

U. S. NUCLEAR REGULATORY COMMISSION
AVAILABILITY OF FINAL TECHNICAL POSITION ON
ITEMS AND ACTIVITIES IN THE HIGH-LEVEL WASTE
GEOLOGIC REPOSITORY PROGRAM SUBJECT TO
QUALITY ASSURANCE REQUIREMENTS

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability.

SUMMARY: The Nuclear Regulatory Commission (NRC) is announcing the availability of NUREG-1318 "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," and a document providing staff responses to public comments on the September 1987 draft of the technical position.

ADDRESSES: These documents are available for purchase through the NRC's Public Document Room, 1717 H Street, N.W., Washington, DC 202/634-3273.

FOR FURTHER INFORMATION CONTACT: Mr. James E. Kennedy, Section Leader, Quality Assurance Section, Operations Branch, Division of High-Level Waste Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301/492-3402.

SUPPLEMENTARY INFORMATION: The Nuclear Waste Policy Act of 1982 (NWPA), Public Law 97-425, and the Commission regulation 10 CFR Part 60 promote interaction between the Department of Energy (DOE) and NRC prior to DOE's submittal of a license application for a geologic repository. These interactions are to fully inform DOE about the types and amounts of information that must be provided in a license application to allow a licensing decision to be made by NRC.

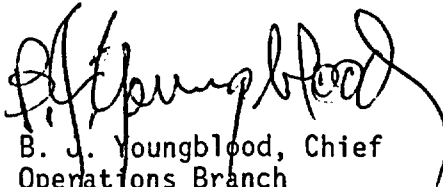
The principal mechanism for providing guidance to the DOE is the NRC staff's Site Characterization Analysis (SCA) of DOE's Site Characterization Plan (SCP). The SCA and SCP are required by the NWPA and 10 CFR Part 60. Additional means have been developed to supplement the guidance provided in the SCA. These include staff technical positions (TPs).

This TP provides guidance to DOE on what the staff considers as appropriate methods for identifying items and activities that are subject to the quality assurance requirements of 10 CFR Part 60.

On July 31, 1986 the NRC published the Notice of Availability for the draft TP and solicited public comments. As a result, ninety-six comments were received from eight different parties. Furthermore, a public meeting was held August 25, 1986 to discuss the draft TP and the NRC staff's responses to the public comments. Representatives for the States, affected Indian Tribes, industry, and the Department of Energy were in attendance and provided feedback to the NRC staff. In September 1987, a revised draft was issued for additional comment. As a result, ninety-three comments were received from six different parties. Changes and clarifications have been made in the final TP as a result of these interactions. The final position has also been reviewed by the Commission's Advisory Committee on Reactor Safeguards (ACRS) Waste Management Subcommittee.

Dated at Rockville, Maryland, this 19th day of April 1988.

FOR THE NUCLEAR REGULATORY COMMISSION



B. J. Youngblood, Chief
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

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MEMORANDUM FOR: Meyer, RPB, ARM
 FROM: Youngblood, HLOB, NMSS
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RESOLUTION OF PUBLIC COMMENTS

ON SEPTEMBER 1987

DRAFT OF Q-LIST

TECHNICAL POSITION

REFERENCE FOR COMMENTORS
ON Q-LIST TECHNICAL POSITION
(SEPTEMBER 1987 DRAFT)

<u>COMMENTOR</u>	<u>AFFILIATION</u>	<u>DATE OF COMMENT</u>
1. Leslie Jardine	U. S. Council for Energy Awareness (USCEA)	November 5, 1987
2. Nancy Montgomery	Utility Nuclear Waste Management Group (NNWVG)	November 5, 1987
3. Susan Zimmerman	State of Texas	October 26, 1987
4. Stephen Hart	Council of Energy Resource Tribes (CERT)	November 5, 1987
5. James Knight	Department of Energy (DOE)	November 5, 1987
6. Max Eisenberg	State of Maryland	December 8, 1987

U. S. Council for Energy Awareness (USCEA)

1. Section 4.2, page 5, Line 10: It is not necessary to utilize an accident dose limit to define a Q-List. As stated in Section 5.2, line 5 in the GTP, the 0.5 rem value is a threshold used to identify Q-list items. It is recommended that the term "accident dose limit" be removed and replaced with the wording used in 10CFR60.2 to define the term "important to safety."

