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

JUN 03 1987

NOTE TO: Mr. Carl Newton
U.S. Department of Energy
Office of Geologic Repositories (RW-242)
Washington, DC 20585

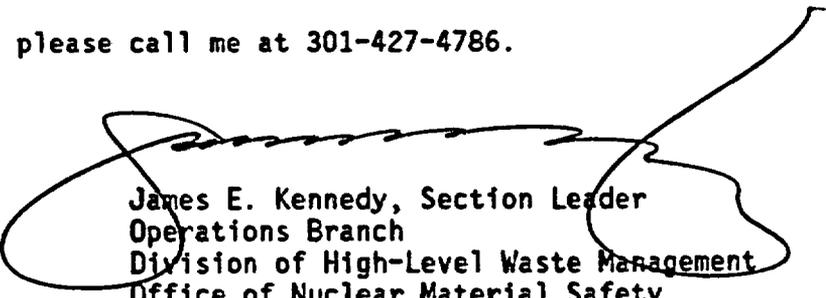
FROM: James E. Kennedy, Section Leader
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

SUBJECT: MEETING MINUTES MAY 14, 1987 ON RESOLUTION OF PUBLIC COMMENTS
ON THE PEER REVIEW QUALIFICATION OF EXISTING DATA GTP'S

Attached please find draft minutes and other information from the meeting held on May 14, 1987 to discuss our resolution of public comments on the Peer Review and Qualification of Existing Data Generic Technical Positions (GTP's). Enclosure 1 contains the meeting summary. Enclosure 2 is a list of attendees and enclosures 3 and 4 contain the meeting handout material and marked-up versions of the GTP's respectively.

We appreciate your participation in this meeting and believe that the quality of the final versions has been enhanced by the discussions during the meeting. We expect to notice the final GTP's in the Federal Register in the near future.

If you have additional comments, please call me at 301-427-4786.



James E. Kennedy, Section Leader
Operations Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosures:
As stated

COPY: D. BROWN, WESTON, 6/10/87

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MEETING SUMMARY

I. Background

On May 14, 1987 a meeting was held at the Nuclear Regulatory Commission's (NRC) office in Silver Spring, Maryland to discuss the NRC staff's resolution of public comments for the draft Generic Technical Positions (GTPs) on "Peer Review for High-Level Nuclear Waste Repositories" and "Qualification of Existing Data for High-Level Nuclear Waste Repositories."

Enclosure 2 is a list of attendees at the meeting. Enclosure 3 is a copy of the handout used at the meeting and enclosure 4 contains marked-up versions of the GTPs based on the comments made at the meeting.

Representatives from the affected States and Tribes, industry, the Department of Energy (DOE), and DOE contractors were in attendance. Several major issues were discussed and consensus was reached on suggested improvements to both of the GTPs. These improvements have been incorporated into the attached mark-ups of the GTPs.

II. Observations and Agreements

1. It was agreed upon that when corroborating data is utilized as a qualification method for existing data, the factors to consider are the quality program under which the data was collected and the number of independent data sets. The emphasis is on and rather than and/or as previously presented in the GTP.
2. As a next step in resolving the existing data issue, DOE should identify an existing data set (e.g., NNWSI core data) which they have qualified and invite NRC to review and comment on their data qualification process.
3. The independence of peer review members was discussed at length. It was reemphasized that the technical qualifications of the peer reviewers should be the primary consideration for any peer review. However, to the extent practical, peer review members should have sufficient freedom from funding considerations to assure the work is impartially reviewed. Specific word changes on the independence criteria were proposed and agreed to by all parties.
4. The comment was made that in order for the affected States and Tribes to have confidence in the independence of peer reviewers, the States, Tribes, and NRC should be closely involved in DOE's peer review process.

5. The suggestion was made that DOE should provide the States, Tribes and NRC with a schedule of upcoming peer reviews and possible peer review members in order that the peer review process can be monitored for its effectiveness and objectivity.

