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U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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REVISION HISTORY

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
0	Initial issue. This document consolidates the *Quality Assurance Requirements Document* and the *Quality Assurance Program Description Document* into one document.	12/18/92
1	Revised Section 1.0, Organization, to reflect OCRWM reorganization.	07/21/94
2	Revised Section 7.0, Control of Purchased Items and Services, to accommodate the transfer of responsibility for the performance of audits from Affected Organizations to OCRWM OQA.	03/27/95
3	Revised Appendix B, Storage and Transportation to provide an exception to the *Quality Assurance Requirements and Description* for organizations working under the provisions of 10 CFR 71, Subpart C or 10 CFR 72, Subpart L.	07/13/95
4	Revised Appendix B, to reflect editorial change to correct 10 CFR Subpart reference.	08/04/95
5	Revised the following sections to incorporate changes requested by various Affected Organizations. • Section RevHist, Revision History • Section TOC, Table of Contents • Section Policy, Quality Assurance Policy • Section Intro, Introduction • Section 1.0, Organization • Section 2.0, Quality Assurance Program • Section 3.0, Design Control • Section 4.0, Procurement Document Control • Section 5.0, Implementing Documents • Section 6.0, Document Control • Section 7.0, Control of Purchased Items and Services • Section 8.0, Identification and Control of Items • Section 9.0, Control of Special Processes • Section 12.0, Control of Measuring and Test Equipment • Section 14.0, Inspection, Test and Operating Status • Section 15.0, Nonconformances	10/31/95

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	• Section 16.0, Corrective Action • Section 17.0, Quality Assurance Records • Section 18.0, Audits • Supplement I, Software • Supplement II, Sample Control • Supplement III, Scientific Investigation • Supplement V, Control of the Electronic Management of Data • Appendix A, High-Level Waste Form Production • Appendix C, Mined Geologic Disposal System • Glossary New section added to incorporate Supplement V, Control of the Electronic Management of Data	
6	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History. • Section TOC, Table of Contents. • Section 3.0, Design Control - Revised to reinstate requirement addressing design calculations. • Section 6.0, Document Control - Revised to eliminate inconsistency with Section 2.2.10. • Section 17.0, Quality Assurance Records - Revised to delete the term authentication from the QARD. • Supplement III, Scientific Investigation - Revised to clarify that data shall be identified in a manner that facilitates traceability to the qualification status, clarify requirement for data review, establish requirement for review of technical reports, clarify when unqualified data relied upon to address safety and waste isolation issues must be qualified, and clarify model validation requirements. • Glossary - Deleted term and definition of authentication.	03/03/97

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3.1 GENERAL

This section provides requirements to ensure that designs are defined, controlled, and verified.

3.2 REQUIREMENTS

3.2.1 Design Input Control

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) shall be controlled by those responsible for the design according to the following requirements:

A. Design inputs shall be identified and documented, and their selection reviewed and approved by those responsible for the design.

B. Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design work to be carried out in a correct manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

C. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

D. Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

3.2.2 Design Process

The design process shall be controlled according to the following requirements:

A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner.

B. Design documents shall be adequate to support design, fabrication, construction, and operation.

C. Appropriate standards shall be identified and documented, and their selection reviewed and approved.

D. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.

E. Desigr methods, materials, parts, equipment, and processes that are essential to the function of an item shall be selected and reviewed for suitability of application.

F. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

G. Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator.

H. The final design shall identify assemblies or components that are part of the item being designed. If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

I. Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

3.2.3 Design Analyses

A. Design analyses shall be planned, controlled, and documented.

B. De . analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.

C. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable.

D. Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of Supplement I, Software.

E. Documentation of design analyses shall include:

1. Definition of the objective of the analyses.

2. Definition of design inputs and their sources.

3. Results of literature searches or other applicable background data.

4. Identification of assumptions.

5. Identification of any computer calculation, including computer type, computer program (e.g. name), revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.

