



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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HQO.871023.0006

OCT 19 1987

Mr. James Knight, Director
Siting, Licensing and Quality
Assurance Division
Office of Geologic Repositories
U.S. Department of Energy
RW-20
Washington, DC 20585

Dear Mr. Knight:

Your letter of August 28, 1987 provided responses to the NRC March 9, 1987 Request for Additional Information (RAI) on the BWIP QA Plan, Revision 1, and the BQARD, Revision 0. Also provided were the BWIP QA Plan, Revision 3, and BQARD, Revision 3. The BWIP and BQARD were subsequently approved by the DOE as indicated in the September 1, 1987 DOE memorandum from you to John Antonnen. The purpose of this letter is to transmit the NRC staff comments on the BWIP and BQARD documents and responses to NRC's March 9, 1987 RAI, which are in the following enclosures:

- Enclosure 1 Request for Additional Information based on NRC review of BWIP Responses to NRC's RAI of 3-9-87
- Enclosure 2 Request for Additional Information based on NRC review of BWIP QA Plan vs. NRC Review Plan
- Enclosure 3 Request for Additional Information based on NRC review of BQARD Responses to NRC's RAI of 3-9-87 and BQARD Revision 3

The BWIP QA Plan was reviewed against the NRC Review Plan to assure Revision 3 to the BWIP QA Plan did not reduce any of the former commitments contained in the BWIP QA Plan. As a result of the review against the NRC Review Plan, eleven questions were generated (Enclosure 2) which require clarification.

It is our understanding from the August 19, 1987 meeting in DOE Headquarters in Washington, DC, the OGR/B-3 QA Plan will undergo a substantive revision to incorporate the Director's Statements on "Managing for Quality" and "Quality Assurance." We have some general comments on these statements which are being provided to you in a separate letter. Also, the OGR/B-3 revision may affect the BQARD and BWIP documents. However, in any case, the NRC staff believes the comments in Enclosures 1, 2, and 3 should be considered for the BQARD and BWIP documents and a response to the NRC comments is requested.

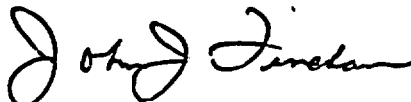
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Questions on the enclosed comments or arrangements for a meeting between our staffs should be referred to Sandra Wastler of my staff on 427-4780.

Sincerely,

A handwritten signature in cursive script, appearing to read "John J. Linehan".

John J. Linehan, Section Leader
Projects Section, Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
As stated

cc: P. Saget, (BWIP)

ENCLOSURE 1REQUEST FOR ADDITIONAL INFORMATION BASED ON NRC REVIEW
OF BWIP RESPONSES TO NRC'S RAI OF 3-9-87

1. Question 1 requested an evaluation to be made on the three NRC Generic Technical Positions (GTPs) and for the BWIP QA Plan to identify any differences between the Plan and GTPs. The response to this request was that this will be addressed when the GTPs are finalized. Enclosed are two GTPs the NRC staff has developed for the high-level waste repository program. Enclosures 1 and 2 were published in their final form on June 30, 1987 and deal with Peer Review and Qualification of Existing Data respectively. It is the NRC staff position that BWIP provide a commitment to comply with the two enclosures or provide equivalent alternatives in sufficient detail for our review.

2. Question 2 requested certain ambiguous phrases in the BWIP QA Plan to be changed or justified. This question has not been totally responded to in Revision 3 to the BWIP QA Plan. These phrases are listed below by the appropriate page and paragraph number and should be clarified.

| <u>Page</u> | <u>Paragraph</u> | <u>Phrase</u> |
|-------------|------------------|-------------------------------|
| 15 | 2.1 | is intended to |
| 20 | 2.3.4 | is expected to |
| 34 | 3.4.2 | is intended to |
| 35 | 3.8 | it is intended that |
| 53 | 10.4 | are expected to |
| 55 | 11.1 | it is expected |
| 63 | 16.1 | is expected to |
| 67 | 18.3 | are expected to (2 locations) |
| 68 | 18.4 | is expected to |
| 68 | 18.5 | is expected to |
| 68 | 18.6 | is expected to |
| 68 | 18.6 | are not expected to |

3. The response to question 3 is acceptable. The second paragraph of the response should be incorporated into the appropriate section of the BWIP QA Plan.

