NUREG-1297

Peer Review for High-Level Nuclear Waste Repositories

Generic Technical Position

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

W. D. Altman, J. P. Donnelly, J. E. Kennedy



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W. D. Altman, J. P. Donnelly, J. E. Kennedy

Division of High-Level Nuclear Waste Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555



ABSTRACT

This document provides guidance on the use of the peer review process in the high-level nuclear waste repository program. The applicant must demonstrate in the license application that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a quality assurance (QA) program as described in 10 CFR Part 60, Subpart G.

Peer reviews may be used as part of the QA actions necessary to provide adequate confidence in the work being reviewed. Because of several unique conditions inherent to the geologic repository program, expert judgment will need to be utilized in assessing the adequacy of work. Peer reviews are a mechanism by which these judgments may be made.

This document provides guidance on areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review.

This document is identical to that which was noticed in the Federal Register, Vol. 52, No. 131, July 9, 1987, 25932-25933. The NUREG format is being used to facilitate referencing and use of the document.

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GENERIC TECHNICAL POSITION ON

PEER REVIEW

FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

I. INTRODUCTION

To obtain a license to operate a high-level nuclear waste repository, the Department of Energy (DOE) must be able to demonstrate in a license application that the applicable health, safety, and environmental regulations in 10 CFR 60 have been fulfilled. Confidence in the adequacy of the data, data analyses, construction activities, and other items and activities associated with the license application is obtained through a quality assurance (QA) program. Subpart G of 10 CFR 60 specifies a QA program for items and activities important to safety and waste isolation. DOE should have a QA program in place, consistent with 10 CFR 60, Subpart G and any applicable regulatory guidance, prior to the start of site characterization activities.

Peer reviews may be employed as part of the QA actions necessary to provide adequate confidence in the work under review where the work may be a design, a plan, a test procedure, a research report, a materials choice, or a site exploration. Because of the potential uncertainty in most geotechnical data and their analyses, the need to make projections over thousands of years, the lack of unanimity among experts, and the first-of-a-kind nature of geologic repository technical issues, expert judgment will need to be utilized in assessing the adequacy of work. Peer reviews are a mechanism by which these judgments may be made.

This Generic Technical Position (GTP) provides guidance on the definition of peer reviews, the areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review. Other methods may be proposed or used and will be reviewed for acceptability by the NRC on a case-by-case basis.

II. REGULATORY FRAMEWORK

The regulatory basis for peer reviews as a QA measure is provided by 10 CFR 60, Subpart G, which states that the repository QA program is to be based on the criteria of Appendix B of 10 CFR 50 "as applicable, and appropriately supplemented by additional criteria as required by 60.151." This peer review GTP supplements the criteria in Appendix B of 10 CFR 50.

III. DEFINITIONS

Peer

A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

Peer Review Group

A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed, and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

Peer Review

A peer review is a documented, critical review performed by peers who are independent of the work being reviewed. The peer's independence from the work being reviewed means that the peer, a) was not involved as a participant, supervisor, technical reviewer or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

A peer review is an in-depth critique of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work. In contrast to peer review, the term "technical review," as used in this GTP, refers to a review to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

Peer Review Report

A documented in-depth report of the proceedings and findings of a peer review.

IV. STAFF POSITIONS

1. Applicability of Peer Reviews

a. A peer review should be used when the adequacy of information (e.g., data, interpretations, test results, design assumptions, etc.) or the suitability of procedures and methods essential to showing that the repository system meets or exceeds its performance requirements with respect to safety and waste isolation cannot otherwise be established through testing, alternate calculations or reference to previously established standards and practices.

b. In general, the following conditions are indicative of situations in which a peer review should be considered:

   Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing

Decisions or interpretations having significant impact on performance assessment conclusions will be made

Novel or beyond the state-of-the-art testing, plans and procedures, or analyses are or will be utilized

Detailed technical criteria or standard industry procedures do not exist or are being developed

Results of tests are not reproducible or repeatable

Data or interpretations are ambiguous

Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program

c. A peer review should be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.

2. Structure of Peer Review Group

The number of peers comprising a peer group should vary with the complexity of the work to be reviewed, its importance to establishing that safety or waste isolation performance goals are met, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review. The collective technical expertise and qualifications of peer group members should span the technical issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. Technical areas more central to the work to be reviewed should receive proportionally more representation on the peer review group.