6. Identification of the originator, reviewer, and approver.

3.2.4 Design Verification

In addition to reviewing completed design analyses and design output in accordance with QARD Subsection 2.2.10, Document Review, the following design control requirements shall be applied:

A. Design verification shall be performed to determine the adequacy of design by using one or a combination of the following methods:

1. Design review.

2. Alternate calculations.

3. Qualification testing.

B. The particular design verification method shall be identified and its use justified.

C. The results of design verification shall be documented, including the identification of the verifier.

D. Design verification shall be performed by competent individuals or groups other than those who performed the original design but may be from the same organization. If necessary, this verification may be performed by the originator's supervisor provided:

1. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or

2. The supervisor is the only individual in the organization competent to perform the verification.

3. The verification is not hastily and superficially done.

4. The determination to use the supervisor is documented and approved, in advance, with concurrence of the Affected Organization's Quality Assurance organization.

E. Design verification shall be performed at appropriate times during the design process.

1. Verification shall be performed before release for procurement, manufacture, or construction or release to another organization for use in other design work. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to support schedule requirements. Unverified portions of the design shall be clearly identified and controlled

2. In all cases, design verification shall be completed before relying on the item to perform its function.

F. The extent of the design verification required shall be a function of the importance to safety or waste isolation, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.

G. Where the design has been subjected to a verification process in accordance with this *Quality Assurance Requirements and Description*, the verification process need not be duplicated for identical designs.

H. Use of previously proven designs shall be controlled according to the following requirements:

1. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.

2. Known problems affecting standard or previously proven designs and their effects on other features shall be considered.

3. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

I. Changes in previously verified designs shall require reverification. Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis upon which the design is based.

3.2.5 Design Reviews

Design reviews shall be controlled and performed to ensure:

A. The design inputs were correctly selected and incorporated.

B. Assumptions necessary to perform the design were adequately described, reasonable and where applicable, identified as requiring confirmation as the design proceeds.

C. Appropriate design methods, and computer programs when applicable, were used.

D. The design outputs are reasonable compared to design inputs.

E. The necessary design input for interfacing organizations were specified in the design documents.

3.2.6 Alternate Calculations

The appropriateness of assumptions, input data, and the computer program or other calculation method used shall be reviewed, and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

3.2.7 Qualification Testing

A. If design adequacy is to be verified by qualification tests, the tests shall be in accordance with Section 11.0, Test Control.

B. The test configuration shall be defined and documented.

C. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.

D. If the tests verify only specific design features, then the other features of the design shall be verified by other means.

E. Test results shall be documented and evaluated to ensure that test requirements have been met.

F. If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

G. When tests are being performed on models or mockups, scaling laws shall be established and reviewed and approved.

H. The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.2.8 Design Change Control

Design changes shall be controlled according to the following requirements:

A. Changes to final designs, field changes, and nonconforming items dispositioned "use-as-is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

B. Design control measures for changes shall include provisions to assess the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.

C. Changes shall be approved by the same affected groups or organizations that approved the original design documents:

1. If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated; and

2. The designated approving organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

D. The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is necessary because of an incorrect design. These design deficiencies shall be documented in accordance with Section 16.0, Corrective Action. Additionally, if the incorrect design causes constructed or partially constructed systems, structures, or components to be nonconforming, the affected items shall be controlled in accordance with Section 15.0, Nonconformances.

E. Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected design documents.

F. Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change.

3.2.9 Design Interface Control

A. Design interfaces shall be identified and controlled.

B. Design efforts shall be coordinated among participating organizations and groups.

C. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and groups for the review, approval, release, distribution, and revision of documents involving design interfaces.

D. Design information transmitted across interfaces shall be documented and controlled.

E. The status of the design information or document provided shall be identified in transmittals. Designs or portions of designs that require further development, analysis, review, or approval shall be identified.

F. When it is necessary to initially transmit design information orally or by other informal means, the design information shall be promptly confirmed with formal documentation initiated in accordance with the initiating organizations approved implementing document.

6.1 GENERAL

This section establishes requirements to ensure documents, including changes thereto, are reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed.

6.2 REQUIREMENTS

6.2.1 Types of Documents

Implementing documents and documents that specify technical requirements or quality requirements shall be controlled in accordance with this section.

