



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: **SCIENTIFIC INVESTIGATION**

Effective Date: **06/05/98**

Section: **SUPPLEMENT III**

Revision No.: **3**

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III.1 GENERAL

This supplement establishes requirements for scientific investigations.

III.2 REQUIREMENTS

III.2.1 Planning Scientific Investigations

- A. Scientific investigations shall be planned in accordance with Section 2.0, Quality Assurance Program.
- B. Planning shall be coordinated with organizations providing input to or using the results of the investigation.
- C. Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

III.2.2 Performing Scientific Investigations

- A. Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.
- B. Scientific notebooks shall contain the following:
 - 1. Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.
 - 2. Identification of method(s) and computer programs to be used.
 - 3. Identification of any samples or measuring and test equipment used.
 - 4. Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.
 - 5. Description of changes made to methods used, as appropriate.
- C. Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:
 - 1. Retrace the investigations and confirm the results, or

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2. Repeat the investigation and achieve comparable results, without recourse to the original investigator.

III.2.3 Data Identification

- A. Data shall be identified in a manner that facilitates traceability to associated documentation.
- B. Data shall be identified in a manner that facilitates traceability to its qualification status.
- C. Identification and traceability shall be maintained throughout the lifetime of the data.

III.2.4 Data Review, Adequacy, and Usage

- A. Data reduction shall be described to permit independent reproducibility by another qualified individual.
- B. Data that are directly relied upon to address safety and waste isolation issues shall be qualified from origin, accepted, or undergo a qualification process.
 1. Data qualified from origin shall be reviewed by individuals other than those who acquired or developed the data in accordance with established review criteria to ensure technical correctness.
 2. Accepted data need not undergo the qualification process. The rationale for considering data to be accepted shall be documented.
 3. Existing data may be used in scientific investigation and design activities, provided traceability to its status as existing data is maintained. Existing data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with III.2.4(C) at appropriate times during the scientific investigations and design process and before:
 - a. OCRWM acceptance of DOE-owned high-level waste or spent nuclear fuel;
 - b. Submittal of the License Application;
 - c. Relying on the item for which the data were used as design input, to perform its function; or
 - d. Data are relied upon to resolve safety or waste isolation issues.
- C. Existing data directly relied upon to address safety and waste isolation issues shall be qualified by one or a combination of the methods that follow:
 1. Determination that the controls under which the data were generated are similar in scope, requirements, and implementation to the QARD.
 2. Evaluation of corroborating data - Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.

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3. Confirmatory testing.
4. Peer review in accordance with Section 2.0, Quality Assurance Program.
5. Technical Assessment to independently evaluate data which includes one or a combination of the following:
 - a. Determination that the employed methodology is acceptable:
 - b. Determination that confidence in the data acquisition or developmental results is warranted; or
 - c. Confirmation that the data have been used in similar applications.

Methods 1, 2, and 3 above shall include a review to determine the technical correctness of the data in accordance with established review criteria. The qualification process shall be planned and documented. Documentation shall include the acceptance criteria used to determine if the data are qualified, and rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process.

III.2.5 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review.

III.2.6 Model Development and Use

- A. The development of models of natural phenomena shall be documented. Documentation shall identify principal lines of investigation considered.
- B. Models of natural phenomena shall be validated to the extent practical to confirm that the mathematical representation appropriately depicts the natural phenomena.
- C. Model validation shall be accomplished by comparing analysis results against data acquired from laboratory, field experiments, natural analogue studies, or observations that were not used in the original development of the model.
 1. When data are not available from these sources, alternative approaches shall be documented and used for model validation.
 2. The need to perform a peer review as an alternative approach shall be consistent with consideration criteria specified for peer review in Section 2.0, Quality Assurance Program.
- D. The selection and use of models of natural phenomena shall be documented and justified.