

YUCCA MOUNTAIN PROJECT ADMINISTRATIVE PROCEDURE

 N-AD-001A
11/88

Title AP-5.9Q QUALIFICATION OF DATA OR DATA ANALYSES NOT DEVELOPED UNDER THE YUCCA MOUNTAIN PROJECT QUALITY ASSURANCE PLAN

1.0 PURPOSE AND SCOPE

1.1 This procedure describes the methods to be used by the Yucca Mountain Project (Project) for the qualification of data or data analyses that will be used in support of licensing, and that were not generated under the controls of a quality assurance (QA) program, as required by 10 CFR 60, Subpart G.

1.2 "Data analyses," as used here, refers to the various means of processing or mathematically converting raw data into other data sets (e.g., piezometer and/or pump test data utilized to calculate hydraulic conductivities). This procedure provides methods by which data not collected under a 10 CFR 60, Subpart G, QA program (including data available from commercial and scientific sources external to the Project) may be qualified to support the license application. The purpose of the methods described in this procedure is to provide a level of confidence that the data are suitable in the context of their intended use in licensing.

1.3 The determination of which existing data or data analyses may need to be qualified, as well as the specific methods for this qualification, must be made on a case-by-case basis. Consequently, this procedure provides generic guidance regarding acceptable qualification methods, and specific guidance regarding minimum requirements for documentation and concurrence. Details of the qualification process, in any specific case, will be developed and documented by the responsible organizational entity, based upon the requirements in this procedure.

2.0 APPLICABILITY

2.1 DATA COVERED BY AP-5.9Q

2.1.1 This procedure applies to the qualification of existing data that are, or may be, included as primary data in support of licensing. Such data relate (1) to systems, structures, and components important to safety; and (2) to the characterization of natural barriers and the design and development of engineered barriers important to waste isolation and related activities. Existing data may be in the form of samples or logs, or in the form of data sets in reports or publications generated on behalf of the Project prior to the approval date of the participating organization's Quality Assurance Plan (QAP).

2.1.2 Qualified data that are generated under Project activities after the approval of the participating organization's QAP for site characterization shall have approved QA Level Assignment Sheets (QALAS). Data generated by a Quality Level II activity may be upgraded to Quality Level I (primary data) using the methods described in this procedure. Data generated by Quality

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Level III activities cannot be used directly as primary data, but may be used as corroborative information.

2.1.3 In general, the kind of data that this procedure is designed to address is in the form of input to a report or publication. Such input is exemplified by physical samples (e.g., core, cuttings, or water); raw or converted data (e.g., thin section point counts, water levels converted from transducer millivolt data, hydraulic conductivities and the data from which they were derived, and bulk density from density logs); graphs defining relationships between variables; and lithologic or geophysical logs. This is not an inclusive list of data, and the participating organizations may identify other forms of data that may require qualification.

2.2 DATA NOT COVERED UNDER AP-5.9Q

2.2.1 Data that are generated by the Project after the approval date for the relevant participating organization's QAP (and with approved QALAS) are considered qualified for use in licensing. If there are deficiencies in the collection and analysis of data, these shall generally be treated under the appropriate corrective action procedures in the applicable Project or participating organization's QAP.

2.2.2 Data in standard tables, or compilations provided by recognized national or international organizations (e.g., American Society of Testing Materials (ASTM) codes, American Society of Mechanical Engineers (ASME) codes, Handbook of Physics and Chemistry, Bureau of Standards Table of Chemical Thermodynamic Data, International Union of Pure and Applied Chemistry (IUPAC) Solubility Tables, and other information accepted by the scientific and engineering community as established facts such as U.S. Bureau of Census data and U.S. Bureau of Mines mineral production information), are considered qualified for use in publications or reports supporting licensing. Such tables shall be referenced in reports that utilize standard table data, when the reports are transmitted to the Yucca Mountain Project Office. Established facts and laws commonly accepted within the scientific community are not subject to the provisions of this procedure.

2.2.3 Conceptual models, hypotheses, or theories regarding phenomena such as volcanism, tectonics, or the hydrodynamics of the unsaturated zone are reviewed in accordance with other Project or peer review procedures, and are not covered by this procedure.