6.2.2 Preparing Documents

The responsibility for preparing and maintaining documents shall be assigned to the appropriate organization.

6.2.3 Reviewing Documents

Documents shall be reviewed in accordance with the requirements of Subs .tion 2.2.10, Document Review.

6.2.4 Approving Documents

The organizational position responsible for approving the document for release shall be identified.

6.2.5 Distribution and Use of Documents

The distribution and use of documents, including changes and editorial corrections to documents, shall include the following:

A. Documents, either in hardcopy or electronic media, used to perform work shall be distributed to, or made available to, and used at, the work location.

B. Effective dates shall be established for approved implementing documents.

C. The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.

D. A method shall be established to identify the current status of each document that is required to be controlled in accordance with this section.

6.2.6 Changes to Documents

A. Changes to documents shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review, prior to approval for release.

B Changes shall be approved for release by the designated organizational position that is responsible for the document.

C. Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

D. Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

6.2.7 Expedited Changes

If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management.

A. After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the document being changed.

B. Implementing documents shall describe the process to control expedited changes according to the following requirements.

1. The level of management with the authority to make expedited changes shall be identified.

2. The time limits for processing expedited changes through the normal change process shall be specified.

3. An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.

6.2.8 Editorial Corrections

Editorial corrections may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document.

A. The following items are considered editorial corrections:

1. Correcting grammar or spelling.

2. Renumbering sections or attachments which do not affect the chronological sequence of work.

3. Changing the title or number of the document.

4. Updating organizational titles.

   Note: A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.

B. The organizational position responsible for approving the document for release shall approve editorial corrections.

17.1 GENERAL

This section establishes requirements to ensure that Quality Assurance (QA) records are specified, prepared and maintained.

17.2 REQUIREMENTS

17.2.1 Classifying Quality Assurance Records

QA records shall be classified as lifetime or nonpermanent.

A. Documents that meet the following requirements shall be classified as lifetime QA records:

1. Documents that provide evidence of the quality of items on a *Q-List*.
2. Documents that provide evidence of the quality of activities related to items on a *Q-List*.
3. Documents that provide evidence of the quality of site characterization data and samples.
4. Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.
5. Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.
6. Documents that provide evidence of the quality of those activities associated with the characterization of DOE spent fuel, and conditioning through acceptance of DOE spent fuel.
7. Personnel training and qualification documents for individuals executing QA program requirements.
8. Documents which are implementing documents as described in Section 5.0, Implementing Documents.

B. Documents that do not meet the requirements for lifetime QA records, but provide objective evidence that the QA program has been properly executed shall be classified as nonpermanent QA records.

17.2.2 Creating Valid Quality Assurance Records

A. Implementing documents shall:

1. Identify those documents that will become QA records.

2. Identify the organization responsible for submitting the QA records to the records management system.

B. Individuals creating QA records shall ensure that the QA records are legible, accurate, complete appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

C. Individuals handling QA records shall protect them from damage or loss until the records are submitted to the records management system.

D. Records shall be considered QA records when stamped, initialed, or signed and dated as complete. If the nature of the record (such as magnetic or optical media) precludes stamping, initialing or signing, then other means of identifying the record as complete by authorized personnel are permitted.

E. QA records may be originals or copies.

17.2.3 Receiving and Indexing Quality Assurance Records

A receipt control system shall be established for QA records according to the following requirements:

A. An individual or organization shall be assigned the responsibility for receiving QA records.

B. A method for verifying that the QA records are those designated.

C. QA records shall be protected from damage, deterioration, or loss when received.

D. Legibility and completeness of QA records shall be verified.

E. The receipt control system shall permit a current and accurate assessment of the status of QA records during processing.

F. QA records shall be indexed to ensure retrievability. The indexing system shall include:

1. The location of the QA records within the records management system.

2. Identification of the item or related activity to which the QA records pertain.

3. The classification of the QA record.

G. QA records shall be submitted to storage after processing has been completed.

17.2.4 Correcting Information in Quality Assurance Records

A. Corrections to QA records including documents which will become QA records shall include the initials or signature of the person authorized to make the correction and the date the correction was made.