Response: The staff is replacing the term "accident dose limit" with appropriate language from the definition of "important to safety" in 10 CFR 60.2 in order to clarify the distinction between these two concepts.

In the licensing of other types of facilities, the NRC has defined "design basis accidents" as those for which engineering safety features assure that the public health and safety will not be endangered. The purpose of the design basis accident concept is to test the facility design to determine if the safety features can adequately cope with accidents. Thus, it provides the facility designer with criteria to guide the design of the facility. In contrast, the concept of "important to safety" in the context of quality assurance, does not provide design criteria, but rather provides assurance that facility structures, systems, and components function as designed.

In terms of a high-level waste repository, the 10 CFR Part 60 rulemaking did not explicitly address design basis accidents. The staff intends to consider the initiation of a rulemaking which would explicitly address the design basis accident dose guideline for the repository. The staff will evaluate dose guidelines, particularly the 5 rem limit currently used in 10 CFR 72.68(a) for an Independent Spent Fuel Storage Installation. Due to the similarities between the activities at a 10 CFR Part 72 facility, and the preclosure activities at a repository, the 5 rem limit may be particularly appropriate for a repository.

However, it should be noted that the establishment of a design basis accident dose limit of 5 rem would not necessarily require a corresponding revision of the 0.5 rem "important to safety" standard. The Commission could choose to retain the 0.5 rem "important to safety" standard in order to build a measure of conservatism into the construction and operation of the repository. Using the definition of "important to safety" in 10 CFR 60.2, the quality assurance program would apply to all structures, systems, and components whose failure could result in a radiation dose of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure. This would not form the basis for the imposition of additional design requirements, but could extend the quality assurance program to a wider range of items than would be necessary to meet the design basis dose guideline.

2. USCEA - Section 4.2, page 5, line 18: The GTP text has introduced the new expression "in excess of 0.5 rem." It is recommended that for consistency the wording of 10CFR60.2 be used instead of this new expression. This would require replacing "in excess of 0.5 rem" with "0.5 rem or greater."

Response: The staff agrees. The wording has been revised to read .5 rem or greater.

3. USCEA - Section 5.2, page 11, lines 11 and 19: As in the specific comment above on Section 4.2, line 18, it is recommended that for consistency with 10 CFR60.2 the term "greater than 0.5 rem" be replaced with "0.5 rem or greater" in both lines 11 and 19. These changes would make the text in lines 11 and 19 consistent with line 3 immediately above.

Response: The staff agrees. The wording has been changed to read .5 rem or greater.

4. USCEA - Section 4.2(b), page 6, line 4: Because there is no explicit NRC guidance on accident dose limits in 10 CFR 60.2 or in any current GTP, consideration should be given to removing or rewording the explicit reference to an offsite dose limit for an accident.

Response: The staff agrees. See response to comment No. 1.

5. USCEA - Section 5.2(b), page 14, lines 4 and 10: As in our comment on Section 4.2(b), consideration should be given to removing or rewording the explicit references to "accident dose limit" and "dose limit for an accident."

Response: The staff agrees. See response to comment No. 1.

6. USCEA - Section 5.0 page 8, line 2: The reference to Section 5.0 apparently should be "4.0".

Response: The staff agrees. The section number has been revised to 4.0.

7. USCEA - Section 4.2 page 5, lines 16 and 20: The GTP uses the term probability of occurrence in terms of "exceedingly small" and "no matter what the probability of occurrence is." It is recommended that these terms be replaced with the term "credible." If this is acceptable, the definition of "credible" deleted from the definitions in Section 3.0 should be reincorporated. There is a wealth of experience and precedence with the term "credible" in the licensing process, so its use in defining a repository Q-list is appropriate.

Response: The staff agrees. The term "credible" has been reincorporated into the GTP.

With respect to the phrase "no matter what the probability of occurrence is," the staff believes that the position is clear without that qualifying phrase. It has therefore been removed. The position is intended to minimize the occurrence of accidents by placing those items which initiate accidents on the Q-list. Installation of mitigating systems to keep off-site releases within limits should not be a basis for removing accident initiating items from the Q-list.

