases the referenced Part 60 section, which does not include "activities". Therefore, on line 2, delete "and activities".
- 4j. Section 5.1, Page 9 - To be consistent with the definitions of the Q-List and the Quality Activities List, on line 1 of the first paragraph, delete "and activities" and add at the end of the sentence "and the activities on the Quality Activities List". This paragraph should be merged with Section 4.1(a).
- 4k. Section 5.3, Page 15 - Certain changes are needed in this section to properly differentiate between items and activities. On lines 1 and 2 of the first paragraph of this section, substitute "engineered and natural barriers" for "items and activities". In bullets 7 and 8, delete "items and". These two bullets refer to activities, while items (i.e., engineered or natural barriers) are already covered under bullets 5 and 6.
- 4l. Section 5.5, Page 17 - To be consistent with the definition of Q-List, delete "and activities" on the first line of this section.
- 4m. Section 6.0, Pages 19 and 20 - To be consistent with the definitions of the Q-List and the Quality Activities List, on line 6 of the last paragraph of page 19, delete "and activities". On the next line, delete "and their related activities". On lines 5, 7, and 9 of page 20, delete "and activities". On lines 6 and 9, insert "and activities on the Quality Activities List" after "Q-list".

Specific Comments Related to General Comment 5:

- 5a. Section 1.0, Page 1 - Not all barriers that contribute to meeting the postclosure requirements are "important to waste isolation"; only those barriers that are being relied upon. Therefore, in line 10, substitute "are relied on to meet" for "contribute to meeting".
- 5b. Section 2.0, Page 3 - For the same reason as stated in Comment 5a, in line 3, substitute "are relied on to meet" for "contribute to meeting".

- 5c. Section 3.0, Page 4 - The definition of "Items and activities important to waste isolation" specifies the site, engineered barrier system, and shaft and borehole seals as important to waste isolation. It is DOE's responsibility to determine which specific barriers are important to waste isolation. These should not be specified by definition. Also, according to 10 CFR 60.2, the site is a "location", not a barrier, and should not be used in the definition. A more correct definition would be: "Items important to waste isolation are those natural and engineered barriers that are relied on to meet the postclosure performance objectives in 10 CFR Part 60 Subpart E."
- 5d. Section 4.3, Page 6 - The GTP should not prescribe those items the staff considers to be important to waste isolation. In the last two lines of the page, delete the parenthetical examples. On line 1 of that same paragraph, insert "engineered and natural barriers" after "those".
- 5e. Section 5.1, Page 9 - The first sentence of the second paragraph indicates that items important to waste isolation are subject to certain design criteria in Part 60 (e.g., 60.135), which is incorrect. Part 60 does not explicitly provide design criteria for items important to waste isolation. It does provide criteria for the underground facility, shaft and borehole seals, and the waste package, regardless of whether these items are important to waste isolation. However, these criteria are not applied to any other items. Also, by referring to 60.135, the GTP is implying that the waste package is important to waste isolation. While this may actually be true, it is something that is DOE's responsibility to determine, and would be based on performance allocation, as supported by waste package investigations and performance assessments. Because of this, and the fact that design requirements are outside the scope of this GTP, the entire paragraph should be deleted.
- 5f. Section 5.3, Page 16 - The first full paragraph inappropriately suggests that most site characterization activities should be under the Subpart G QA program. The staff has revised the text from the July 1987 draft GTP by indicating that scoping and feasibility tests may not need to be conducted under Subpart G if tests for collecting similar data are planned. This would imply that if similar tests are not planned, the scoping or feasibility tests would need to be conducted under Subpart G. However, one outcome of the scoping or feasibility tests could be that no further data should be taken or that taking some other data would be more productive. In such cases, the data originally planned for would not be used in performance assessments nor in support of licensing findings and, therefore, would not be important to waste isolation. The scoping and feasibility tests would, in effect, be part of the planning process for site characterization, not characterization itself. This excessive conservatism is related to management of programmatic risk, which is DOE's responsibility. This paragraph should be deleted.

Specific Comments Related to General Comment 6:

- 6a. Section 4.2, Page 6 - The determination of when redundancy should be employed is out of the scope of this GTP. Redundancy should be discussed only to the extent to which it relates to the Q-List. Also, the second

Part 60 requirement cited is not strictly a redundancy requirement. Paragraph (b) should be revised to read: "DOE is required to employ redundancy with respect to utility service systems important to safety, as specified in 10 CFR Part 60 [i.e., 60.131(b)(5)(ii)]. Structures, systems, and components used to provide redundancy for items important to safety should be included on the Q-List."