4. Question 17 requested information on three issues. The first issue covering design characteristics was satisfactorily responded to. The second issue requested a description of those measures to ensure that design checking includes confirmation of the numerical accuracy and computations and the accuracy of the data input to computer codes, will be performed. The third issue requested clarification on whether personnel performing design verification could be from the same organization. (It is preferable to have qualified personnel not associated with the responsible design organization

conduct verification activities). Additional information should be provided in the BWIP QA plan to address issues two and three above.

5. Questions 17 and 29 state that ANSI/ASME NQA-1-1986 is required to be complied with per the BWIP QA Plan. However, the use of the phrase "is intended to comply with" in paragraph 2.1 in the BWIP QA Plan appears to contradict the intended required compliance in the responses to questions 17 and 29. The intent of compliance to ANSI/ASME NQA-1-1986 should be more clearly stated in the BWIP QA Plan.

6. Question 30 requested information on whether the qualifications and certifications of inspectors (both in and outside QA) are documented and kept current. The response indicated that this was addressed in the revised Section 10.2 of the BWIP QA Plan. Section 10.2 does not address this request and additional information is needed in the BWIP QA Plan to address this request.

7. Question 39 requested an identification of what records will be maintained within the records management system. The response states that the specific types of records within the Records Management Plan are inappropriate for the BWIP QA Plan. It is the NRC staff position that the BWIP QA Plan identify the types of records that will be maintained within the Records Management System in order to demonstrate sufficient records will be maintained to furnish evidence affecting quality.

8. Question 40 requested a description of the responsibilities of the project participant's QA organization in the records management system. The response indicates the participating contractor's QA organizations and AMC Quality System Divisions involvement in the records program is through surveillances and audits. It would seem prudent for QA records, that the QA organization would be more involved than just performing an audit/surveillance function. As a minimum, we would expect QA organizations to be involved in reviewing the procedures for those organizations that perform activities related to the maintenance of QA records. It would also be expected that QA organizations would be involved in establishing a program for the identification of QA records. Additional information should be provided in the BWIP QA Plan to describe the total involvement of the QA organizations in the QA records program.

ENCLOSURE 2REQUEST FOR ADDITIONAL INFORMATION BASED ON NRC REVIEW OF BWIP
QA PLAN VS. NRC REVIEW PLAN

1. Positions 1.2, 1.5, and 1.9 of the NRC QA Review Plan (RP) request that the major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations be described. This description should identify the principal organizations and their primary functions. It is our understanding that the BWIP has the Westinghouse, Kaiser Engineering, Parsons/Brinkerhoff, Morris Knudsen, Boeing, and Pacific Northwest Laboratory organizations involved in the BWIP QA program implementation. The BWIP QA Plan describes the requirements for the project participants but does not identify them or describe their responsibilities. This information should be provided in the BWIP QA Plan.
2. Position 2.4 of the RP requests that the QA organization review and document concurrence with the quality-related procedures relative to QA requirements. Section 5.2 of the BWIP QA Plan states that technical procedures require review by the participant's QA personnel. The BWIP QA Plan should describe provisions to assure whether the review by QA personnel is documented.
3. Position 2.6 of the RP requests a list to identify the existing or proposed QA procedures reflecting that each criterion of 10 CFR Part 50, Appendix B, appropriate to specific items and activities will be met. Section 2.2.2 in the BWIP QA Plan refers to Table 2-1 which lists the DOE-RL AMC BWI Project QA Administrative Procedures. Table 2-1 does not contain a reference to procedures that exist for Appendix B to 10 CFR Part 50 criterion 8 through 14. Additional information is needed in the BWIP QA Plan to assure that necessary provisions and procedures will be provided for Appendix B to 10 CFR Part 50 criterion 8 through 14. If these are not applicable to DOE-RL AMC, so indicate and justify.
4. Position 3.3 of the RP requests a description of the organizational responsibilities for preparing, reviewing, approving, and verifying design and design information documents. Section 3.0, Design Control, of the BWIP QA Plan does not address these responsibilities. Additional information on these responsibilities should be provided in the BWIP QA Plan.
5. Position 5.1 of the RP requests organizational responsibilities be described for assuring that quality-related activities are specified in instructions, procedures, and drawings. Section 5.7 of the BWIP QA Plan states that the preparation of procedures for use within AMC Division is controlled by AMC Procedure 5.1. Section 6.1.b states that Project Participants document control systems are required to provide for identification of responsibility assignments for preparing, reviewing, approving and issuing documents. Sections 5.0 or 6.0 of the BWIP QA Plan do not identify the specific positions responsible for assuring that quality-related activities are specified in