8. USCEA - Section 5.2, page 11, line 17: As in the specific comment on Section 4.2, lines 16 and 20, it is recommended that the use of the term "credible" be used rather than "exceedingly small."

Response: The staff agrees. See response to comment No. 7.

9. USCEA - Section 5.2, page 11, lines 28 to 33: It is not necessary to retain this paragraph in this GTP. However, if it is retained, Section 3.0 should include the definition of the term "credible" which was deleted in this latest proposed revision of the GTP.

Response: The paragraph has been retained and moved to Section 4.2 since it contains a staff position. The term "credible" has been defined in Section 3.0, as suggested.

10. USCEA - Section 5.2(c), page 14, line 9: The wording in this sentence should be reviewed. The expression "to help eliminate the need to develop acceptable new approaches" may not be what the authors intended.

Response: The wording has been revised to clarify the meaning intended.

11. USCEA - Section 5.2(d), page 14, line 2: Does the expression "If retrieval is found to be necessary" imply that it will be unnecessary for DOE initially to design a detailed retrieval system--rather than simply make provision for one if needed--unless and until the repository is found to be unsuitable for permanent disposal? The Task Force believes that this should be the intent and, if so, that it might be expressed more clearly.

Response: The staff has clarified the expression by adding "at that time" after "If retrieval is found to be necessary."

12. USCEA - Section 8.0, page 20, line 1: Because Section 5.2(c) has deleted the reference to the Chang document BMI/ONWI-588, it may be appropriate to remove this reference from the bibliography.

Response: The staff agrees. The Chang document BMI/ONWI-588 will be removed from the bibliography.

13. USCEA - From the presentational standpoint, the Task Force believes that stating the staff positions in Section 4.0 and then discussing them in a parallel section (5.0) results in a significant amount of redundancy and creates some apparent inconsistencies, particularly through the use of different nomenclature and terminology.

Response: The TP follows the standard format for TP's including the recently approved GTPs on Qualification of Existing Data and Peer Review. Every effort has been made to remove any inconsistencies and redundancies from the TP.

14. UNWGMG - Activities on the Q-List:

During the August 25, 1987 Public Meeting to resolve comments on the original draft version (August 1986) of the "Q-List" GTP, our consultant, Mr. Tom Colandrea, discussed our rationale for placing only items on the Q-List as opposed to items and activities. As expressed in our October 29, 1986 comments on the original draft GTP, we believe that activities do not belong on the Q-List. The NRC indicated at the August 25 meeting that

it would be satisfactory for DOE to maintain a separate list of key activities of a specific nature, as opposed to activities of a generic nature (e.g., designing, inspecting, etc.). Accordingly, we recommended that reference to or inference that the Q-List contain activities be deleted. It was our understanding that the final draft version of the GTP would be revised to reflect this.

Response: The staff agrees and appropriate changes have been incorporated.

15. UNWMG - 0.5 Rem Dose Limit

We are concerned about the 0.5 rem or greater (apparently over a lifetime) accident dose limit (at or beyond the nearest boundary of the unrestricted area) established by the NRC in the draft GTP for determining which items go on the Q-List. Instead, we recommend that a 5.0 rem accident dose limit be used.

Response: See response to comment No. 1.

16. UNWMG - Should v. Shall

As explained by Mr. Colandrea at the August 25 Public Meeting, the original draft version of the GTP used a variety of terms interchangeably, including "should", "shall", "must", "need to", "may", etc. Although the final draft version (September 1987) of the GTP has made significant progress toward correcting this matter, there are still statements within the GTP that should be revised to obtain consistency and accurately convey the intent of the statement. The enclosed marked-up version of the final draft identifies several examples of such needed revisions.

Response: The staff agrees. The TP has been revised to reflect the noted examples.

17. UNWMG - Redundant Information

At the August 25 Public Meeting, Mr. Colandrea indicated that the draft GTP contained considerable redundant information. We recommended that the GTP should be reviewed to eliminate duplication where such redundancy makes no positive contribution to the guidance contained in the GTP.