B. Corrections to QA records shall be approved by the originating organization. If an organization that was originally responsible for approving a particular document is no longer responsible, the new responsible organization shall be identified.

17.2.5 Storing and Preserving Quality Assurance Records

A. QA records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides:

1. A description of the storage facility.

2. A description of the filing system to be used.

3. A method for verifying that the QA records received are in agreement with the transmittal document.

4. A description of controls governing QA record access, retrieval, and removal.

5. A method for filing supplemental information.

6. A method for disposition of superseded QA records.

B. Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:

1. The storage area shall minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions and infestations of pests or molds.

2. Approved filing methods shall require QA records to be firmly attached in binders, or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored.

3. The storage arrangement shall provide adequate protection of special processed QA records (such as radiographs, photographs, negatives, microform, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored.

4. The storage area shall be protected from unauthorized entry, larceny, and vandalism.

17.2.6 Retrieval of Quality Assurance Records

A. The records management system shall provide for retrieval of QA records with planned retrieval times based on record type.

B. Access to storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the QA records.

17.2.7 Retention of Quality Assurance Records

A. OCRWM or its designee shall retain and preserve lifetime QA records for the operating life of the item or facility.

B. Nonpermanent QA records shall be retained for a minimum of three years or as specified by procurement documents, whichever is longer. Nonpermanent QA records shall not be disposed of until the following conditions are met:

1. Regulatory requirements are satisfied.

2. Operational status permits.

3. Purchaser's requirements are satisfied.

17.2.8 Turnover of Quality Assurance Records

A. Affected Organizations shall submit, to the Office of Civilian Radioactive Waste Management (OCRWM) or the purchaser, those QA records being temporarily stored by them that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete, or as items are released for shipment, or as prescribed by the purchaser.

B. The OCRWM records management organization shall inventory the submittal, acknowledge receipt, and process the QA records.

C. The responsible OCRWM line organizations shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system.

17.2.9 Long Term Single Storage Facility

A. OCRWM's single storage facility for the storage of lifetime QA records shall meet the following design and construction requirements:

1. Reinforced concrete, concrete block, masonry, or equal construction.

2. Floor and roof with drainage control. If a floor drain is provided, a check valve or equal shall be included.

3. Doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2-hour fire rating.

4. Sealant applied over walls as a moisture or condensation barrier.

5. Surface sealant on floor providing a hard wear surface to minimize concrete dusting.

6. Foundation sealant and provisions for drainage.

7. Forced air circulation with filter system.

8. Fire protection system.

9. Only those penetrations that are used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All penetrations shall be sealed or dampered to comply with the minimum 2-hour fire protection rating.

B. If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.

C. Construction details shall be reviewed for the adequacy of record protection by a person competent in the technical field of fire protection and fire extinguishing.

17.2.10 Dual Storage Facilities

A. The OCRWM's dual storage facilities for the storage of lifetime QA records shall provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

B. Dual storage facilities are not required to meet the design and construction requirements specific for a long term single storage facility.

17.2.11 Temporary Storage Facility

The OCRWM and Affected Organizations shall provide for temporary storage of QA records during processing, review, or use until turnover to the OCRWM for disposition, according to the following requirements:

A. QA records shall be temporarily stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided.

B. For single storage, containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection, or be certified by a person competent in the technical field of fire protection.

C. The maximum time limit for keeping QA records in temporary storage shall be specified by the OCRWM or the purchaser consistent with the nature or scope of work.

17.2.12 Replacement of Quality Assurance Records

Organizations originating QA records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records.

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

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 and Technical Report Review

A. A documented independent review of acquired and developed data shall be performed in accordance with established review criteria to ensure technical correctness.

B. Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10.