instructions, drawings, and procedures. Additional information is needed in the BWIP QA Plan to address this position.

6. Position 6.5 of the RP requests a commitment that a master list or equivalent document control system be established to identify how current revisions to documents are controlled. Section 6.1.1 in the BWIP QA Plan states that an "effective way" will be provided for document users to determine whether a document is current and in effect. Additional information should be provided in the BWIP QA Plan describing what the "effective way" is and how current revisions to documents are controlled.

7. Page 46 of the BWIP QA Plan is missing from the August 23, 1987 submittal to NRC and, consequently, we are unable to complete our review for RP positions 7.1 and 7.2. This page should be furnished to the NRC in the next submittal of the BWIP QA Plan from the DOE.

8. Position 9.1 of the RP requests as complete a listing as possible of special processes be described in the BWIP QA Plan. Section 9.1 of the BWIP QA Plan identifies what a special process consists of but does not include the listing of special processes that would fall in the category of the definition. Additional information is needed in the BWIP QA Plan to provide as complete a listing as possible of special processes which fall into the category described in Section 9.1 of the BWIP QA Plan.

9. Position 9.2 of the RP requests the BWIP QA Plan to identify the organizational responsibilities including those for the QA organization for qualification of special processes, equipment, and personnel. Section 9.2 in the BWIP QA Plan indicates the QA organization is involved but does not identify the specific QA position or other positions involved. Additional information is needed in the BWIP QA Plan to provide a description of the organizational responsibilities including those for the QA organization for qualification of special processes, equipment, and personnel.

10. Section 10.2 of the BWIP QA Plan states that the use of the SNT-TC-1A-1980 Qualified Level I NDE inspectors for inspection acceptance is not allowed for the BWI Project. Section 10.2 explains that when experts are required for special inspections, the QA and technical organization determines the inspection requirements and evaluates individual qualifications and provides the necessary QA training to ensure the individual can perform the inspections, use the inspection equipment, and document the inspection results. The rationale appears to meet the requirements of SNT-TC-1A-1980 for a Level I NDT inspector. The BWIP QA Plan does not address why Level I NDE Inspectors are not allowed, whether Level II and III inspectors will be used, and whether the SNT-TC-1A-1980 requirements will be adopted for the BWI Projects. Additional information is needed in the BWIP QA Plan to address these issues.

11. Position 12.3 of the RP requests a commitment to describe whether procedures are established for calibration (technique and frequency), maintenance and control of the measuring and test equipment used for

measurement, inspection, and monitoring. Section 12 of the BWIP QA Plan states that a calibration control system is implemented but does not address the details of the above RP position. Additional information should be provided in the BWIP QA Plan to explain, in more detail, what the BWIP calibration control system includes and how it meets position 12.3 of the RP.