As a general rule, the size of the peer review group is less important than the technical qualifications of the peer reviewers and their ability to span the technical issues involved. The peer review group should represent major schools of scientific thought. The potential for technical or organizational partiality should be minimized by selecting peers to provide a balanced review group. One example of technical partiality is when all the reviewers favor one method of data collection when other appropriate methods are available. An example of organizational partiality is when all the reviewers are from the same university, agency, state organization, etc.

3. Acceptability of Peers

The acceptability of any peer review group member is based on two requirements; technical qualifications and independence, both of which should be satisfied.

a. The technical qualifications of the peer reviewers, in their review areas, should be at least equivalent to that needed for the original work under

review and should be the primary consideration in the selection of peer reviewers. Each peer reviewer should have recognized and verifiable technical credentials in the technical area he or she has been selected to cover. The technical qualifications of each peer, and hence of the peer review group as a whole, should relate to the importance of the subject matter to be reviewed.

b. Members of the peer review group should be independent of the original work to be reviewed. Independence in this case means that the peer, a) was not involved as a participant, supervisor, technical reviewer or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed.

Because of DOE's pervasive effort in the waste management area, the lack or unavailability of other technical expertise in certain areas, and the possibility of reducing the technical qualifications of the reviewers in order that total independence is maintained, it may not be possible to exclude all DOE or DOE contractor personnel from participating in a peer review. In those cases where total independence cannot be met, a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected should be placed in the peer review report.

The pervasive nature of DOE's effort in the waste management area also makes it necessary that both the work under review as well as the peer review of this work be allowed to be funded by DOE.

The independence criteria is not meant to exclude eminent scientists or engineers upon whose earlier work certain of the work under review is based so long as a general scientific consensus has been reached regarding the validity of their earlier work.

4. Peer Review Process

The peer review process may vary from case to case, and should be determined by the chairperson of the peer review group, consistent with the guidance provided in this GTP. In meetings and/or correspondence, the peer review group should evaluate and report on: (a) validity of assumptions; (b) alternate interpretations; (c) uncertainty of results and consequences if wrong; (d) appropriateness and limitations of methodology and procedures; (e) adequacy of application; (f) accuracy of calculations; (g) validity of conclusions; (h) adequacy of requirements and criteria. Furthermore, full and frank discussions between the peer reviewers and the performers of the work are encouraged.

Procedures should be developed for the peer review process to implement the guidance and staff positions in this GTP. Written minutes should be prepared of meetings, deliberations, and activities of the peer review process.

Procedures should provide methods for initiating a peer review. For any given peer review, procedures should require a planning document that describes the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule to arrive at a peer review report.

5. Peer Review Report

A written report documenting the results of the peer review should be issued. It is usually prepared under the direction of the chairperson of the peer review group, and is signed by each member individually. It should clearly state the work or issue that was peer reviewed and the conclusions reached by the peer review process (item 4 above). The report should include individual statements by peer review group members reflecting dissenting views or additional comments, as appropriate. The peer review report should contain a listing of the reviewers and any acceptability information (i.e., technical qualifications and independence) for each member of the peer group, including potential technical and/or organizational partiality. The NRC will evaluate the acceptability information for peer review group members on a case-by-case basis.

V. DISCUSSION

Due to the first-of-a-kind nature of a repository, beyond the state-of-the-art testing, and potential uncertainty in most geotechnical and scientific work, peer reviews should be used as a management tool to achieve confidence in the validity of certain technical and programmatic judgments. The intent of a peer review is to pass judgment on the technical adequacy of the work or data submitted for review, to identify aspects of the work on which technical consensus exists, to identify aspects on which technical consensus does not exist, and to identify aspects of the reviewed work which the reviewers believe to be incorrect or which need amplification. A peer review provides assurance in cases where scientific uncertainties and ambiguities exist but in which technical and programmatic judgments and decisions still must be made.

In general, peer reviews should be used in a confirmatory sense. Peer reviews should not be used as a substitute for readily collectable data. Conclusions based on inadequate or limited data cannot be improved by subjecting those conclusions to the peer review process. Peer reviews should not be confused with technical reviews. Technical reviews are performed to verify compliance to predetermined requirements; industry standards; or common scientific, engineering, and industry practice.