- 6b. Section 5.2, Page 14 - The discussion of redundancy goes beyond Part 60 requirements in suggesting the use of redundancy whenever there is a potential for exceeding the accident dose limit. Paragraph (b) should be deleted.

Specific Comments Related to General Comment 7:

- 7a. Section 4.2, Pages 5 and 6 - The implication of the heavy reliance on PRA over other methods should be removed from this section. On line 1 of the second paragraph of page 5, delete "such as probabilistic risk assessment". Also, the discussion of PRA techniques at the top of page 6 (paragraphs (1), (2), and (3)) should be deleted.
- 7b. Section 5.2, Page 11 - PRAs have not been used in reactor licensing to determine whether a license should be granted; they have been used as design tools for performing systematic analyses of designs. On line 4 of the bottom paragraph, substitute "design" for "licensing".
- 7c. Section 5.2, Pages 12 and 13 - The discussion of PRA is too elementary to be useful guidance. Delete the seven paragraphs starting with "Certain activities" and ending with "system performance." It could be replaced with a simple reference to NUREG/CR-2300, PRA Procedures Guide, January 1983, and merged into Section 4.2(a).
- 7d. Section 5.5, Page 17 - The first paragraph of this section implies an unprecedented reliance on PRA results, which may be based on insufficient Failure Modes and Effects Analyses (FMEAs) or on FMEAs based on tests in dissimilar environments. Other methods may be appropriate to apply a system of graded QA. On line 7 of this paragraph, substitute "safety" for "probabilistic". On lines 8 and 9, delete "qualitative and quantitative".

Specific Comments Related to General Comment 8:

- 8a. Section 4.1, Page 4 - The guidance in paragraph (c) is already contained in another GTP. In order to prevent redundancy and potential confusion, this paragraph should be deleted.
- 8b. Section 4.4, Page 7 - Paragraph (b) discusses the content of the SCPs, something already addressed in R.G. 4.17 and DOE's SCP Annotated Outline (OGR/B-5). The last sentence on non-Q-List items goes beyond these two guidance documents. The entire paragraph should be deleted.

- 8c. Section 5.1, Page 10 - The discussion of qualification of existing data is already covered under a separate GTP. Delete the three paragraphs on this page..
- 8d. Section 5.4, Page 17 - It is inappropriate for this GTP to include guidance on SCP content, which is already addressed in other guidance documents. Delete paragraph (b).

Specific Comments Related to General Comment 9:

- 9a. Section 5.1, Page 8 - The paragraph at the bottom of the page contains material that is very basic and does not provide useful guidance. This paragraph should be deleted or moved to Section 4.1 as an introduction.
- 9b. Section 5.1, Page 9 - Paragraph (b) is redundant with Section 4.1(b). The last sentence of the paragraph should be merged with Section 4.1(b), and the remainder deleted.
- 9c. Section 5.2, Page 11 - The first two paragraphs are redundant with Section 4.2. They should be deleted. The third and fourth paragraphs should be merged with Section 4.2.
- 9d. Section 5.2, Pages 13 and 14 - The last paragraph on page 13 and the first paragraph on page 14 should be merged with Section 4.2(a).
- 9e. Section 5.2, Page 14 - Paragraph (c) should be merged with the discussion of previously established guidelines in Section 4.2(c).
- 9f. Section 5.3, Pages 15 and 16 - The information in this section, except for the last paragraph (on page 16), should be merged with Section 4.3.
- 9g. Section 5.4, Page 16 - The discussion in paragraph (a) is redundant with Section 4.4(a) and should be deleted.
- 9h. Section 5.5, Pages 17 through 19 - The information in this section should be merged with Section 4.5.

Specific Comments Related to General Comment 10:

- 10a. Section 3.0, Page 3 - This section should be reserved only for those new terms the staff wants to define. Therefore, since "Barrier" is already defined in Part 60, it should be deleted from this section (it is already in Appendix A). Also, "Items and activities important to safety" should be moved from this section to Appendix A, after it is revised to reflect the exact Part 60 definition (i.e., "and related activities" deleted).
- 10b. Section 4.2, Page 5 - "Single failure" is not defined in the GTP. The staff should state explicitly if it intends to use the same meaning here as in 10 CFR Part 50 Appendix A. This potentially very important concept should not be introduced without some discussion. Here, the term is used

to identify front-line systems for inclusion in the Q-List. In Part 50, it is applied in evaluating the sufficiency of safety systems. Because of this apparent difference in application, "single" should be removed from the last sentence of the first paragraph.