ENCLOSURE 3

REQUEST FOR ADDITIONAL INFORMATION BASED ON NRC REVIEW OF
BQARD RESPONSES TO NRC'S RAI OF 3-9-87 AND BQARD REVISION 3

1. NRC comment 16 requested clarification to assure both technical and QA programmatic audits will be performed. In the DOE response to NRC comment 16, the BWIP QA Plan is referenced and states, "judicious use of technical participants on all audit teams to verify the appropriateness and adequacy of technical approaches being employed on samples of activities being performed in their areas of expertise" will be used. It is the NRC understanding that the BQARD provides the specific QA requirements for all participants in the BWIP project. The above statement, "judicious use of technical participants" does not necessarily assure technical audits will be performed in conjunction with QA programmatic audits. It is also stated in the response to NRC comment 16, that technical audits are not a federally mandated requirement.

Criterion 18 of Appendix B to 10 CFR Part 50 requires that the effectiveness of a QA program be determined by audits. It is difficult to see how program effectiveness can be assessed without technical audits being a part of the audit program. For example, we believe that effective implementation of a design control program requires an assessment of the technical adequacy of the design process as well as an assessment of the quality of design. Recent NRC independent design inspections have revealed that programmatic audits have not been effective in this area in the past.

NQA-1, Supplement 2S-3, Section, 2.1, requires that "The responsible auditing organization shall establish...requirements for the use of technical specialists..." The use of technical specialists by the auditing organization as described in the standard certainly implies, at least, that technical audits will be performed.

It is the NRC staff position, that both technical and programmatic audits be performed to verify, by objective evidence, that the QA program is being effectively implemented. Therefore, the BQARD should describe provisions for assuring both technical and programmatic audits will be performed.

2. References to OGR/B-3 are made in the following locations of the BQARD document:

1. Introduction page 2
Criterion 1 Sheet 7
Criterion 2 Sheets 3, 5, 6, 10, 17, 18, 19
Criterion 3 Sheet 2, 5
Criterion 11 Sheet 8
Criterion 17 Sheet 3, 4

The OGR/B-3 document is still under review by NRC and we understand is (conceivably) being revised. Therefore, our acceptance of BQARD could be impacted by changes to the OGR Plan.

3. The Introduction, page 2, Criterion 1, Sheet 1 and Criterion 2, Sheet 2 generally state that QA requirements that apply to potentially licensable construction is not included in the BQARD, such as that associated with the exploratory shaft. These activities do not necessarily have to be addressed in BQARD, however, such potentially licensable construction work and applicable QA requirements should be addressed and identified in other appropriate documents. These documents should be provided for staff review.

4. Introduction, page 3, item 5, states that the documents listed in 5a, 5b, and 5c are not included in the BQARD and will be distributed separately. Clarify that when these documents are distributed separately, they will become requirements of the BQARD.

5. Criterion 3, Sheet 9, states for Review Plan Section 3.9, the requirements of NQA-1-1986, Supplement 3S-1 shall be implemented. Clearly identify what section of Supplement 3S-1 will be implemented to meet the NRC Review Plan Section 3.9.

6. Criterion 3, Sheet 11, states that additional guidance is provided in NQA-1, Appendix 3A-1. Clarify whether the nonmandatory guidance in Appendix 3A-1 will be implemented as a requirement or used as nonmandatory guidance.

7. Criterion 10, Sheet 4, change the "should"s to "shall"s in the second paragraph of Review Plan, Section 10.2.

8. Criterion 11, Sheet 3, states that Supplement 11S-1 of NQA-1 shall be met by implementing these requirements "as further defined herein". Explain the intent of "as further defined herein".

9. Criterion 13, Sheet 2, changes the words of NQA-1 Supplement 13S-1, Sections 2, 3, and 4 from "sampling, handling" to "sample handling". The change in the requirement should clarify whether it applies to both samples and items.

10. Criterion 14, sheets 3 and 4 state the requirement is addressed in NQA-1, Basic Requirement 14. Clarify whether this requirement will be implemented for the BQARD program.