It appears that the NRC has addressed our recommendation to some extent in the final draft version of the GTP, but there are still a number of places within the document with duplicative wording that could be eliminated. For example, the Glossary in Appendix A contains all of the definitions listed in Section 3.0, Definitions, using identical wording in both places. Similarly, much of the information in Section 5.0, Discussion, has already been covered in Section 4.0, Staff Positions. Both sections should be consolidated into one section in order to reduce repetition and help assure consistency.

Response: The TP follows the standard format for TP's including the recently approved GTP on Qualification of Existing Data and Peer Review. Every effort has been made to remove any inconsistencies and redundancies from the GTP.

18. UNWVG - Areas Requiring Clarification:

There were a number of specific areas in the original draft version (August 1986) of the GTP where the wording should have been revised for the sake of clarity. Most of these areas have been revised. However, there are still several places where the wording should be clarified. These are reflected in the attached marked-up version of the GTP.

Response: Every effort has been made to clarify all the areas where clarification was needed. See Text for actual clarifications.

19. UNWVG - Other Miscellaneous Comments:

In Section 4.2, the wording states that "DOE should generate all accident sequences...". This could lead to virtually infinite analysis. Some threshold should be established, otherwise, accident analysis will be completely open-ended. We recommend that the process for the waste program resemble that already in place for the industry.

Response: The paragraph has been reworded to better express the intent. See also response to comment No. 7.

20. State of Texas 1. Section 4.4(a): Why was the word "shall" changed to "should" for the identification of the structures, systems and components important to safety...? At the time of license application, the DOE should know this information. Suggest replacing "should" with "shall", like in the original.

Response: The 10 CFR 60 requirements contained in this section are now cited as such. The term "shall" refers to a requirement and the term "should" refers to staff guidance/recommendations, and the TP now reflects this convention.

21. State of Texas - Section 5.4(a): Same comment as above.

Response: The 10 CFR 60 requirements contained in this section are cited as such. As the term "shall" refers to a requirement and the term "should" refers to staff guidance/recommendations, it would not be appropriate to replace these terms as used in the reference paragraph.

22. Council of Energy Resource Tribes - The only significant change that is needed is the statement on page 24 that "The following example(s) of how grading can be accomplished are helpful in interpreting the guidance given above." The two examples given in the original document were then deleted. Either this sentence should be deleted, or the "are" should be changed to "is" and the single example under discussion should be clearly identified, not just included as part of the discussion of graded QA.

Response: The staff agrees. The example has been clearly noted.

23. DOE - 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.

Response: See response to comment No. 1.

24. DOE - 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.

Response: The staff has revised the TP to address several of the concerns identified. The staff believes that although probability will be the principal criterion for screening accidents to be considered in design, it will not be the only one. For conservatism, it may be desirable in some instances for low probability, high consequence events to be included as design basis accidents. This concept is reflected in the NNWSI Consultation Draft SCP, Section 8.3.5.5.1, and the staff believes it is appropriate for this stage of the program.

25. DOE - 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.

Response: The regulations do not exempt the retrieval operations from being covered by the definition of "important to safety". Therefore, if retrieval is found to be necessary, a detailed design analysis will need to be performed to determine if any structures, system or components are important to safety. The staff agrees that only plans are required by Part 60 at the time of license application (see response to comment 11) and that identification of addition items for the Q-list can be determined if and when detailed designs are developed.

26. DOE - 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.

Response: The staff agrees and the TP has been revised. The staff's primary objective in requesting the list is to help develop confidence that the QA program is being applied to the appropriate items and activities. DOE's proposal to provide that information in two lists instead of one will provide the staff with the necessary information.

With respect to the natural barriers, the staff agrees that the state of the barriers as found are not controlled by DOE. However, DOE can affect the quality of the natural barriers through the activities that affect

them. The data collected on the site which will be used to characterize its performance in isolating waste and other activities are important and need to be controlled. The application of the Subpart G QA program to these activities, as identified in a Quality Activities List, will assure their quality. The TP has therefore been revised to require that only engineered barriers be included on the Q-list.

27. DOE - 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.

Response: The staff agrees in part. The staff has deleted the phrase which appeared to prescribe that certain specific engineered barriers were to be on the Q-list. The staff believes that the basic position which states that items important to waste isolation are those which are relied on to meet the performance objectives is accurate and sufficient.