As a minimum, the QA organization should provide surveillance of the peer review process to ensure that the procedures conform to the guidance of this GTP and that they are followed by the peer review group.

The NRC staff will selectively evaluate DOE's peer review process from their inception (e.g., initial peer selection) through the peer review group deliberations, until the issuance of the peer review report.

The NRC staff will use this GTP as guidance in its evaluation of DOE's peer review process and to determine the acceptability of peer review reports for licensing.

APPENDIX

RESOLUTION OF COMMENTS FOR THE GENERIC TECHNICAL POSITION ON PEER REVIEW FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

INSTRUCTIONS

The following instructions are being provided so that the comment resolution package is easy to reference and follow.

First, all the comments have been grouped under the section of the Generic Technical Position (GTP) which they address. For example, "Section III Definitions" would be a heading and all comments corresponding to that section would follow. If a comment did not address a specific section of the GTP, it was grouped under "General" or another appropriate heading and placed in the beginning of the comment response package.

Second, the individual comments have been identified. An example is "9. Comment #4-2 (DOE)." The numeral "9" is merely the chronological numbering system. The numeral "4" corresponds to numeral "4" of the "Reference Key of Commentors" (see the next page). The numeral "2" simply indicates it was the second comment made by the commentor. If the commentors did not number their respective comments, the NRC assigned numbers to each. Lastly, "(DOE)" is merely an abbreviated reference to an individual commentor.

REFERENCE KEY ON COMMENTS
RECEIVED FOR GENERIC TECHNICAL POSITIONS (GTPs)
ON " PEER REVIEW " AND " QUALIFICATION OF EXISTING DATA."

	Commentor	Affiliation	Date of Comment
1.	Norman C. Frank	Private Citizen	8-1-86
2.	Robert R. Loux	State of Nevada Nuclear Waste Project Office	10-3-86
3.	John J. Kearney	Edison Electric Institute	10-29-86
4.	James P. Knight	Department of Energy	11-7-86
5.	David G. Scott	State of New Hampshire Office of State Planning	11-7-86
6.	Richard A. Strait	Department of the Interior National Park Service	11-12-86
7.	Patrick D. Spurgin	State of Utah High Level Nuclear Waste Office	11-13-86
8.	John W. Green	State of Mississippi Department of Energy and Transportation	11-14-86
9.	Max Eisenberg	State of Maryland Department of Health and Mental Hygiene	11-17-86
10.	Steve Frishman	State of Texas Nuclear Waste Programs Office	11-21-86
11.	Robert M. Hallisey	State of Massachusetts Department of Public Health	12-12-86

RESOLUTION OF COMMENTS FOR THE GTP ON PEER REVIEW FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

General

1. Comment #3-1 (EEI):

The stated purpose of the "Draft Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories" is to provide guidance on the definition of peer review, the areas where peer review is appropriate, the qualification of peers, and the conduct and documentation of a peer review. The Department of Energy (DOE) currently has in place its own internal procedure for the conduct of peer reviews as part of planned and systematic actions necessary to provide confidence in the results of its own work. EEI/UNWMG suggests that, rather than develop a GTP regarding peer review for issues related to high-level nuclear waste repositories, the NRC endorse the peer review procedure currently implemented by DOE.

The approach described above would be similar to that adopted by the NRC in its Regulatory Guide program where specific industry standards are referenced as acceptable, some with and some without qualification. Further, the endorsement of a specific DOE procedure would minimize the possibility of conflicts between the DOE procedure and NRC guidance on this topic.

Response:

The NRC GTP and DOE internal procedure were developed concurrently and hence there was no DOE procedure to endorse until recently. Because the GTP has been noticed in the Federal Register and numerous public comments have been received, the GTP will be issued as a final position. The staff believes that the quality and defensibility of the GTP have been improved because of this process.

Nonetheless, the DOE Office of Geologic Repositories (OGR) has its own internal procedure for peer review in Quality Assurance Plan for High-Level Radioactive Waste Repositories, OGR B-3, dated August 1986. The NRC has reviewed and commented on this procedure based on the guidance found in NRC's draft peer review GTP. The staff's comments state that any differences between their procedure and the GTP should be noted and justified. If DOE submits such a justification, and it is reviewed and approved by NRC, then DOE's peer review procedure would be acceptable.

