



# Office of Civilian Radioactive Waste Management

## Quality Assurance Requirements and Description

Title: GLOSSARY

Effective Date: 06/05/98

Section: GLOSSARY

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

**Accepted Data:** Data considered as established fact (e.g., engineering handbooks, density tables, gravitational laws, or other physical constants) or data generally accepted by the scientific and engineering community and found to be technically defensible by those using it.

**Acquired Data:** Data which are obtained as a result of a data-gathering activity.

**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.

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**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.

**Developed Data:** The results of reducing, analyzing, or interpreting data after data acquisition.

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**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.

**Existing data (formerly designated as "Unqualified Data"):** Data that were not acquired or developed in accordance with an approved Quality Assurance program that meets 10 CFR Part 60 Subpart G and do not meet the definition of accepted.

**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.

**Expert Elicitation:** A formal, structured and documented process for obtaining the judgements of multiple experts.

**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.

**Generalist:** An individual with technical background in one or more disciplines needed to address the problem of interest and who has a general understanding of the technical aspects of the problem.

**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.

**Normative Expert:** An individual with a theoretical and conceptual knowledge of probability and practical experience in the elicitation of judgements from individuals.

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**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.

**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.

**Qualified Data:** Data acquired or developed under an approved Quality Assurance program that meets the requirements of 10 CFR Part 60 Subpart G (i.e., qualified from origin) or data that have undergone the qualification process.

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

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

**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.

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**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 Point:** 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.

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**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.

**Subject-Matter Expert:** An individual recognized by his or her peers as an authority on a specific topic.

**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 Assessment:** Used for data qualification purposes, a technical assessment is an evaluation of the technical merit of existing data against established criteria.

**Technical Report:** As it pertains to scientific investigation, a document that presents scientific information such as data, analyses, interpretations, or conclusions.

**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.

**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*.

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
Introduction	NUREG-1563 (1996), "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program" was added as a guidance document in the list of source documents since this was used as guidance in establishing requirements for expert elicitation in Appendix C.2.1.	This is not a reduction in commitment.
2.2.11 Quality Assurance Program Information Management	The word "appraised" was changed to "apprised" to correct a typographical error.	This is not a reduction in commitment.
2.2.12 Personnel Selection	This subsection was rewritten to allow a graded approach for qualification of personnel. A comparison of the requirements of Revision 7 against those in Revision 8 follows.	The graded approach for qualification of personnel is a reduction in commitment as described below.