2.2.4 This administrative procedure (AP) is not designed to cover the qualification of software, which is addressed in Appendix H of NNWSI/88-9. Data used as input to software, however, may be qualified under this procedure.

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3.0 DEFINITIONS

The definitions used in this procedure are derived from Appendix A of NNWSI/88-9 and from Nuclear Regulatory Commission guidance found in NUREG 1298, "Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories" (2/88).

3.1 CONFIRMATORY TESTING

3.1.1 Confirmatory testing refers to the performance of an analysis to ensure validity of a data set. The analysis is conducted under the same environmental conditions, and with the same or similar procedures, test material, and equipment, as the original analysis. Confirmatory testing also refers to testing conducted using different test methods and equipment, but which still investigates the parameter of interest on the same or similar material.

3.1.2 Confirmatory testing shall be conducted in accordance with a 10 CFR 60, Subpart G, QA program as defined in NNWSI/88-9.

3.2 CORROBORATIVE DATA

Corroborative data are data that may or may not have been acquired and controlled in a manner consistent with Quality Level I requirements, but which may be used to support or substantiate other data.

3.3 EQUIVALENT QA PROGRAM

An equivalent QA program is a QA program that is similar in scope and implementation to a 10 CFR 60, Subpart G, QA program.

3.4 EXISTING DATA

Existing data refer to (1) data developed prior to the implementation of a 10 CFR 60, Subpart G, QA program by the U.S. Department of Energy (DOE) and its contractors; (2) data developed outside the DOE repository program (e.g., by oil companies, national laboratories, and universities); or (3) data published in technical or scientific publications. Existing data do not include data that are accepted by the scientific and engineering community as established facts.

3.5 PEER REVIEW

3.5.1 A peer review is a documented, critical examination of work. The peer review is performed by qualified individuals who were not involved in the original work. The peer's independence from the work being reviewed means that the peer (1) was not involved as a participant, supervisor, technical

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reviewer, or advisor in the work being performed; and (2) to the extent practical, has sufficient freedom from funding considerations to ensure that the work is impartially reviewed.

3.5.2 Specifically, peer review is an in-depth critique of (1) the assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed in the original work; and (2) the conclusions drawn in the original work. Peer reviews confirm the adequacy of work.

3.6 QUALIFICATION OF DATA

Qualification of data is a formal process intended to provide a desired level of confidence that data are appropriate for their intended use.

3.7 QUALIFIED DATA

Qualified data are data initially collected under a 10 CFR 60, Subpart G, QA program, or data qualified in accordance with this procedure. The terms qualified data and primary data are synonymous for the purposes of this procedure.

3.8 TECHNICAL REVIEW

A technical review is a documented, traceable review performed by qualified personnel who are independent of those who performed the work, but who have expertise in the work described. Specifically, technical reviews are in-depth critical reviews, analyses, and evaluations of documents, material, or data that require technical verification and/or validation for applicability, correctness, adequacy, and completeness.

4.0 RESPONSIBILITIES

4.1 PARTICIPANT STAFF

Participant technical and management staff are responsible for (1) identifying data requiring qualification, (2) justifying the need for qualification, and (3) supporting qualification activities undertaken in accordance with this procedure.

**4.2 YUCCA MOUNTAIN PROJECT DIRECTOR, REGULATORY AND SITE EVALUATION
DIVISION (RSED DIRECTOR)**

The RSED Director or designee is responsible for initiating and coordinating qualification actions undertaken in accordance with this procedure, utilizing participant technical support as necessary. The RSED Director is also responsible for (1) supplying the Local Records Center with copies of

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all documentation from the qualification review, and (2) ensuring that results of qualification reviews conducted under this AP are distributed to the managers of Project data bases (e.g., the Site and Engineering Properties Data Base (SEPDB), Reference Information Base (RIB), etc.).

