

GENERIC TECHNICAL POSITION
ON
PEER REVIEW
FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

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ENCLOSURE 1

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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.