

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

Proc. QAP-015
Revision 2 Change 1
Page 1 of 6

QUALITY ASSURANCE PROCEDURE

Title

QAP-015 QUALIFICATION OF EXISTING DATA

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 9/4/2003. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
1-2	1	7/23/2004
3-5	0	9/4/2003
6	1	7/23/2004

Change 1 incorporates editorial changes and uses the term Manager instead of Element Manager.

Supersedes Procedure No. QAP-015, Revision 2, Change 0 dated 9/4/2003.

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	7/26/2004	/s/Patrick Mackin	7/23/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark Ehnstrom	7/26/2004	/s/Budhi Sagar	7/27/2004

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-015

Revision 2 Change 1

Page 2 of 6

QAP-015 QUALIFICATION OF EXISTING DATA

1. PURPOSE

The purposes of this procedure are to (i) provide criteria for identifying of data subject to qualification and (ii) establish a method for qualifying such data. It implements the requirements of the Center for Nuclear Waste Regulatory Analyses (CNWRA) Center Quality Assurance Manual (CQAM) and the applicable portions of NUREG-1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories. Existing data that are expected to be used to challenge DOE or other licensee or their contractors' positions or data, shall be subject to this procedure.

2. RESPONSIBILITIES

2.1 Technical staff are responsible for identifying existing data that may need qualifying.

2.2 Managers are responsible for implementing the requirements of this procedure.

2.3 The Technical Director and Director of Quality Assurance (QA) are responsible for approving any exemptions to existing data qualification.

3. REFERENCE

Qualification of Existing Data for High-Level Nuclear Waste Repositories, U.S. Nuclear Regulatory Commission (NRC), NUREG-1298, February 1988.

4. DEFINITIONS

4.1 Qualification of Data

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

4.2 Qualified Data

Qualified data are data that were collected under an NRC approved Quality Assurance (QA) program or existing data that have been qualified in accordance with this procedure or another procedure meeting the requirements of NUREG-1298.

4.3 Existing Data

Existing data are (i) data that were developed prior to the implementation of an NRC approved program; or (ii) data that were developed outside NRC regulated programs, such as by oil, exploration, and mining companies; national laboratories; universities; or data published in

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-015

Revision 2 Change 0

Page 3 of 6

technical or scientific publications. Existing data do not include information that is accepted by the scientific and engineering community as established facts (e.g., engineering and scientific data handbooks, density tables, gravitational laws).

4.4 Corroborating Data

Corroborating data are existing data that are used to support or substantiate other existing data.

4.5 Confirmatory Testing

Confirmatory testing consists of laboratory or field measurements conducted under an NRC approved QA program that investigate the properties of interest (e.g., physical, chemical, geologic, mechanical) in an existing data base.

4.6 Equivalent QA Program

An equivalent QA Program is one that is similar in scope and implementation to an NRC approved QA program.

5. PROCEDURES

5.1 Identification of Data Subject to Qualification

CNWRA Technical staff may determine that data acquired during the technical work may be used by the NRC or CNWRA to challenge the data or positions of the DOE or other licensees or their contractors. The sources of such data shall be identified and reviewed to determine if existing data qualification is necessary using the following criteria.

5.1.1 Inclusion and exclusion criteria shall be used to determine whether existing data are subject to qualification under Section 5.2 of this procedure. The candidate data must be evaluated with respect to each of the criteria stated in Sections 5.1.2 and 5.1.3.

5.1.2 To be subject to the requirements for "qualification of existing data," such data shall meet each of the following inclusion criteria. The basis or rationale for each criterion is included in brackets below (see Section 3. Reference). It is not necessary to evaluate the data in the sequence indicated below.

- The data are related to systems, structures, and components important to safety, to design and/or characterization of barriers important to waste isolation, or to activities related to these matters. [NUREG-1298, Staff Position 1.]
- The data, or the analyses or calculations resulting from using the data, will be used to support an NRC or CNWRA staff position that may challenge a (potential) licensee position or data.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-015