2. Comment #4-1 (DOE):

It should be made clearer that this GTP is only one method of assessing the adequacy of work.

See specific comments (Nos. 3, 5, and 6)

Response:

Agreed. Section I, second paragraph, the last sentence has been changed to, "Peer reviews are a mechanism by which these judgments may be made."

3. Comment #4-2 (DOE):

References to salary, performance, reviews, funding and financial stake are considered inappropriate and too prescriptive. It should be the responsibility of the person requesting the Peer Review to determine and document the independence of Peer Reviewers.

See specific comments (No. 11, 19, and 21).

Response:

To address the points made in the first sentence, certain independence criteria must be met and this guidance is found in Section IV.3.b., which has been revised. For the points in the second sentence, the staff agrees. The person requesting the peer review should determine and document the independence of potential peer review members. Furthermore, that information should be part of the peer review report. See the revised guidance in Section IV.5.

4. Comment #4-3 (DOE):

Page 1, Sect. I para. 1: The paragraph appears to be contradictory in that it states: "Peer reviews may be employed..." then later in the paragraph it states "Peer reviews are the mechanism..."

Change latter statement to read: "Peer reviews are a mechanism. . . ." Also see comment #5.

Response:

Agreed. See the response to comment #2.

5. Comment # 4-5 (DOE):

Page 1, Sect. I, para. 1, last sentence: Peer reviews are one of the methods by which judgments are made.

Rewrite last sentence to state: "Peer reviews are a mechanism to aid in making these judgments."

Response:

Agreed. See the response to comment #2.

6. Comment #7-1 (Utah):

At present, we have no specific comments on the generic technical positions. As a general observation, we would note our concern that the GTPs not be worded in such a way as to provide the inference that the Commission will look favorably upon the use of conservative assumptions in lieu of data, where data collection is both practicable and reasonable. We would urge you to assure that such concepts as nonmechanical failures, peer review, and alternative means of qualification of existing data are placed firmly in the context of the Commission's commitment to base its licensing decisions on as complete a set of data as is practicable.

Response:

The NRC agrees with your remarks. To the extent practical and reasonable, a complete, accurate, and defensible data base has been and will be the basis for NRC's licensing decisions.

7. Comment #9-2 (Texas):

Page 1, paragraph 1: The last sentence states that peer reviews are the mechanisms needed to make expert judgments. Unless the NRC intends to require that all judgments are required to have peer reviews, then the sentence should read that peer reviews are a mechanism.

Response:

Agreed. See the response to comment #2.

8. Comment #11-1 (Massachusetts):

The document presents a thorough summary of the peer review process to be used by DOE. An additional element which needs to be mentioned however is the amount of time needed to complete the peer review process. While this

would be expected to vary from case to case, there must be some limit on the time expended on what are sure to be rather controversial and open-ended discussions. It is recognized that this cannot be predetermined here, but some indication of the average and/or maximum amount of time necessary for an adequate review would provide some clarity.

We hope these comments will be helpful in the development of the final Generic Technical Position.

Response:

Due to the large range of potential peer review topics and different levels of complexity, the NRC cannot prescribe "the average and/or maximum amount of time necessary for an adequate review." However, DOE should provide procedures requiring a planning document that outlines the schedule for arriving at a peer review report. This thought has been incorporated in Section IV.4., the last paragraph.

Editorial

9. Comments #4-12 to 17 and #4-20 to 23 (DOE):

12. Page 3, Section IV, 1a, b & c: Three different terms are used: "should be used," "is appropriate or necessary," "is recommended." These are confusing and should be consistent.

Make these terms consistent by using "should be used."

13. Page 3, Section IV, 1b: Clarify first item to quantify "uncertainty." To eliminate all uncertainty may be impossible.

Add "significant" before uncertainty."

14. Page 3, Section IV, 1b: Reword second item to qualify that these decisions and interpretations have been made in the face of uncertainty.

Second item to read: "Decisions or interpretations having significant impact on performance assessment conclusions when such decisions and interpretations have been made in the face of significant uncertainty."

15. Page 3, Section IV 1b: The last item in section b. should be clarified to use the last part of item as an example.

Last item should read: "Data adequacy is questionable--such as, data may not have been collected in conformance with an established QA program."