Attendance Sheet

Resolution of Public Comments
on Peer Review and Existing Data GTI's
5/14/87

| Attendee | Organization | Telephone |
|--------------------|-------------------------------|---|
| DON PROVOST | STATE OF Washington | 206-459-6718 |
| Stephen S. Hart | Council of Energy Res. Tribes | 303-832-6600 |
| Susan W. Zimmerman | State of Texas | 512-463-2198 |
| Jake Lefman | Battelle / DOE-SRPO | 513-424-7250 FTS-976-7280 |
| Dave Brown | Weston QA | 212-646-6760 |
| HANK BERMANIS | WESTON / UNITED ENGINEERS | 202/646-6664 |
| Zandra Kitchell | NRC QA | 301/427-4679 |
| Tom JUNGUNG | NRC TECHNICAL BRANCH | 301-427-4540 RS 575-0858 702-275-0858 |
| Stephen Metta | SAIC / WMPO | |
| CARL JOHNSON | STATE OF NEVADA | 702 885-3744 |
| Larry Collins | Conf. Tribes of the Unm. Res. | (505) 272-3015 |
| TOM COLANDREA | EET - UNWMS | (619) 487-7510 |
| Nancy Still | NRC Systems Eng. | 301/427-4664 |
| CARL NEWTON | DOE - HQ | 202-586-5059 |
| Sim Oliver | UTAH | 801-538-5548 |
| King Stabilem | NRC - Operations Branch | 301-427-4796 |
| Bill BELKE | NRC/QA | 301-427-4795 |
| Alan Duncan | NRC QA | 301-427-4685 |
| Ken CZYSCINSKI | Weston | 202-646-6647 |
| Mike Bell | NRC/HLW | 301-427-4280 |
| James Donnelly | NRC | 301-427-4678 |
| Jim Kennedy | NRC | 301-427-4778 |

QUALIFICATION OF EXISTING DATA

TWO TYPES OF DATA SETS EXIST:

- o EXISTING (NON-QUALIFIED) DATA - DATA DEVELOPED PRIOR TO THE IMPLEMENTATION OF A 10 CFR 60 SUBPART G QA PROGRAM.
- o QUALIFIED DATA - DATA INITIALLY COLLECTED UNDER AN APPROVED 10 CFR 60, SUBPART G QA PROGRAM, OR EXISTING (NON-QUALIFIED) DATA QUALIFIED IN ACCORDANCE WITH THIS GTP.

Enclosure }
}

QUALIFICATION OF EXISTING DATA

QUALIFICATION METHODS:

- PEER REVIEW
- CORROBORATING DATA
- CONFIRMATORY TESTING
- EQUIVALENT QA PROGRAM

QUALIFICATION OF EXISTING DATA

ISSUE: MUST CORROBORATING DATA BE COLLECTED UNDER AN NRC APPROVED QA PROGRAM.

RESPONSE: NO. THE LEVEL OF CONFIDENCE ASSOCIATED WITH CORROBORATING DATA IS RELATED TO THE QA PROGRAM UNDER WHICH IT WAS DEVELOPED AND/OR THE NUMBER OF INDEPENDENT, EXISTING, DATA SETS. THUS, SOME CORROBORATING DATA NOT COLLECTED UNDER AN NRC APPROVED QA PROGRAM COULD BE ACCEPTABLE.

QUALIFICATION OF EXISTING DATA

ISSUE: THE NRC SHOULD SPECIFY THE MINIMALLY ACCEPTABLE LEVEL/AMOUNT OF CORROBORATING DATA.

RESPONSE: BECAUSE OF THE DIVERSE TYPES, AMOUNTS AND IMPORTANCE OF EXISTING DATA TO BE QUALIFIED, IT IS NOT POSSIBLE TO DEFINE A MINIMALLY ACCEPTABLE AMOUNT. THE AMOUNT OF CORROBORATING DATA SHOULD BE DEALT WITH ON A CASE-BY-CASE BASIS.

QUALIFICATION OF EXISTING DATA

ISSUE: SHOULD DOE DOCUMENT THE DECISION PROCESS USED IN ARRIVING AT THE CHOICE OF THE QUALIFICATION PROCESS.

RESPONSE: YES. THIS IS NECESSARY TO VERIFY THAT CERTAIN QUALIFICATION PROCESSES ARE NOT SUBSTITUTED FOR READILY COLLECTABLE DATA. DATA SHOULD BE THE PRIMARY FACTOR ON WHICH TO BASE ENGINEERING AND SCIENTIFIC DECISIONS.

QUALIFICATION OF EXISTING DATA

ISSUE: THE COMPOSITION OF THE GROUPS RESPONSIBLE FOR APPROVING THE TYPE AND AMOUNT OF DATA COLLECTED AND THE NATURE OF TESTS RUN SHOULD BE MORE FULLY DESCRIBED. THE NEED AND PARTICIPATION OF TECHNICALLY INDEPENDENT PERSONNEL SHOULD BE DISCUSSED.