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12 (first sentence) of QARD Revision 7 stated, "Each Affected Organization shall establish a program for the evaluation, selection, indoctrination, training, and qualification of personnel performing work subject to the QARD." This statement was deleted. The Section was reorganized to state the training and indoctrination requirements in Paragraph A, and the requirements for establishment of position descriptions, minimum education and experience, and verification requirements in Paragraph B. The positions that require positions descriptions, minimum education and experience, and verification of education and experience have been limited to personnel who conduct, verify or manage design, scientific investigation, and software development activities. The statement "each affected Organization shall establish a program" was deleted to allow for the establishment of OCRWM-wide procedures. "Work subject to the QARD" was deleted because work by the definition in the Glossary is subject to the QARD.</p>	<p>This is a reduction in commitment since the lead in statement in paragraph B limits the applicability of the requirements in this paragraph. However, this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12A of QARD, Revision 7 stated, "Evaluate each job position to determine whether the responsibilities of the position include performing work subject to the QARD." This statement was deleted because it required an evaluation to be conducted for personnel who do not perform activities subject to the QARD.</p>	<p>This is a reduction in commitment; however this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
2.2.12 Personnel Selection (continued)	<p>Section 2.2.12B of QARD Revision 7 stated, "Establish descriptions for those positions that include work subject to the QARD."</p> <p>Section 2.2.12B.1. of QARD Revision 8 states the same requirement with editorial differences. The applicability of this requirement has been limited as discussed above.</p>	<p>This is a reduction in commitment as discussed for 2.2.12 (first sentence) above; however this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>
2.2.12 Personnel Selection (continued)	<p>Section 2.2.12C of QARD Revision 7 stated, "Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities"</p> <p>Section 2.2.12A.2 of QARD Revision 8 states the same.</p>	<p>This is not a reduction in commitment.</p>
2.2.12 Personnel Selection (continued)	<p>Section 2.2.12D of QARD Revision 7 stated, "Establish minimum education and experience requirements for each position commensurate with the scope, complexity, and nature of the work."</p> <p>Section 2.2.12B.2 of QARD Revision 8 states the same requirement and adds an allowance for documented justification to be provided for positions for which no specific education and experience is required. The applicability of this requirement has been limited as discussed above.</p>	<p>This is a reduction in commitment as discussed for 2.2.12 (first sentence) above; however this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12E of QARD Revision 7 stated, "Ensure personnel have the experience, education, training, and proficiency commensurate with the minimum requirements established."</p> <p>Training and proficiency of personnel are addressed in Section 2.2.12A.2 of QARD Revision 8. Assurance that personnel have the experience and education commensurate with the minimum requirements established is addressed in Section 2.2.12B.3 with a limited applicability as discussed above.</p>	<p>This is a reduction in commitment as discussed for 2.2.12 (first sentence) above; however this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12F of QARD Revision 7 stated, "Ensure minimum education and experience are verified or, when minimum education and experience cannot be specifically verified, provide a statement and justification for personnel assignment."</p> <p>Section 2.2.12B.4 of QARD Revision 8 states the same requirement with editorial differences. The applicability of this requirement has been limited as discussed above.</p>	<p>This is a reduction in commitment as discussed for 2.2.12 (first sentence) above; however this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12G of QARD Revision 7 stated, "Ensure supervisors evaluate and assess the need for additional indoctrination and training as assignments, positions, and implementing documents change."</p> <p>Section 2.2.12A.3 of QARD Revision 8 states, "Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change."                      "Supervisors" was removed to clarify that each supervisor does not need to conduct this evaluation. For example, if an editorial change is made to a procedure and the training organization agrees that there is no impact on training, it should not be necessary to have each supervisor conduct an evaluation. "And implementing documents" was changed to "or implementing documents" to clarify that this evaluation applies when any one or a combination of the three change.</p>	<p>This is not a reduction in commitment.</p>
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12H of QARD Revision 7 stated, "Ensure the required indoctrination and training for a specified task is completed prior to performing the task."</p> <p>Section 2.2.12A.4 of QARD Revision 8 states essentially the same requirement, "Ensure indoctrination and training are completed prior to performing the work."</p>	<p>This is not a reduction in commitment.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12I of QARD Revision 7 stated, "Ensure records on individuals generated by training and qualification programs are collected and maintained."</p> <p>This requirement has been removed since it duplicates Section 17.2.1A7 which states, "Documents that meet the following requirements shall be classified as lifetime QA records...7 Personnel training and qualification documents for individuals executing QA program requirements."</p>	<p>This is not a reduction in commitment.</p>
<p>2.2.12 Personnel Selection (continued)</p>	<p>Section 2.2.12J of QARD Revision 7 stated, "Ensure personnel are indoctrinated in the following topics as they relate to a particular function:</p> <ol style="list-style-type: none"> <li>1. General criteria, including the QARD, applicable codes, regulations, and standards.</li> <li>2. Applicable implementing documents.</li> <li>3. Job responsibilities and authority."</li> </ol> <p>Section 2.2.12A.5 of QARD Revision 8 states the same requirement.</p>	<p>This is not a reduction in commitment.</p>
<p>2.2.13 Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing</p>	<p>This section was revised to explicitly state the special Quality Assurance functions.</p>	<p>This is not a reduction in commitment.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
I Software	<p>The second paragraph of I.1 was rewritten to clarify the applicability of Supplement I and Supplement V to operating systems; administrative and management systems; system utilities and compilers and their associated libraries; word processing programs; and industry standard software such as database managers, graphing and visual display software, spreadsheets, and statistical analysis software. Revision 7 indicated that these types of software “may” need to meet the requirements for the software covered by Supplement I or Supplement V. Revision 8 requires software routines and macros written for use within these types of industry standard software to meet the requirements of Section I.2.1C. The reference to meeting Supplement V has been deleted from the second paragraph because this is addressed in the first paragraph.</p> <p>In making the above change it was noted that the limited requirements in I.2.1C should be clarified by deleting the term “baseline” from I.2.1C.1. A “software baseline” is not established for software that can be verified by visual inspection and/or hand calculations. This now reads as follows, “Listing of the version and any subsequent changes to the software.”</p>	This is not a reduction in commitment.
III.2.4 Data Review, Adequacy, and Usage III.2.5 Technical Report Review	These sections were reorganized with clarifications made and a new methodology for data qualification provided. A comparison of the requirements of Revision 7 against those in Revision 8 follows.	This is not a reduction in commitment.