16. Pages 3 and 4, Section IV: The following terms need to be defined to clarify use and to avoid controversy: "Ambiguous" - Section IV.1.b, 10th line; "Professional stature" - Sect. IV, 2nd para.; "ability to span the technical issues" - Sect. IV, 2nd para.; "major schools of scientific views" - Sect. IV, 2nd para.; "recognized technical credentials" - Sect. IV, 3.a., 1st line; "prestige" - Sect. IV, 3.a., 5th line; "eminent scientist" - Sect. IV.3.b., 1st line; "general scientific consensus has been reached regarding the validity of their earlier work" - Section IV.3.b, 3rd line; "differing viewpoints" - Sect. IV.2, 1st para.

DOE understands these terms to be generic.

17. Page 4, Sect. IV.3.a, 2nd sentence: Clarify last part of sentence to be consistent with definition of peer.

Reword sentence to read: "The technical qualifications of the peer reviewers in their review areas should be at least equivalent to that needed for the original work."

20. Page 4, Sect. IV.4, 4th line in 1st para.: Adequacy of requirements and criteria should be added to listing.

Add to listing: "Adequacy of requirements and criteria."

21. Page 4, Section IV, 5, 4th and 5th sentences: These two sentences are redundant.

Delete the 5th sentence.

22. Pages 4&5, Sect. IV, 1st para. last sentence: Reference to salary, funding, and performance reviews should be deleted. This requirement is outside qualification criteria and does not provide any added assurance of objectivity.

Delete sentence.

23. Page 5, Sect. IV, 2nd para.: This paragraph should be deleted. The statement is already made in the 1st para., 6th line.

Delete second paragraph.

Response:

These editorial comments are agreed to by the staff except #4-14, parts of #4-16 and #4-23.

Section I Introduction:

10. Comment #2-1 (Nevada):

Page 1, paragraph 1, line 7, the statement is made, "a quality assurance (QA) program meeting subpart G of 10 CFR 60 must be implemented by DOE to ensure that disciplined and documented plans and actions are utilized." The statement should mention the time frame for implementing the QA program.

Response:

Agreed. The following has been added to Section I, the first paragraph, the last sentence, "DOE should have a QA program in place, consistent with 10 CFR 60, Subpart G and any applicable regulatory guidance, prior to the start of site characterization activities."

11. Comment #4-4 (DOE):

Page 1, Sect. I, Para. 1, line 12: "Inherent": appears to be inappropriate. Not all geotechnical data and analyses are subject to uncertainty.

Change "inherent" to "potential."

Response:

Agreed. This sentence has been revised as follows: "Because of the potential uncertainty in most geotechnical data and their analyses,..."

12. Comment #4-6 (DOE):

Page 1, Sect. I, para. 2: This paragraph should be reworded to provide clarification.

"This GTP provides a definition of peer reviews and provides guidance on areas where a peer review is appropriate, the qualifications of peers, and the conduct and documentation of a peer review. Other methods of assessing adequacy of work may be proposed or used on technical data and documents required in the licensing process and will be reviewed for acceptability by the NRC on a case-by-case basis."

Response:

This paragraph has been slightly modified. The staff believes the draft GTP is quite clear and little additional clarification is needed. See the revised paragraph for the minor changes.

Section II Regulatory Framework:

13. Comment #4-7 (DOE):

Page 2, Sect. II, top line: "State-of-the-art" should be defined. For example, "state-of-the-art" equipment does not necessarily mean it is unproven, simply that it is the best available.

This phrase should be changed to read "beyond the state-of-the-art."

Response:

At this time, the "NRC Review Plan" for permanent geologic repositories (June 1984) is being revised and will be noticed in the Federal Register for public comment. Therefore, the staff believes the present quote should be removed from the GTP. However, the revised "NRC Review Plan" will still provide for the use of peer reviews to meet certain quality assurance requirements.

With regard to your comment, the staff agrees. Any additional use of "state-of-the-art" in the GTP will be replaced with "beyond the state-of-the-art."

Section III Definitions:

14. Comment #4-8 (DOE):

Page 2, Sect. III, Peer: "A person knowledgeable in the subject matter" should be more clearly defined.

Change to read: "A peer is a person having technical expertise in the subject..."