4.3 PROJECT QUALITY MANAGER (PQM)

If an equivalent QA program is one of the alternative conditions (Section 5.1) to be used for qualification, the RSED Director or designee shall provide the PQM with the available records and procedures to document the performance of the work that generated the data. The PQM, utilizing participant QA resources as appropriate, shall review the documents for the purpose of evaluating similarities between the controls on the generating activity and comparable 10 CFR 50, Appendix B, criteria. The PQM shall forward the results of the review to the RSED Director or designee for incorporation in the qualification package. The PQM shall also provide a copy to the Local Records Center.

4.4 TECHNICAL PROJECT OFFICERS (TPOs)

The TPOs or designees are responsible for supporting qualification activities conducted under this procedure as directed by the RSED Director or designee.

4.5 TECHNICAL REVIEWER

The Technical Reviewer is responsible for reviewing and evaluating the data or data analyses, including the supporting and/or rebutting evidence supplied by the originating RSED Director or designee. The Technical Reviewer shall use any additional appropriate data along with his/her professional knowledge in evaluating the existing data for qualification. The Technical Reviewer's recommendations may include the need for later confirmatory testing, or peer review. The Technical Reviewer shall forward a copy of his/her evaluation and recommendations to the RSED Director or designee.

4.6 YUCCA MOUNTAIN PROJECT OFFICE (PROJECT OFFICE)

The Project Office, through its Division Directors or designees and/or through the PQM or designee, has the responsibility for reviewing and evaluating all reports or publications submitted in support of licensing and for recognizing the need for the qualification of data or data analyses where appropriate. The appropriate Project Office Division Director and/or the PQM may request, through the RSED Director or designee, that a formal qualification process as defined in this AP, be instituted.

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5.0 PROCEDURE

5.1 DISCUSSION

5.1.1 In general, the methods applied to qualifying data follow good scientific practice in identifying and justifying the use of data in an investigation. Methods acceptable for use in the qualification of data include (1) use of corroborative data, (2) conducting confirmatory tests, (3) peer review, and (4) verification that work was performed in whole or part under a QA program equivalent to 10 CFR 60, Subpart G, requirements. Additional confidence/credibility can be achieved when a combination of the above methods is used. Documentation of the qualification review process is necessary to provide an auditable record of the decision process, including (1) how the need for the data was determined, (2) how the methods for qualification were determined, and (3) how these methods led to the qualification decision. Qualification by peer review should normally be reserved for the types of data or data interpretations described in the applicable Project QAP.

5.1.2 There are a number of attributes that are appropriate for consideration in the qualification process; however, not all of these attributes will need to be examined for each data set under review. The following attribute-related questions are formulated to (1) assist in determining if qualification is possible or cost effective, and (2) provide guidance in conducting the qualification review itself:

1. Are the qualifications of the personnel or organizations who generated the data comparable to the qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G, program?
2. Were the equipment and procedures used to collect and analyze the existing data technically adequate? Were industry recognized practices or standards used?
3. Do the existing data sufficiently address the properties of interest (e.g., physical, chemical, geologic, and mechanical)?
4. Were the environmental conditions under which the data were obtained relevant to the quality of the data? Could the environmental conditions negatively influence confidence in the results or applicability of the results?
5. To what extent do the controls under which the data were generated meet, in whole or part, 10 CFR 60, Subpart G, requirements?

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6. What were the prior uses of the data and what is the level of acceptance of the data within the technical community?
7. Are there other existing professional, technical, or peer reviews of the data that would lend confidence? Were the data published in a refereed journal?
8. What is the extent and reliability of the documentation associated with the data?
9. What, if any, corroborative data or confirmatory testing results are available?
10. What, if any, independent audits or surveillances of the process that generated the data were conducted?
11. To what extent are the data fundamentally important to demonstrating compliance with regulatory requirements?

5.2.1 A request for qualification of existing data may be initiated within any participating organization based upon the responsible technical or management staff member's assessment of the need for qualification and the anticipated end use of the data in the licensing process.

5.3 QUALIFICATION REVIEW PROCESS

The individual recommending data qualification shall prepare and forward a request for qualification to the RSED Director or designee. This document shall describe the basis for the request, including (to the extent practicable) the information set forth in Section 5.3.1.1.