RESPONSE: THE COMPOSITION OF THE GROUPS APPROVING THE TYPE, AMOUNT AND NATURE OF DATA AND TESTS SHOULD BE A DOE MANAGEMENT PREROGATIVE. HOWEVER, THE NRC WILL REVIEW THE RATIONALE FOR THE SELECTION OF THE QUALIFICATION METHOD(S) AND THE DECISION AS TO THE QUALIFICATION OF THE DATA.

PEER REVIEW

BACKGROUND:

- o MANY UNCERTAINTIES ASSOCIATED WITH SITE CHARACTERIZATION
- o LACK OF UNANIMITY AMONG EXPERTS
- o RAPIDLY CHANGING STATE OF THE ART
- o NO CLEARLY PREFERRED TECHNICAL APPROACH EXISTS
- o HEAVIER RELIANCE ON PROFESSIONAL JUDGEMENT

PEER REVIEW

ISSUE: WHAT SHOULD BE THE INDEPENDENCE CRITERIA FOR POTENTIAL PEER REVIEW MEMBERS.

RESPONSE: PEER REVIEW MEMBERS SHOULD NOT BE INVOLVED AS A PARTICIPANT, SUPERVISOR, TECHNICAL REVIEWER OR ADVISOR IN THE WORK BEING REVIEWED, AND TO THE EXTENT PRACTICAL SHOULD HAVE NO PAST OR EXISTING FINANCIAL STAKE IN THE WORK BEING REVIEWED.

PEER REVIEW

ISSUE: THE NRC SHOULD ADOPT DOE'S SUPPLEMENT ON PEER REVIEW.

RESPONSE: SINCE THE DOE AND NRC DOCUMENTS WERE DEVELOPED CONCURRENTLY, THERE WAS NO DOE PROCEDURE TO ENDORSE UNTIL RECENTLY. FURTHERMORE, THE STAFF BELIEVES THE PUBLIC COMMENT PROCESS HAS IMPROVED THE QUALITY AND DEFENSIBILITY OF THE POSITIONS IN THE GTP.

PEER REVIEW

ISSUE: THE PEER REVIEW PROCESS SHOULD, IN SOME CASES, BE USED AS A PRIOR TO ACTIVITY FOR SOME TESTS, STUDIES, PROBES, AND DATA GATHERING ACTIVITIES.

RESPONSE: THE INTENT OF THE GTP HAS ALWAYS BEEN TO INCLUDE THIS TYPE OF PEER REVIEW. FOR EXAMPLE, THE INTRODUCTION STATES THAT PEER REVIEW MAY APPLY TO "... A DESIGN, A PLAN, A TEST PROCEDURE... OR SITE EXPLORATION."

PEER REVIEW

ISSUE: WHAT IS THE ROLE OF THE QA ORGANIZATION IN THE PEER REVIEW PROCESS.

RESPONSE: THE QA ORGANIZATION SHOULD PROVIDE SURVEILLANCE OF THE PEER REVIEW PROCESS TO ENSURE THAT THE PROCEDURES CONFORM TO THE GUIDANCE OF THIS GTP AND INTERNAL DOE PROCEDURES AND THAT THEY ARE BEING FOLLOWED BY THE PEER REVIEW GROUP.

DRAFT

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 Part 60 have been fulfilled. Subpart G of 10 CFR 60 specifies the quality assurance (QA) program for items and activities important to safety and waste isolation. Confidence in the adequacy of data and data analyses, covered by Subpart G, is obtained through a quality assurance program. The staff expects that some data which have not been initially generated under a quality assurance program meeting the requirements of 10 CFR Part 60, Subpart G will be needed to support DOE's license application to construct and operate a geologic repository for high-level 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 Part 60, Subpart G QA program.

II. REGULATORY FRAMEWORK

NRC regulations (10 CFR 60, Subpart G) require that DOE implement a quality assurance 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 a DOE license application to construct and operate a permanent geologic repository. All data used in support of the license application that is important to safety or waste isolation must ultimately be qualified to meet the quality assurance requirements of 10 CFR 60, Subpart G. Data may meet these requirements by being initially developed under a Subpart G quality assurance 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 an approved 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 an ^a ~~approved~~ 10 CFR 60, Subpart G quality assurance program, or existing (non-qualified) data qualified in accordance with this GTP.

Existing (Non-qualified) 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 (non-qualified) 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 of 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 no past or existing financial stake in the work being reviewed.~~ ^(has sufficient freedom from funding considerations to assure the work is impartially reviewed.)

A peer review is an indepth critique of assumptions, extrapolations, ^{alternate interpretation} 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 conformance to predetermined requirements.

Corroborating Data:

Existing (non-qualified) data used to support or substantiate other existing data.