Response:

Agreed. This comment has been incorporated.

15. Comment #4-9 (DOE):

Page 2, Sect. III, Peer Review Group: Specifying the minimum number of peer reviewers in a group is inappropriate and should be deleted.

Delete the last sentence.

Response:

Agreed. This comment has been incorporated.

16. Comment #4-10 (DOE):

Page 2, Section III, Peer Review: The first sentence should be clarified. If "personnel" is changed to "peers" then the last part of the sentence can be deleted.

First sentence should read: "A peer review is a documented critical review performed by peers who are independent of the work being reviewed."

Response:

Agreed. This comment has been incorporated.

17. Comment #4-11 (DOE):

Page 2, Section III, Peer Review, para. 1: "Funding" in the last sentence should be deleted as it is understood that DOE will fund peer reviews.

Delete reference to "funding."

Response:

The definition has been revised, but not as a result of your comment. The staff is aware and accepts the fact that peer reviewers will be "funded" by DOE for performing the peer review. This is stated in Section IV.3.b., the third paragraph. Furthermore, the definition has been revised for better continuity between Section IV.3.b. See the revised definition.

18. Comment #9-1 (Maryland):

Page 2, III. Definitions: In addition to the independence aspect of peers, prejudice and bias in their viewpoints must be addressed. Most experts are guilty of this to some extent, and it must be handled by balancing it in constructing the peer review group.

Response:

Agreed. The second paragraph of Section IV.2., addresses your comment. See the revised paragraph.

19. Comment #9-2 (Maryland):

Page 2: Since the word "adequacy" is used several times in this document, and its definition bears heavily on the meaning of several critical statements, a discussion of its definition would be appropriate. The phrase "suitability for its intended purpose" is offered under "Validation," but more than this would be very useful. Perhaps ideas such as "well-grounded," "correctly derived," "based on known methodology," or "having an acceptable error" should be discussed to fill out the NRC's intended meaning for "adequacy."

Response:

In general, adequacy means the ability to satisfy a requirement. Synonyms: suitability, sufficiency.

20. Comment #10-3 (Texas):

Page 2, paragraph 2: The definition of a peer should include the stipulation that the qualifications of a peer shall be documentable and verifiable.

Response:

The staff agrees that a peer's qualifications should be documented and verifiable. This concern is covered in Section IV.5., Peer Review Report. The fifth sentence states, "The peer review report should contain a listing of the reviewers and any acceptability information (i.e., technical qualifications and independence) for each member of the peer group, including potential technical and/or organizational partiality."

Section IV Staff Positions:

21. Comment #2-2 (Nevada):

Page 3, structure of Peer Group. The DOE will usually rely on peers selected internally or from its contractors. This is well demonstrated in the writing of DOE/RW-0074, A Multiattribute Utility Analysis of Sites Nominated for the First Radioactive-Waste Repository - A Decision-Aiding Methodology. The National Academy of Sciences (NAS) criticized the DOE

for not drawing on value judgement from a variety of sources outside the DOE. This paragraph should be very specific to prevent the recurrence of reviews by peers of the DOE-industrial complex. The paragraph should also point out whether peers representing the interests of the affected states and tribes should be participants.

Response:

The NRC staff has added to Section IV.3., an introductory sentence: "The acceptability of any peer review group member is based on two requirements; technical qualifications and independence, both of which should be satisfied."

Because of the pervasive nature of DOE's effort in the waste management areas, the lack or unavailability of technical expertise in certain areas, and the possibility of reducing the technical quality of reviewers in order that independence is maintained, it may not be possible to exclude every member of the "DOE-industrial complex" from participating in a peer review. However, in those cases where independence cannot be met, a documented rationale as to why someone of equivalent technical qualifications and grester independence was not selected should be placed in the peer review report. It is expected that acceptable peers "representing the interests of the affected States and Tribes" could become members of a peer review group. See Section IV.3.b., which has been modified, for further clarification.

22. Comment #2-3 (Nevada):

During the development of the repository and perhaps more important, during the characterization phase, many tests, studies, probes and data gathering activities will necessarily be "one-shot deals" with little or no chance for reruns or a second batch of readings. It might be prudent if a portion of the peer review preceded the tests and determined the validity of the proposed plans, procedures, methods, etc. In this way, perhaps some of the glitches and bugs could be avoided during a critical no-repeat period--sort of a "Peer Review." The GTP, in general, seems to indicate that peer review and the resulting reports are after the fact, which in some cases, could be too late.