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5.3.1.1 The documentation package shall contain the following information:

1. The reason why the existing data or data analyses need to be qualified.
2. The reason why it is not practicable to repeat the collection and analysis of the existing data, including cost/scheduling factors.
3. An assessment of the existing data with respect to the qualification methods and attributes listed in Section 5.1.
4. Known information, supporting and/or rebutting the intended use of the data, and a summary of the arguments. Copies of available referenced documentation shall also be included.
5. A recommendation for the application of one or more of the methods listed as alternative conditions for qualification described in Section 5.1, if appropriate.

5.3.1.2 The RSED Director or designee will review the submitted Qualification Request and determine whether a qualification effort is required. This determination will be based on an assessment of regulatory or licensing needs and will, at a minimum, include the following considerations:

1. Will the data be part of a component of a License Application product?
2. Will a repeated attempt to collect the data jeopardize the ability of the site to isolate radioactive waste?
3. Will a repeated attempt to collect the data jeopardize the ability to characterize the site?
4. Using the criteria established in Section 2.2.2 of this procedure, does the data proposed for qualification constitute an established fact?

5.3.1.2.1 Should the RSED Director or designee determine that a qualification effort is not required, he/she will document the basis for his/her decision in a written response to the individual who submitted the qualification request.

5.3.1.2.2 Should the RSED Director or designee determine that a qualification effort is required, he/she shall, following consultation with the appropriate Project participant staff and management, assemble a documentation package in accordance with Section 5.3.1.1, and proceed with the qualification process as described below.

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5.3.2 Conducting the Qualification Review

Upon receipt of a request for a qualification review, and upon concurrence that qualification of data or analyses is appropriate, the RSED Director or designee shall plan and initiate the qualification process. The scope and content of the qualification plan shall reflect the characteristics and intended end use of the existing data or data analyses, and shall implement additional assessments using the qualification methods in Section 5.1, as appropriate. In developing the qualification plan, the RSED Director or designee shall consult, as appropriate, with the author of the qualification request, and any affected Project and participant management.

5.3.2.1 Identification of an Equivalent QA Program

If part of the qualification methodology involves evaluation of the QA program under which the existing data were generated, the PQM (utilizing participating organization QA functions as appropriate) shall review the quality program that was applied. The QA review shall include an assessment of the extent to which available procedures/records document how the work was accomplished (e.g., availability of detailed technical procedures, calibration or sample handling records, surveillance, etc.). A copy of the QA review shall be returned to the RSED Director or designee for inclusion in the qualification report.

5.3.2.2 Selection of Technical Reviewers

The RSED Director or designee shall, with the concurrence of the involved TPOs, designate two qualified, independent Technical Reviewers to evaluate the evidence for or against qualification.

5.3.2.3 Technical Review

The Technical Reviewers shall review the evidence in the documentation package using the qualification methods and attributes in Section 5.1 as guidelines. The Technical Reviewers shall supply any known additional evidence supporting or rebutting the use of the existing data. Upon completion of their reviews, the Technical Reviewers shall forward their qualification reports to the RSED Director or designee. The reports shall document the Reviewers' evaluation of the supporting evidence for or against qualification, and shall include the Reviewers' recommendation that (1) the existing data or analyses be considered qualified in whole or in part based on the existing record and assessments, or (2) further actions (peer review, confirmatory testing, etc.) be undertaken prior to making a qualification determination, or (3) the existing data should not be considered qualifiable.

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5.3.2.4 Resolution

5.3.2.4.1 If, in the course of the qualification process, the Technical Reviewers or other involved parties are unable to reach a final disposition on differing opinions relative to the qualification of the existing data, the RSED Director or designee shall initiate a process to achieve resolution. The resolution process shall be determined on a case-by-case basis appropriate to the existing data under consideration. Where the peer review qualification method was utilized, the resolution process in the applicable peer review procedure will apply.

5.3.2.4.2 Technical Reviewers and other involved parties will verify, in writing, that their concerns have been resolved.

5.3.2.4.3 The RSED Director or designee shall make a determination with respect to the qualification status of the data in those cases where resolution cannot be obtained. The following considerations shall apply:

1. Is the differing opinion of such significance that it could jeopardize acceptance of the data in the licensing process?
2. Does the preponderance of evidence in the qualification package support qualification?
3. Have all reasonable avenues to resolve the conflict been explored?