11. Criterion 15, Sheet 3, for the NRC Review Plan Section 15.3, the BWIP Project Implementation states that this requirement is also addressed in NQA-1-1986, Basic Requirement 15. Clarify whether this requirement will be implemented and whether the disposition of the nonconformance includes signature approval of the disposition.

12. Criterion 18, Sheet 2, NRC Review Plan Section 18.2 states that audits should be initiated early enough to assure effective QA. Provide a commitment in the BQARD to assure this will be accomplished.

13. Criterion 18, Sheet 7, 10 CFR 50, Appendix B criterion 18 requires follow-up action, including reaudit of deficient areas, to be taken where indicated. The BQARD should describe provisions to assure reaudits of deficient areas will be accomplished in order to meet the requirements of Criterion 18 of Appendix B.

HQO.871109.0098

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

U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
June 1987

~~8712610342 (7pp)~~

Enclosure 1

ACKNOWLEDGEMENTS

A number of Nuclear Regulatory Commission staff members contributed to the development of this Generic Technical Position. The primary authors were Willard Altman, James Donnelly, and James Kennedy. Linda Riddle, Fred Forscher, Francis Cameron, Tom Jungling, John Trapp, and Dinesh Gupta also made significant contributions to the position.

**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.

HQO.871023.0008

GENERIC TECHNICAL POSITION
ON
QUALIFICATION OF EXISTING DATA
FOR
HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
June 1987

~~871023.0008~~
(8pp)

Enclosure 2

ACKNOWLEDGEMENTS

A number of Nuclear Regulatory Commission staff members contributed to the development of this Generic Technical Position. The primary authors were Willard Altman, James Donnelly, and James Kennedy. Linda Riddle, Fred Forscher, Francis Cameron, Tom Jungling, John Trapp, and Dinesh Gupta also made significant contributions to the position.

GENERIC TECHNICAL POSITION ON
QUALIFICATION OF EXISTING DATA
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 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.

The staff expects that some data which have not been initially generated under a QA program meeting the requirements of 10 CFR 60, Subpart G will be needed to support DOE's license application to construct and operate a geologic repository for high-level nuclear waste. The purpose of this Generic Technical Position (GTP) is to provide guidance to DOE on the use and qualification of data that have not been initially collected under a 10 CFR 60, Subpart G QA program.

II. REGULATORY FRAMEWORK

NRC regulations (10 CFR 60, Subpart G) require that DOE implement a QA program that applies to all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. These activities will include the development of site characterization data which will be used in support of the DOE license application. All data used in support of the license application that is important to safety or waste isolation must ultimately be qualified to meet the QA requirements of 10 CFR 60, Subpart G. Data may meet these requirements by being initially developed under a Subpart G QA program or by satisfying alternative conditions. This GTP provides guidance on a set of alternative conditions which may be used to qualify data not initially collected under a 10 CFR 60, Subpart G QA program. Other methods may be proposed or used and will be reviewed for acceptability by the NRC on a case-by-case basis.

III. DEFINITIONS

Qualification (of data):

A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

Qualified Data:

Data initially collected under a 10 CFR 60, Subpart G quality assurance (QA) program, or existing data qualified in accordance with this GTP.

Existing Data:

Data developed prior to the implementation of a 10 CFR 60, Subpart G QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.)

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.

Corroborating Data:

Existing data used to support or substantiate other existing data.

Confirmatory Testing:

Testing conducted under a 10 CFR 60, Subpart G QA program which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing data base.

Equivalent QA Program:

A QA program which is similar in scope and implementation to a 10 CFR 60, Subpart G QA program.

IV. STAFF POSITIONS

1. Data related to systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto which are used in support of a license application should be qualified to meet the quality assurance requirements of 10 CFR 60, Subpart G.