III.2.5 Data Usage

A. Unqualified data may be used in scientific investigation and design activities provided traceability to its status as unqualified data is maintained. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with III.2.5D. at appropriate times during the scientific investigation and design process and before:

1. OCRWM acceptance of DOE owned high-level waste or spent nuclear fuel, or

2. Submittal of the License Application, or

3. Relying on the item, for which the data were used as design input, to perform its function, or

4. Data is relied upon to resolve safety or waste isolation issues.

B. Data reduction shall be described to permit independent reproducibility by another qualified individual.

C. Data considered as established fact by the scientific and engineering community do not require qualification (for example, engineering handbooks, density tables, gravitational laws, etc.).

D. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified as follows:

1. One or a combination of the following methods shall be used:

a. Determination that the controls under which the data were generated are similar in scope, requirements and implementation to the *Quality Assurance Requirements and Description.*

b. Corroborating Data - Rationale for selecting one set of data to corroborate another set of unqualified data shall be clearly explained and justified.

c. Confirmatory testing.

d. Peer review in accordance with Section 2.0, Quality Assurance Program.

2. Qualification shall be planned and documented. The documentation shall include the following:

a. The factors used in arriving at the choice of qualification methods and also the acceptance criteria used to determine if the data are qualified.

b. A documented review to determine the quality of the data when qualification methods (a), (b), or (c) are used.

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.

Acceptance (document): The documented determination by the receiving organization that work is suitable for the intended purpose.

Administrative and Management Software: Software that provides tracking, monitoring, retrieving, sorting, or other function and does not serve as the controlled source of quality information used in design analysis, process control, or scientific investigation. Such software may support activities, subject to the QARD, but does not require the controls of Supplement I.

Affected Organization: An organization performing Program work subject to QARD requirements whose organizational relationships are defined in OCRWM Program documents.

Alternate Calculations: Calculations that are made with alternate methods to verify correctness of the original calculation.

Approval: The documented determination by a responsible organization that work is suitable for the intended purpose and shall be used as required.

Audit: A planned and documented quality assurance program verification performed to determine by investigation of objective evidence the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

Audit Team Leader: A lead auditor who is assigned to direct the efforts of an audit team.

Auditor: An individual who is qualified to perform assigned portions of an audit.

Baseline Element (Software): An individual component of a software baseline.

Certificate of Conformance: A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification: The act of determining, verifying, and attesting in writing to the achievement or compliance with specified requirements.

Characteristic: A property or attribute of an item, process or service that is distinct, describable, and measurable.

Code Listing: An ordered display or printout of program statements.

Commercial Grade Item: An item that is (i) not subject to design or specification criteria unique to the Program or nuclear facilities, (ii) used in applications other than the nuclear industry, and (iii) ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description.

Computer Program: A sequence of instructions suitable for processing by a computer.

Condition Adverse to Quality: A state of noncompliance with quality assurance program requirements.

Confirmatory Testing: An evaluation subject to implementing documents that investigates the properties of interest of data in an attempt to confirm the quality of the data.

Controlled Document: A document that is prepared, reviewed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process.

Corrective Action: Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Corroborating Data: Data that is used to support or substantiate other data.

Data: As it pertains to Supplement III, information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analysis.

Database: A collection of previously distinct data (not created by the database) which have been logically organized to facilitate data access.

Data Reduction: Processes that change the form of expression, quantity of data or values, or the number of data items.

Design Bases: Information that identifies the specific functions to be performed by items and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design Change: Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design Input: Those criteria, parameters, bases, or other design requirements upon which design output documents are based.

Design Output: Drawings, specifications, and other documents resulting from the translation of design input requirements of items.

Design Process: Technical and management process that commences with identification of design input and ends with the issuance of design output documents.

Design Review: A documented evaluation of design output during the design process to determine design adequacy and conformance to specified acceptance criteria.

Document Control: The process for controlling documents that provides for adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations.

Expedited Change: An abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary delays. The management responsible for the work makes the expedited change.

Field Surveying: The process of determining the boundaries, area, elevation, and location of land, structures, reference points, or other designated features either on, above, or below the earth surface relative to a permanent system of horizontal and vertical controls.

Indoctrination: Method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks.

Inspection: A quality assurance program verification that is used to verify whether an item conforms to specified technical criteria.

Item: An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit that is identified in a design document.