5.3.2.4.4 Resolution of differences concerning the qualification of existing data for their intended use shall be documented in writing (e.g., verbal communication reports, letters, etc.), which supplies a traceable record of the resolution.

5.3.2.5 Peer Review Recommendation

Peer reviews, if required, shall follow the applicable participating organization or Project Office peer review procedures.

5.3.2.5.1 If a peer review is undertaken, a determination of whether the existing data are qualified shall not be made until the peer review is completed.

5.3.2.6 Confirmatory Testing Recommendation

Confirmatory testing, if needed to qualify existing data, shall be performed under a QA program meeting 10 CFR 60, Subpart G, requirements. The Principal Investigator responsible for any confirmatory testing shall forward the results of the confirmatory testing to the Technical Reviewers and the RSED Director or designee. After a review of these results, the Technical

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Reviewers shall inform the RSED Director or designee, in writing, of their evaluation of the results and acceptability of the existing data. For resolution of differences, see Section 5.4.2.4.

5.3.2.6.1 If confirmatory testing is undertaken, a determination of whether existing data are qualified shall not be made until the testing program is complete.

5.4 QUALIFICATION CONCURRENCE

Upon completion of the process defined in this procedure, the RSED Director or designee shall review the qualification package for completeness. The qualification package shall include the following documentation as a minimum:

1. The documentation package (Section 5.3.1.1).
2. All technical review documentation (Section 5.3.2.3).
3. Documented disposition of differing opinions (Section 5.3.2.4).
4. All documentation of related peer reviews or confirmatory tests (Section 5.3.2.5 and 5.3.2.6).

5.4.1 The RSED Director or designee shall certify, in writing, that the data or data analyses are considered qualified for licensing purposes. The RSED Director or designee shall provide copies of the certification to affected participant and Project management.

5.4.1.1 Should it be determined that the data are not qualifiable, the RSED Director or designee shall document that determination and provide copies to affected participant and Project management.

5.5 IDENTIFICATION OF QUALIFIED DATA

5.5.1 Project Data Bases

Qualified data or analyses shall be submitted for inclusion in Project data bases in accordance with AP-5.2Q (Technical Information Flow to and from the Site and Engineering Properties Data Base) and AP-5.3Q (Information Flow to the Reference Information Base), as appropriate.

5.5.2 Use of Qualified Data in Reports or Publications

Where data, qualified in accordance with this procedure, is used in a report or publication satisfying a milestone, that fact will be specifically noted by the author in the report as transmitted for Project Office review.

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5.6 DEVIATIONS FROM AP-5.9Q

5.6.1 Procedure for Handling Deviations

Sections may arise in which, because of the nature of the existing data or the way in which the data were generated, some deviations in responsibilities and/or procedure as described herein may be necessary. Requests for deviation, including the reason(s) why it is necessary, shall be documented and approved by the appropriate Project Office Division Director and forwarded to the PQM for review and approval. The PQM shall return the signed approval document to the Division Director and submit a copy to Records Control.

6.0 REFERENCES

AP-5.2Q, Technical Information Flow to and from the Site and Engineering Properties Data Base.

AP-1.7Q, Records Management.

AP-5.3Q, Information Flow Into the Reference Information Base.

Currently Applicable QA Plan: NNWSI/88-9, Yucca Mountain Project Quality Assurance Plan.

NRC Generic Technical Position, Peer Review for High-Level Nuclear Waste Repository.

NRC Generic Technical Position, Qualification of Existing Data for High-Level Nuclear Waste Repositories, NUREG 1298.

10 CFR 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures.

10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

7.0 APPLICABLE FORMS

None.

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8.0 RECORDS

8.1 QA RECORDS

Upon completion of the qualification process, the RSED Director or designee shall prepare and forward to the appropriate Local Records Center a complete package of all documentation, including correspondence, confirmatory or corroborating data, and review results. The transmittal shall be in accord with applicable procedures and shall clearly indicate whether the data or analyses are considered qualified.

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