

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

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ENCLOSURE 2

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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.