Lead Auditor: An individual who is certified to organize, perform, and direct an audit; report audit results; and evaluate related corrective actions.

Management Assessment: A quality assurance program verification that is conducted by management above or outside the Quality Assurance organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program.

Measuring and Test Equipment: Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Model Validation: The process that demonstrates that the model is an acceptable representation of the process or system for which it is intended.

Nonconformance: A deficiency in characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.

Objective Evidence: Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity based on observations, measurements, or test which can be verified.

Organizational Interface: The relationship between organizations when one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

Peer: A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.

Peer Review: A documented, in-depth critique of work by a group of peers independent from the work being reviewed.

Performance Confirmation: The program of tests, experiments and analyses which is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

Personnel Qualification: See Qualification (Personnel).

Process: A series of actions that achieves an end result or accomplishes work.

Procurement Document: Purchase orders, contracts, specifications, or other document used to define technical and quality assurance requirements for the procurement of items or services.

Qualified Data: Data initially collected or developed under a NRC approved quality assurance program or unqualified data that has been qualified in accordance with the *Quality Assurance Requirements and Description*.

Quality Assurance Record: A completed document (or other medium) that furnishes evidence that items or work comply with requirements.

Qualification (Personnel): The capabilities gained through education, training, or experience that qualify an individual to perform a required function.

Qualification of Data: A formal process that is intended to provide a desired level of confidence that data is suitable for its intended use.

Qualification Testing: A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Quality Assurance: All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

Readiness Review: A systematic assessment of the preparedness of an organization to start or continue a process or project phase.

Regression Testing: Selective retesting of a system or component to verify that modifications have not caused unintended effects and that the system or component still complies with its specified requirements.

Release (Software): The formal notification and distribution of approved software.

Remedial Action: The actions taken to correct specifically identified conditions adverse to quality.

Repair: The process of restoring an item to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement.

Rework: The process by which an item is restored to original specifications by completion or correction.

Right of Access: The procurement requirement that permits the purchaser or designated representative to enter the premises of a supplier for verification purposes.

Root Cause: The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality.

Sample (Physical): A physical part of a whole whose properties are studied to gain information about the whole.

Scientific Investigation: Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena.

Scientific Notebook: A record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

Service: The performance of activities such as design, fabrication, inspection, nondestructive examination, repair or installation.

Significant Condition Adverse to Quality: A condition adverse to quality which, if uncorrected, could have a serious effect on safety, or the ability to isolate waste.

Site Characterization: The program of exploration and research both in the laboratory and the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the implementing documents.

Software: A software item and associated documentation.

Software Baseline: (1) A specification or product that has been formally reviewed and agreed upon, that thereafter is the basis for further development, and that can be changed only through formal change procedures. (2) A document, a set of documents, or a product formally designated and controlled at a specific time during the software life cycle.

Software Control Points: Milestones in the software life cycle when controls are applied to the software baselines.

Software Item: Source code, object code, job control code, control data, or a collection of these items that function as a single unit.

Software Life Cycle: A series of activities that begins when software planning is initiated and ends when the software is no longer available for use.

Software Validation: The process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements.

Software Verification: The process of determining whether the products of a given software life cycle phase satisfy the conditions imposed at the start of that phase.

Special Process: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Stop Work Order: A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality.

Supplier: Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, or subcontractor.

Surveillance: The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

Technical Specialist: An individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Testing: An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Traceability: The ability to trace the history, application, or location of an item, data, or sample using recorded documentation.

Training: Systematic process provided to personnel so that they achieve proficiency, maintain proficiency, and adapt to changes in technology, methods, processes, or responsibilities as necessary to perform assigned tasks.

Unqualified Data: Data developed prior to the implementation of an NRC approved quality assurance program that meets Office of Civilian Radioactive Waste Management requirements or data developed outside an approved NRC Quality Assurance Program such as by oil companies, universities, or data published in technical or scientific publications. Unqualified data does not include information accepted by the scientific and engineering community as established fact.

Use-As-Is: A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Work: Activities that are subject to the *Quality Assurance Requirements and Description*.