Response:

The NRC staff agrees that the peer review process can and should be used as a prior to activity. However, the staff believes this point has already been made. For example, the Introduction states that peer reviews may apply to "...a design, a plan, a test procedure...or a site exploration." Thus, the staff believes no additional clarification is needed.

23. Comment #2-4 (Nevada):

We would urge that the definition of "independent of the original work" in Section 3b be expanded and clarified. Definition (b) concerning independence does state that the candidate "has no past, existing, or anticipated financial stake in the work being reviewed." However, a technically well-qualified prospective reviewer may be employed by a DOE contractor, but has always been assigned to unrelated projects. Now he is selected to participate in peer review on a repository project. While he is "clean" as far as past association, he is immediately aware that future contracts for his employer could hinge indirectly on his review of the work at hand. This type of indirect association needs to be recognized and avoided.

Response:

With regard to your first point, "independent of the original work" is explained in Section IV.3.b., a) and b). An example will provide additional clarification. An individual involved in designing an untried hydrologic test for one of the candidate sites would not be "independent of the original work" and thus could not participate as a peer review member of that particular test.

Concerning your other point, the technical qualifications of a potential peer review member should be the primary consideration in selecting peer review members. Technical competence should not be compromised in order that "total independence" is maintained. Thus, in some cases, DOE contractor personnel could become peer group members. However, when potential peer group members of equal technical qualifications are available, those members with the greatest degree of independence should be strongly considered. The staff believes that Section IV.3.b., expresses this thought. See the response to comment #21 for additional clarification.

Furthermore, the NRC will review the peer review process and the specific report on a case-by-case basis. If any doubts remain about the quality or independence of the peer review, NRC could require a repeat review or perform one of their own.

24. Comment #2-5 (Nevada):

Also in the second paragraph of Section 3 (b) the word "eminent" as used in the context of this paragraph needs definition. The application of the word can be subjective. If, in the context of this paragraph, "eminent scientists or engineers" is used as a restrictor or in a segregated fashion, then a precise and narrow definition must be applied.

Response:

The staff considers the definition contained in the reference paragraph sufficient to allow a determination of eminence. Webster's New Collegiate Dictionary defines eminent as standing above others in some quality or position. Synonyms: prominent, renowned, famous.

25. Comment #4-18 (DOE):

Page 4, Sect. IV.3.b(b): This part should be deleted. The requirement is outside the qualification criteria and does not provide any added assurance of objectivity when dealing with professionals in the realm of technical issues. In addition, it would be very difficult to document and/or demonstrate for credibility.

Delete part (b).

Response:

The staff disagrees. The independence criteria should be met. Section IV.3.b., has been revised for clarification. Also, see the responses to comments #21 and #23.

26. Comment #4-19 (DOE):

Page 4, Sect. IV.3.b last sentence in first paragraph: This sentence should be deleted. It is understood that DOE will fund the original work as well as any peer reviews of it.

Delete sentence.

Response:

The staff disagrees. This topic covers a subject of wide interest based on comments received and should be addressed.

27. Comment #8-1 (Mississippi):

(1) Although NRC has defined that in a peer review, the peer is independent of funding, supervision and accountability for the original work under review, DOE has in the past used scientists from its contractors and subcontractors to provide peer review on certain issues. Although these scientists may be qualified and may not be associated with the original work, the practice of using contractor personnel or potential contractor personnel may be inappropriate.

Response:

The definition of peer review has been modified for better continuity between Section IV.3.b. See the revised definition and the responses to comments #21 and #23 for further information.

28. Comment #10-1 (Texas):

The major element to be considered in any peer review process is the independence of the members of the peer review group. This NRC GTP under review does not seem to go far enough in requiring definitive independence of the peer reviewers. The Department of Energy has shown reluctance in the past to involve non-DOE or DOE contractor reviewers in their review process. The National Academy of Science cited this same reluctance in their review of the multi-attribute methodology for DOE. To have any credibility at all, the peer review process for the high-level waste repository program must be required to have a certain degree of independence, possibly by requiring non-DOE or DOE contractor personnel in the peer review group. This GTP also needs to address the issue of having peers representing the interests of the affected States and Tribes participating in the peer review process.