2. Four alternative methods or combinations of methods are acceptable for the process of qualifying existing data: (a) peer review in accordance with the NRC's Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories; (b) use of corroborating data; (c) use of confirmatory testing; and (d) demonstrating that a quality assurance (QA) program equivalent to Subpart G had been utilized. Methods b, c, and d should be accompanied by a documented technical review to determine the quality of the data. Additional confidence/credibility could be achieved when a combination of methods is used. These methods are briefly described in Section V, Discussion.
3. Existing data should be qualified in accordance with approved and controlled procedures. These procedures should provide for the documentation of the decision process, and provide an auditable trail of all factors used in arriving at the choice of the qualification method(s), and the decision as to the qualification of the data (item). The procedures may provide for a graded approach to qualification depending on the importance of the data to assuring safety or waste isolation.

V. DISCUSSION

The process of qualification of existing data may consist of any of the four methods or combination of methods stated in Section IV. 2., above. The level of confidence in the data should be commensurate with their intended use. Attributes which may need to be considered in the qualification process are:

Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G program.

The technical adequacy of equipment and procedures used to collect and analyze the data.

The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

The environmental conditions under which the data were obtained if germane to the quality of data.

The quality and reliability of the measurement control program under which the data were generated.

The extent to which conditions under which the data were generated may partially meet Subpart G.

Prior uses of the data and associated verification processes.

Prior peer or other professional reviews of the data and their results.

Extent and reliability of the documentation associated with the data.

Extent and quality of corroborating data or confirmatory testing results.

The degree to which independent audits of the process that generated the data were conducted.

The importance of the data to showing that the proposed DOE repository design meets the performance objectives of 10 CFR 60, Subpart E.

It is not expected that all of these attributes will need to be examined for each data set under review. In certain cases, replication of test results, for example, could provide confidence in data in lieu of specific QA measures such as independent audits. The four qualification methods and a brief description are as follows:

A. Peer Review

Existing data may be qualified through the use of a peer review process in accordance with the staff's Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories.

B. Corroborating Data

Existing data may be qualified through the use of corroborating data. Inferences drawn to corroborate the existing data should be clearly identified, justified, and documented. The level of confidence associated with corroborating data is related to the quality of the program under which it was developed and the number of independent data sets. The amount of corroborating data needed should be dealt with on a case-by-case basis in the documented reviews for qualification.

C. Confirmatory Testing

Existing data may be qualified through confirmatory testing. Such confirmatory testing should be conducted in accordance with a 10 CFR 60, Subpart G quality assurance (QA) program. One example of confirmatory testing is testing conducted under the same environmental conditions and with similar or the same procedures, test material, and equipment as the original test which generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment but which still investigates the same parameter of interest. The amount of confirmatory testing required should be dealt with on a case-by-case basis in the documented reviews for qualification.

D. -Equivalent QA Program

Existing data may be qualified by showing that it was collected under a QA program which is equivalent to a 10 CFR 60, Subpart G QA program.

RECORD OF CORRESPONDENCE, CONCURRENCE AND DISTRIBUTION

SUBJECT: Transmittal of NRC's Comments on the BWIP QA Plan and "BQARD"

FROM: J. P. Knight, RW-24

TO: J. Anttonen, BWIP

PC CODE: KS135 (MARIE ADAMS' IBM)

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memorandum

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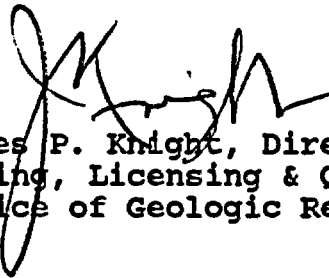
SUBJECT: Transmittal of NRC's Comments on the BWIP QA Plan and "BQARD"

TO: John Antonnen, BWIP

Reference: Letter, Linehan (NRC) to Knight (HQ-OGR) dated
October 19, 1987

The above referenced letter (copy attached) transmitted additional NRC comments on the BWIP QA Plan and "BQARD". We would appreciate BWIP reviewing these NRC comments and providing proposed resolutions, in writing, to this Office by November 25, 1987.

If you have any questions, please contact Karl Sommer at FTS 896-1639.



James P. Knight, Director
Siting, Licensing & QA Division
Office of Geologic Repositories

Attachments

WM Record File

101-7

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10

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