- 10c. Section 5.2, Page 11 - While the EPA postclosure containment requirement is probabilistic, the other two postclosure standards (individual protection and ground-water protection) are not. Therefore, on the last line of the page, insert "for overall system containment" before "for the period".
- 10d. Section 5.2, Page 12 - DOE disagrees with the statement in the first full sentence that the repository is a first-of-a-kind facility. This is only true for the postclosure phase, which is not the subject of this section. Even though no HLW repository has ever been built in this country, a correlation can be made to similar operations at other nuclear facilities and to the mining industry. Moreover, because the term is value-laden rather than factual, it is open to varying meanings depending on the experience and perspective of the reader. The first full sentence should be deleted.
- 10e. Section 5.5, Page 17 - NQA-1 Appendix 4A-1 has not been modified for use in the repository program. On line 4 of the second paragraph of this section, substitute "adopted" for "modified".
- 10f. Appendix A, Pages 23 through 26 - The following definitions should be deleted because they are rather basic, do not really provide guidance, or are not very germane to this GTP: "Backfill", "Design", "Design process", "Finding", "Licensing assessment", "Packing", "Reliability", "Reliability analysis", "Site", "Site characterization plan", "System or component performance", and "Waste form".
- 10g. Appendix A, Pages 23 through 26 - The following definitions should be deleted because they are already more appropriately contained in Section 3.0: "Activities", "Items and activities important to waste isolation", and "Q-list".
- 10h. Appendix A, Pages 23 through 26 - It would be more appropriate to present the following definitions in Section 3.0, rather than the Glossary, which should be limited to terms actually defined in regulations: "Consequence analysis", "Non-mechanistic failures", "Performance assessment", "Performance allocation", "Performance goals", "Risk", "Risk analysis", "Scenario", "Scenario analysis".
- 10i. Appendix A, Page 23 - In the definition of "Accessible environment", the statement that the overall system performance is calculated at this boundary is not totally correct. The overall performance standard (40 CFR Part 191, Subpart B) includes the ground-water protection requirement which applies to special sources of ground water, which can be up to 5 kilometers from the controlled area. Also, the individual protection

requirement applies anywhere within the accessible environment, not just at the boundary of the controlled area. The statement should be deleted or clarified to indicate that it applies only to the 40 CFR Part 191 containment requirement.

- 10j. Appendix A, Page 23 - The definition of a key term such as "Design basis" should be consistent with what is used in reactors and other fuel storage facilities, as given in Parts 50 and 72, respectively. Delete "Design basis" and its definition, and replace it with "Design bases" as stated in 10 CFR 50.2.
- 10k. Appendix A, Page 24 - The definition of "Items and activities important to safety" should reflect the exact Part 60 definition. Delete "and activities" in the phrase being defined; delete "and related activities" on line 2 of the definition.

Specific Comments Related to General Comment 11:

- 11a. Section 1.0, Page 1 - Part 60 does not require that compliance with regulatory requirements be demonstrated. On line 2 of the second paragraph, substitute "provide reasonable assurance" for "demonstrate". On the next line, substitute "assurance" for "demonstration".
- 11b. Section 5.1, Page 8 - DOE is not required to demonstrate that the repository will function as required. On line 4 of the bottom paragraph, substitute "provide reasonable assurance" for "demonstrate".
- 11c. Section 5.2, Page 11 - DOE is not required to demonstrate that failure of an item is not credible. On line 4 of the third paragraph, substitute "provide reasonable assurance" for "demonstrate".
- 11d. Section 6.0, Page 19 - DOE is not required to demonstrate compliance with Part 60. On line 4 of the last paragraph, substitute "provide reasonable assurance of" for "demonstrate".

Other Specific Comments:

- 12. Section 4.2, Page 6 - The use of previously established guidelines and standards should not be limited to those of nuclear power reactors only; guidance from other nuclear facilities may also prove useful. On line 1 of paragraph (c), substitute "facility" for "power reactor".
- 13. Section 5.5, Page 18 - The last paragraph introduces the examples of graded QA that appear on the following page, which are related to items important to waste isolation, not safety. On line 1 of the paragraph, substitute "waste isolation" for "safety".
- 14. Section 8.0, Page 20 - The contractor report, BMI/ONWI-588 is still undergoing DOE internal review. It should be deleted from the Bibliography.

8/28

Distribution: PCB MIE JOB Ballard
MELKOPP Youngblood
SBILKORN (Rec'd to WM, Dec 88)

WM Project 1
Docket No. ✓
JOB ✓
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