Response:

See the responses to comments #21 and #23.

29. Comment #10-6 (Texas):

Page 4, Section 3b: The statement that the peer reviewer has "no past, existing, or anticipated financial stake in the work being reviewed" needs further clarification. Conceivably, DOE contractor personnel, working for the same contractor that did the work under review but not working on the project itself, may be used, if qualified, in the peer review process. This person will be aware that his review of this work might have an effect on the contract of his employer or on future contracts. This type of indirect dependence should be addressed and avoided.

Response:

See the responses to comments #21 and #23.

30. Comment #9-6 (Maryland):

Page 3, Item IV.2: In the second paragraph, the idea of balancing the bias and prejudice in the viewpoints of the peers in a group should be

added. For instance, a person may have a pre-conceived conviction that a particular material, or any material, will not produce a reliable borehole seal.

Response:

Agreed. The paragraph has been modified to read as follows: "The peer review group should represent major schools of scientific thought. The potential for technical or organizational partiality should be minimized by selecting peers to provide a balanced review group."

31. Comment #9-7 (Maryland):

Page 4, Item 5: If prejudice and bias are readily apparent, they should be reported in the Peer Review Report.

Response:

Agreed. The fifth sentence of Section IV.5., states, "The peer review report should contain a listing of the reviewers and any acceptability information (i.e., technical qualifications and independence) for each member of the peer group, including potential technical and/or organizational partiality."

32. Comment 10-5 (Texas):

Page 3, Section 1b: Since many of the data gathering activities will be a "one-time deal," especially during the site characterization phase, the NRC should consider the idea of having peer reviews prior to the activity to determine that the proposed plans and procedures are valid and have the best chance of yielding adequate data. Peer reviews are generally after the fact, but in some cases, the review may be too late.

Response:

This thought is reflected in the Introduction which states that peer reviews may apply to "...a design, a plan, a test procedure....or a site exploration." In addition, see the response to comment #22.

Section V Discussion:

33. Comment #2-6 (Nevada):

Lastly, the final paragraph in Section V indicates that the NRC staff will use this GTP "to determine acceptability of peer review reports for

licensing." If this is NRC staff's intent, then the GTP must define criteria for acceptability of peer review reports for licensing.

Response:

The GTPs, like Regulatory Guides, are guidance documents that indicate to the licensee (or user of the GTP) what is an acceptable interpretation of regulatory requirements. Section IV, Staff Positions, provides the appropriate conditions for acceptability of peer review documents.

34. Comment #4-24 (DOE):

Page 5, Section V, 2nd para., 2nd & 3rd sentences: These two sentences contradict the last sentence in the 1st paragraph. Scientific uncertainties exist but technical judgments must still be made. A peer review lends additional confidence to those judgements.

Delete the 2nd and 3rd sentences in the 2nd paragraph.

Response:

The NRC staff considers these sentences self-explanatory and not contradictory to the last sentence in the 1st paragraph.

35. Comment #4-25 (DOE):

Page 5, Section V, 3rd paragraph: This paragraph should be clarified to state that the QA organization will overview the peer review process. Overview will include audits and surveillance of the peer review process and review of implementing plans and procedures.

Clarify paragraph.

Response:

The referenced paragraph was modified as follows: "The quality assurance organization should provide surveillance of the peer review process to ensure that the procedures conform to the guidance of this GTP and that they are followed by the peer review group."

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13. ABSTRACT (200 words or less)

This document provides guidance on the use of the peer review process in the high-level nuclear waste repository program. The applicant must demonstrate in the license application that the applicable health, safety, and environmental regulations in 10 CFR Part 60 have been met. Confidence in the data used to support the license application is obtained through a quality assurance (QA) program as described in 10 CFR 60, Subpart G.

Peer reviews may be used as part of the QA actions necessary to provide confidence in the work being reviewed. Because of several unique conditions inherent to the geologic repository program, expert judgment will need to be utilized in assessing the adequacy of work. Peer reviews are a mechanism by which these judgments are made.

This document provides guidance on areas where a peer review is appropriate, the acceptability of peers, and the conduct and documentation of a peer review.

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