Revision 2 Change 0

Page 4 of 6

- The data were developed prior to the implementation of an NRC approved QA program. [NUREG-1298, definition of existing data.]
- 5.1.3 Data meeting all of the inclusion criteria in Section 5.1.2 shall be subsequently evaluated against the following exclusion criteria to make a final determination of whether such data are subject to the procedural requirements of “qualification of existing data.” Data shall be excluded if they meet one or more of the following criteria. It is not necessary to evaluate the data in the sequence indicated below.
- The existing data are accepted in the scientific and engineering community as established fact. For example, the data are contained in handbooks, standard tables, or other recognized reference works. [NUREG-1298, definition of existing data.]
 - The existing data were generated by the (potential) licensee or its contractors and the purpose of the CNWRA activity or project is to provide an independent evaluation of that data. [Neither the NRC nor the CNWRA is responsible for qualifying data for which a licensee has primary responsibility.]
- 5.1.4 The results of the determination with respect to the criteria in Sections 5.1.2 and 5.1.3 shall be documented on the Quality Requirements Application Matrix in accordance with QAP-013.
- 5.2 Qualification of Existing Data
- 5.2.1 Data meeting the criteria provided in Section 5.1 of this procedure shall be qualified prior to their use in a challenge of (potential) licensee positions or data. Any one of four alternative methods or a combination of those methods is acceptable for qualifying existing data. These are (i) peer review; (ii) use of corroborating data; (iii) use of confirmatory testing; and (iv) demonstration that a QA program equivalent to the NRC regulatory criteria had been utilized. Methods 5.2.2, 5.2.3, and 5.2.4 shall be accompanied by a documented technical review accomplished in accordance with QAP-002 to substantiate the quality of the data and sufficiency of the qualification. Additional confidence and credibility may be achieved by using a combination of methods.
- 5.2.2 Peer Review

Existing data may be qualified through the use of a peer review process in accordance with QAP-002, Review of CNWRA Documents, Reports and Papers. In qualifying data by this method, factors such as the following should be considered:

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-015

Revision 2 Change 0

Page 5 of 6

- Prior uses of the data and associated verification processes;
- Prior peer or other professional reviews of the data and their results;
- The extent to which the data demonstrate the physical, chemical, geologic, mechanical, or other properties of interest; and
- The environmental conditions under which the data were obtained, if germane to the quality of data.

5.2.3 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. In qualifying data by this method, one must, as a minimum, consider the extent and quality of corroborating data. A technical review of such data shall be accomplished in accordance with QAP-002.

5.2.4 Confirmatory Testing

Existing data may be qualified through confirmatory testing. Such confirmatory testing shall be conducted in accordance with an NRC approved 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 that generated the existing data. Another type of confirmatory testing is testing conducted by different test methods and equipment that investigates the same parameters and properties of interest. The amount of confirmatory testing required should be dealt with on a case-by-case basis in the documented reviews for qualification. A technical review of confirmatory testing results shall be accomplished in accordance with QAP-002.

5.2.5 Equivalent QA Program

Existing data may be qualified by showing that they were collected under a QA program that is equivalent to an NRC approved QA program. In qualifying data by this method, factors such as the following should be considered:

- The extent to which conditions under which the data were generated may partially meet QA regulatory criteria.

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES
QUALITY ASSURANCE PROCEDURE**

Proc. QAP-015

Revision 2 Change 1

Page 6 of 6

- The extent to which qualifications of personnel or organizations generating the data were comparable to qualification requirements of personnel generating similar data under the approved program;
- The technical adequacy of equipment and procedures used to collect and analyze the data;
- The quality and reliability of the measurement control program under which the data were generated;
- The degree to which independent audits and surveillances of the process that generated the data were conducted and the results of such QA evaluations;
- The extent to which the data have been subjected to technical and/or peer reviews; and
- The extent and reliability of data documentation.

The Director of QA shall review the determinations of equivalent QA programs to verify their adequacy.

5.2.6 The results of qualification of existing data in accordance with Sections 5.2.2 through 5.2.5 shall be documented.

5.3 Exemptions

In certain circumstances, programmatic requirements and constraints or other factors may necessitate using data that are not qualified. When such circumstances arise, the cognizant manager shall petition the Technical Director and Director of QA for exemption from this procedure. Exemptions shall be documented on the Quality Requirements Application matrix in accordance with QAP-013.

5.4 Data Acknowledgement

CNWRA reports utilizing data shall include in their acknowledgements: (i) the status of the data if the data were generated, collected, or qualified by the CNWRA; (ii) the sources of data used in the report (if other than the CNWRA); and (iii) a statement that data sources other than the CNWRA should be consulted to determine their levels of QA.

6. RECORDS

All items used to document: (i) the identification of existing data subject to qualification; (ii) the method and results of qualification of such existing data; and (iii) any exemptions that have been granted shall be maintained and retained as QA records in accordance with QAP-012.