With respect to DOE's comment that the TP addresses issues related more to management of programmatic risk than to safety, the staff believes that its positions encompass only those which affect safety or waste isolation issues and the documentation of how these will have been resolved. Some may also affect the programmatic risk, but that has not been a concern of the staff in the development of its positions.

28. DOE - 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 in 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 TP and possibly covered under separate guidance.

Response: The Commission does not require redundancy except as specified in 10 CFR Part 60. The GTP has been modified to clarify this point.

29. DOE - 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.

Response: In the TP the staff has stated that DOE "may" use probabilistic risk assessment as a tool for identifying items and activities which are important to safety. PRA's are being relied on increasingly in the power reactor program as a means of assessing the safety of plants and supplementing the deterministic approach used for licensing of power reactors. The staff believes that PRA's are a logical and useful method for assessing safety during the preclosure phase. In addition, this approach is consistent with the approach prescribed by the EPA standard for post-closure performance assessments of the repository, and with the Consultation Draft of the NNWSI Site Characterization Plan.

The discussions of PRA's have been reviewed and several unnecessary sections deleted. Other sections have been retained for the general audience of the TP.

30. DOE - 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.

Response: With respect to the information to be supplied in the Site Characterization Plans, the information requested in the technical position is consistent with the February 14, 1985 Annotated Outline, which the staff reviewed and approved, and the July 1, 1985 minutes of a meeting between the staff and DOE on the Q-List. The staff believes that the process for resolving the staff comments on the consultation draft SCP,

which were developed consistent with the guidance stated above, is the preferred way to resolve this concern.

31. DOE - 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.

Response: The TP follows the standard format for TP's including the recently approved TP on Qualification of Existing Data and Peer Review. Every effort has been made to remove any inconsistencies and redundancies from the TP. The staff's resolution of the Specific Comments is also provided in this package.

32. DOE - 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.

Response: The staff has placed all of the important definitions in the position in Section 3. The glossary consists of all the definitions necessary to understand the TP. The staff agrees with most of the points in the comment and has made appropriate revisions to the TP. In Section 3, all definitions which list Part 60 as a reference are now consistent with Part 60. The definitions section has been reserved for significant terms, whereas the glossary contains other terms which are helpful in understanding the TP.

33. DOE - 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.

Response: The staff does not agree. 10 CFR Part 60, Section 60.101(a)(2), and 60.101(b) describe a "demonstration of compliance" with the criteria in Part 60 by DOE as the basis for a finding of reasonable assurance by the Commission. The TP refers to actions DOE must take and therefore "demonstrating" is correct. In one location, the TP stated "a demonstration of

performance was required". This has been revised to be consistent with the language in 10 CFR 60 requiring a demonstration of compliance.

34. DOE - Specific 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.

Response: See response to comment No. 1.

35. DOE - 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."

Response: The paragraph has been revised to address this comment and other similar comments. See response to Comment No. 7.

DOE - Specific Comments Related to General Comment 3:

36. 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."

Response: The staff has revised the position and added the phrase "at that time" to help clarify the position.

37. 3b. DOE - 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.

Response: See response to comment No. 36.

DOE - Specific Comments Related to General Comment 4:

38. 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 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".

Response: The staff agrees that the "Q-list" is not the full scope of the QA program. The sentence has therefore been revised.

39. 4b. DOE - 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."

Response: The staff agrees and the definition has been modified as suggested.

40. 4c. DOE - 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.

Response: The staff agrees. To emphasize, however, that activities are also important, the staff has defined "Quality Activities List" and noted that they need to be covered under Subpart G of 10 CFR Part 60.

41. 4d. DOE - 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."

Response: The staff generally agrees and most of the above definition has been added to the TP. The phrase "the characterization or evaluation..." has not been included because certain activities (such as blasting of shafts and drifts) are neither characterization nor evaluation activities, yet belong on the list of activities.

42. 4e. DOE - 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.

Response: The staff agrees and the suggested changes have been incorporated.

43. 4f. DOE - 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".

Response: The staff agrees and the proposed changes have been incorporated.

