GEOSCIENCES AND ENGINEERING DIVISION QUALITY ASSURANCE PROCEDURE	Proc. QAP–015 Revision 3 Chg 0 Page 1 of 6

Title: **QAP–015 QUALIFICATION OF EXISTING DATA**

EFFECTIVITY AND APPROVAL

Revision 3 of this procedure became effective on 8/25/2005. This procedure consists of the pages and changes listed below.

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All	0	8/25/2005

Supersedes Procedure No. QAP–015, Revision 2, Change 1 dated 7/23/2004.

Prepared by	Date	Approved by	Date
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QAP–015 QUALIFICATION OF EXISTING DATA

1. PURPOSE

The purposes of this procedure are to (i) provide criteria for identifying data subject to qualification and (ii) establish a method for qualifying such data. It implements the requirements of the Geosciences and Engineering Division (Division) Quality Assurance Manual (QAM) Section 3 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 U.S. Department of Energy (DOE) or other licensee or their contractors' positions or data, shall be subject to this procedure.

2. RESPONSIBILITIES

2.1 Technical staff members are responsible for identifying existing data that may need to be qualified.

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

2.3 The Center for Nuclear Waste Regulatory Analyses (CNWRA) President and the Geosciences and Engineering Division (Division) 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 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, and mechanical) in an existing data base.

4.2 Corroborating Data

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

4.3 Data Qualification

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

4.4 Equivalent QA Program

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

4.5 Existing Data

Existing data are (i) data that were developed prior to implementation of a 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 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, universal constants, and the like).

4.6 Qualified Data

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

5. PROCEDURE

5.1 Identification of Data Subject to Qualification

Technical staff may determine that data acquired in support of their technical work may be used to challenge the data or positions of the DOE, other licensees, or their contractors. The sources of such data shall be identified and reviewed to determine if existing data qualification is necessary. 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 in Sections 5.1.1 and 5.1.2.

5.1.1 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 the criterion is included in brackets (see Section 3, Reference) when applicable. It is not necessary to evaluate the data in the sequence indicated.

- 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 staff position that may challenge a (potential) licensee position or data.
- The data were developed prior to the implementation of an NRC approved QA program. [NUREG–1298, definition of existing data.]

5.1.2 Data meeting all the inclusion criteria in Section 5.1.1 shall be subsequently evaluated against the following exclusion criteria to make a final determination of whether such data are subject to the procedural requirements for qualification of existing data. Data shall be excluded if they meet any of the following criteria. It is not necessary to evaluate the data in the sequence indicated.

- 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 Division activity or project is to provide an independent evaluation of that data. [Neither the NRC nor the Division is responsible for qualifying data for which a licensee has primary responsibility.]

5.1.3 The results of the determination with respect to the criteria in Sections 5.1.1 and 5.1.2 shall be documented on the Quality Requirements Application Matrix for the task using the data in accordance with QAP–013, Quality Planning.

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 of the alternative methods described in Sections 5.2.2–5.2.5 or a combination of those methods is acceptable for qualifying existing data.

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

- Prior use 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

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.

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. Confirmatory testing may be 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. Alternatively, confirmatory testing may use different test methods and equipment to investigate the same parameters and properties of interest. The amount of confirmatory testing required should be determined on a case-by-case basis.

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.
- The extent to which qualifications of personnel or organizations generating the data were comparable to qualification requirements of personnel generating similar data under the NRC 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 or peer reviews
- 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 methods and results of qualification of existing data shall be documented in a technical report and reviewed in accordance QAP–002.

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 responsible manager shall petition the CNWRA President and Director of QA for exemption from this procedure. Exemptions shall be documented on the Quality Requirements Application Matrix for the associated technical activity in accordance with QAP–013.

5.4 Data Acknowledgment

Reports utilizing data shall include in their acknowledgment sections: (i) the status of the data if the data were generated, collected, or qualified by the Division; (ii) the sources of data used in the report (if other than the Division); and (iii) a statement that data sources other than the Division should be consulted to determine their qualification level.

6. RECORDS

Documentation of (i) the identification of existing data subject to qualification; (ii) the method and results of qualification of such existing data; and (iii) any exemptions granted shall be maintained and retained as QA records in accordance with QAP-012, Quality Assurance Records Control.