Confirmatory Testing:

Testing conducted under a 10 CFR 60, Subpart G quality assurance program which investigates the properties of interest (e.g., physical, chemical, geologic, mechanical) of an existing (non-qualified) 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 Reviews for High-Level Nuclear Waste Repositories; (B) use of corroborating data; (C) use of confirmatory testing; and (D) demonstrating that a QA program equivalent to Subpart G had been utilized. Methods B, C, and D should be accompanied by a documented technical review. Additional confidence/credibility could be achieved when a combination of methods is used. These methods are briefly described in Section V, Discussion. } to determine the quality of the data
3. Existing (non-qualified) 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 (non-qualified) data may consist of any of the four methods or combination of methods described below. ~~The method(s) used for qualification depend(s) on the importance of the data to safety or waste isolation and/or the nature of the data.~~

make one paragraph {
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 of 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; and 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.

A. Peer Review

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

B. Corroborating Data

Existing (non-qualified) data may be qualified through the use of corroborating data. Inferences drawn to corroborate the existing (non-qualified) 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~~ 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 (non-qualified) data may be qualified through confirmatory testing. Such confirmatory testing should be conducted in accordance with a 10 CFR 60, Subpart G quality assurance 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 (non-qualified) data may be qualified by showing that it was a) collected under a quality assurance program which is equivalent to a 10 CFR 60, Subpart G quality assurance program, and b) ~~underwent a documented technical review by DOE.~~

Enclosure 4 (co.)

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

U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
June 1986

GENERIC TECHNICAL POSITION ON
PEER REVIEW

FOR HIGH-LEVEL NUCLEAR WASTE REPOSITORIES

I. INTRODUCTION

Subpart G of 10 CFR 60 specifies the quality assurance (QA) program for items and activities important to safety and waste isolation

To obtain a license to operate a high-level 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 Program. 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. DOE should have an approved QA program in place prior to the start of site characterization activities. Peer reviews may be employed as a part of the planned and systematic 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 analysis, 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 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 quality assurance 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 Part 50 "as applicable, and appropriately supplemented by additional criteria as required by 60.151."

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 ^{be sufficient} knowledge and experience in the subject matter to be reviewed, and should ~~vary~~ in size ~~according to~~ the subject matter and importance of the subject matter to ^{based on} 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 of 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 no past or existing financial stake in the work being reviewed.~~ ^{has sufficient freedom from funding considerations to assure the work is impartially reviewed.}

A peer review is an indepth critique of assumptions, extrapolations, 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 conformance 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.

Validation

The documented confirmation of the adequacy (suitability for its intended purpose) of the work under review.

Verification

The documented determination that work under review conforms to ^{predetermined} ~~specified~~ requirements; industry standards; or common scientific, engineering and industry practice.

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, such as planning for research, ^{data collection,} and exploration ^{or} 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 professional stature 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 (~~e.g., all reviewers from the same university, agency, state, etc.~~) 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 prestige of each peer, and hence of the peer review group as a whole, relates 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 no past or existing financial stake in the work being reviewed.~~ has sufficient freedom from funding considerations to assure the work is impartially reviewed. The technical qualifications of the peer reviewers should be the primary consideration for any peer review. In some instances, it may be difficult to meet the independence criteria without reducing the technical quality of the peer reviewers. In those cases where independence cannot be met, a documented rationale should be placed in the peer review report.

The independence criteria^a 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. Nothing in this section is intended to impede full and frank discussions between the peer reviewers and the performers of the original work during the review.

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.

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 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} ~~to establish information that is not available by other means.~~ Arbitrary 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 conformance to predetermined requirements; ^{such as industry standards;} ~~requirements listed in a technical specification or on a design drawing.~~ ^{or common scientific, engineering and industry practice.}

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.

Because of the pervasive nature of DOE's effort in the waste management area, it is acceptable that both the work under review as well as the peer review of this work are funded by DOE.

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

Place in Section IV., 3., b., the new second paragraph.

The NRC 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.

RECORD OF CORRESPONDENCE CONCURRENCE AND DISTRIBUTION

SUBJECT: Status of NRC GTP's
FROM: Carl Newton, RW-24
TO: Distribution (QACG Members)
PC CODE: CN145 (MARIE ADAMS' IBM)
ORIGINATOR: CARL NEWTON, 6-5059

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R. Poe, EH-32
L. Barrett, RW-33

D. Siefken, Weston
L. Skoblar, Weston
G. Faust, Weston
J. Kennedy, NRC

CONCURRENCES:

C. Newton 7/8/87
C. Newton, RW-24