44. 4g. DOE - 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".

Response: The staff agrees and the proposed change has been incorporated.

45. 4h. DOE - 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".

Response: The staff agrees with most of the comment and has made appropriate changes. The phrase "site and engineered barriers" has not been replaced with "natural barriers..." as suggested since data collection on engineered barriers is a site characterization activity.

46. 4i. DOE - 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".

Response: The staff agrees and a deletion has been made. Activities are within the scope of the QA program but the specific reference to Part 60 does not include that term.

47. 4j. DOE - 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).

Response: The first sentence has been revised to state only the scope of the QA program, rather than the scope of the Q-list and Quality Activities List. This change eliminates the inference that activities must be on the Q-list. The paragraph has not been merged with 4.1(a) since it contains background material. Section 4 is reserved for staff positions only.

48. 4k. DOE - 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.

Response: The staff agrees. The suggested changes have been incorporated.

49. 4l. DOE - Section 5.5, Page 17 - To be consistent with the definition of Q-List, delete "and activities" on the first line of this section.

Response: The staff has deleted the term Q-list and added "scope of the QA program." This change also eliminates the implication that activities are on the Q-list.

50. 4m. DOE - 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".

Response: The staff agrees with the proposed changes and has incorporated them into the TP.

DOE - Specific Comments Related to General Comment 5:

51. 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".

Response: The staff agrees. The requested change has been made.

52. 5b. DOE - 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".

Response: The staff agrees. The suggested change has been made.

53. 5c. DOE - 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."

Response: The staff agrees and the proposed change has been incorporated.

54. 5d. DOE - 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".

Response: The staff agrees and the proposed changes have been incorporated.

55. 5e. (DOE) 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.

Response: The staff agrees that 60.135 applies to only the waste package and not all items important to waste isolation. The wording has been revised. The references to important to safety have been retained since there is a direct reference in the design criteria in 60.131(b) to important to safety items.

The staff disagrees with the statement that the waste package is not or will not be important to waste isolation. The TP and DOE define items important to waste isolation as those natural and engineered barriers that are relied on to meet the postclosure performance objectives in 10 CFR Subpart E. Since one of the performance objectives is the 300-1000 year lifetime for the waste package, the waste package (or portions of the package that are relied on to achieve the performance objective) will be Q-listed.

56. 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.

Response: The staff agrees that it may not be possible for DOE to have planned additional tests before the scoping or feasibility tests have been completed. The reference to planned tests has therefore been deleted.

The staff disagrees with the statement that the entire paragraph should be deleted. Since it is not known at this time which barriers will be relied on for waste isolation, most of the data collected during this phase could potentially be used in licensing. The paragraph emphasizes that the assumption should be made that data will be utilized in the license application until it can be shown otherwise.

Specific Comments Related to General Comment 6:

57. 6a. DOE - 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.

Response: The staff agrees that requiring additional redundancy is out of the scope of this TP. The requirement has been deleted.

58. 6b. DOE - 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.

Response: The staff agrees that requiring additional redundancy is out of the scope of this TP. The requirement has been deleted.

59. 7a. DOE - 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.

Response: The phrase "such as probabilistic risk assessment" has been deleted since the position is clear without it. The discussion in the position of the techniques has also been deleted since this material is included in Section 5.2.

60. 7b. DOE - 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".

Response: PRA's have been utilized in licensing, although not as the primary bases for determining whether a license should be granted. The word "licensing" has been deleted and "design" added to eliminate any confusion.

61. 7c. DOE - 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).

Response: This TP is written for a broad audience, not all of which are familiar with PRA's. This discussion is intended to help them in understanding what is included in a PRA analysis.

62. 7d. DOE - 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".

Response: The staff agrees that other methods of analysis may be utilized to determine an item's importance to safety or isolation and the QA measures required. To remove the implication that only PRA's may be used, the staff has revised the statement as suggested above.

Specific Comments Related to General Comment 8:

63. 8a. DOE - 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.

Response: The paragraph describes the types of information that may need to be qualified for use in licensing and gives some context to the GTP reference. The staff believes it is useful for readers not familiar with repository quality assurance programs. The language of the paragraph has been revised slightly, however, to be consistent with the language in the Generic Technical Position.

64. 8b. DOE - 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.

Response: See response to Comment No. 30.

65. 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.

Response: See response to Comment No. 63.

66. 8d. DOE - 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).

Response: See response to comment No. 30.

Specific Comments Related to General Comment 9:

67. 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.

Response: The staff agrees that the material is basic, but is necessary to provide the background material for organizations or individuals that are not familiar with the quality assurance program.

68. 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.

Response: The paragraph has been revised to remove some of the redundant information. Due to the standard TP format this section will not be deleted. The last sentence has been incorporated into 4.1(b) as suggested.

69. 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.

Response: The staff agrees in part with the comment. The second paragraph has been deleted. The first has been retained because it contains some additional background information not found in 4.2. The positions in the third and fourth paragraphs have been included in 4.2 and background material has been retained in 5.2.

70. 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).

Response: The last paragraph on page 13 has been merged with 4.2.(a). The first paragraph on page 14 has been retained in 5.2 because it does not contain a staff position. Section 4 is intended to permit staff positions only.

71. 9e. Section 5.2, Page 14 - Paragraph (c) should be merged with the discussion of previously established guidelines in Section 4.2(c).

Response: This paragraph is consistent with the format for Technical Positions and is being retained in 5.2. It contains no new staff positions (which are presented in 4.2), only a discussion the positions previously presented.

72. 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.

Response: See response to comment no. 71.

73. 9g. Section 5.4, Page 16 - The discussion in paragraph (a) is redundant with Section 4.4(a) and should be deleted.

Response: The revised paragraph has been retained to provide some background information on the position.

74. 9h. Section 5.5, Pages 17 through 19 - The information in this section should be merged with Section 4.5.

Response: The paragraph contains some background information on the positions contained in 4.5. It is being retained to be consistent with the format established for TPs.

Specific Comments Related to General Comment 10:

75. 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).

Response: The staff has included in Section 3.0 the most important terms in the TP. The glossary contains a larger listing of terms from the TP. This arrangement has been retained in the final position. The definition of "important to safety" has been revised to be consistent with Part 60.

76. 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.

Response: The staff agrees and the word "single" has been deleted.

77. 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".

Response: The staff agrees and has revised the wording in the TP.

78. 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.

Response: The staff agrees and has removed the sentence.

79. 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".

Response: The NQA-1 Appendix 4A-1 has been modified somewhat in the GTP to permit grading of site characterization data collection activities. The wording has been retained.

80. 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".

Response: The glossary has been reviewed to eliminate a number of terms which are not very germane to the TP. Those included are believed to provide necessary background information.

81. 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".

Response: The glossary is designed to include all terms which need to be defined including those which are sufficiently important to be highlighted within the "Definition" Section.

82. 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".

Response: See response to comment 81.

83. 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.

Response: The staff agrees and the statement has been deleted from the definition.

84. 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.

Response: See response to comment no. 1. The term has been deleted as a result of the discussion in (1).

85. 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.

Response: The staff agrees. The reference to "activities" has been deleted from the definition.

Specific Comments Related to General Comment 11:

86. 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".

Response: See response to comment no. 33.

87. 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".

Response: See response to comment no. 33.

88. 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".

Response: See response to comment no. 33.

89. 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".

Response: See response to comment no. 33.

Other Specific Comments:

90. 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".

Response: The staff agrees. The change has been made as requested.

91. 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".

Response: "Waste Isolation" has been added to safety to provide the necessary guidance. The term "safety" has been retained since the sentence contains information relevant to both safety and isolation items.

92. 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.

Response: The staff agrees. The Chang document BMI/ONWI-588 will be removed from the bibliography.

93. State of Maryland - We would just like to re-emphasize the fact that a geological repository will store large volumes and activities of spent fuel. It is also true that we have no operating history on such a facility. In the event that an accident should occur involving a geological repository the potential impact would be enormous. Consequently, we believe that the 0.5 rem limit should not be changed prior to collecting sufficient data on an operational geological repository.

Response: See response to comment no. 1. The staff believes that a design basis accident dose limit needs to be considered for rule-making since it is not explicitly addressed in Part 60. This issue will be settled outside of this staff technical position.