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.4A of Revision 7 stated, "A documented independent review of acquired and developed data shall be performed in accordance with established review criteria to ensure technical correctness."</p> <p>Section III.2.4B.1 of Revision 8 states, "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."</p>	<p>This provides a clarification of an independent review. This also clarifies that this requirement applies only to data qualified from origin since existing data which undergo the qualification process are subject to a peer review or an independent technical review. This is not a reduction in commitment.</p>
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.4B of Revision 7 stated, "Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10."</p> <p>Section III.2.5 of Revision 8 states the same.</p>	<p>This was moved due to the reorganization of the Sections. This is not a reduction in commitment.</p>
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.5A (first sentence) of Revision 7 stated, "Unqualified data may be used in scientific investigation and design activities provided traceability to its status as unqualified is maintained."</p> <p>Section III.2.4B.3 (first sentence) of Revision 8 states, "Existing data may be used in scientific investigation and design activities provided traceability to its status as existing data is maintained."</p>	<p>The term "unqualified data" has been changed to "existing data" making the terms used consistent with NUREG-1298. See also the discussion of the changes in the glossary definitions below. This is not a reduction in commitment.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.5A (second sentence) of Revision 7 stated, "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 scientific investigation and design process and before:</p> <ol style="list-style-type: none"> <li>1. OCRWM acceptance of DOE-owned high-level waste or spent nuclear fuel, or</li> <li>2. Submittal of the License Application, or</li> <li>3. Relying on the item, for which the data were used as design input, to perform its function, or</li> <li>4. Data is relied upon to resolve safety or waste isolation issues." <p>Section III.2.4B.3 (second sentence) of Revision 8 states the same thing with editorial changes only.</p> </li></ol>	<p>This is not a reduction in commitment.</p>
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.5B of Revision 7 stated, "Data reduction shall be described to permit independent reproducibility by another qualified individual."</p> <p>Section III.2.4A of Revision 8 states the same.</p>	<p>This is not a reduction in commitment.</p>

EVALUATION OF QARD, REVISION 8 CHANGES

REVISED SECTION	ANALYSIS OF CHANGE	COMMENTS
<p>III.2.4 Data Review, Adequacy, and Usage                      III.2.5 Technical Report Review                      (continued)</p>	<p>Section III.2.5C of Revision 7 stated, "Data considered as established fact by the scientific and engineering community do not require qualification (for example, engineering handbooks, density tables, gravitational laws, etc.)."</p> <p>Section III.2.4B.2 of Revision 8 states, "Accepted data need not undergo the qualification process. The rationale for considering data to be accepted shall be documented."</p> <p>The Glossary of Revision 8 defines "accepted data" as follows: "Data considered as established fact (e.g. engineering handbooks, density tables, gravitational laws, or other physical constants), or data generally accepted by the scientific and engineering community, and found to be technically defensible by those using it."</p>	<p>This changes the term "established fact" to "accepted data" and adds a requirement for documenting the rationale for considering data to be accepted. The definition clarifies that in addition to established facts, data that are generally accepted by the scientific and engineering community (e.g., information from the National Weather Service) do not need to undergo a qualification process. This is not a reduction in commitment.</p>

<p>III.2.4 Data Review, Adequacy, and Usage III.2.5 Technical Report Review (continued)</p>	<p>Section III.2.5D. 1. of Revision 7 states, "Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified as follows:</p> <ol style="list-style-type: none"> <li>1. One or a combination of the following methods shall be used:             <ol style="list-style-type: none"> <li>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.</li> <li>b. Corroborating data - Rationale for selecting one set of data to corroborate another set of unqualified data shall be clearly explained and justified.</li> <li>c. Confirmatory testing.</li> <li>d. Peer review in accordance with Section 2.0, Quality Assurance Program.</li> </ol> </li> </ol> <p>Section III.2.4C (first paragraph) of Revision 8 states the same requirement with editorial differences, and this provides technical assessment as a new method for qualification of data as follows: "Technical Assessment to independently evaluate data which includes one or a combination of the following:</p> <ol style="list-style-type: none"> <li>a. Determination that the employed methodology is acceptable;</li> <li>b. Determination that confidence in the data acquisition or developmental results is warranted; or</li> <li>c. Confirmation that the data have been used in similar applications." </li></ol>	<p>Section II (sixth sentence) of NUREG 1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories" states, "Other methods may be proposed or used and will be reviewed for acceptability by the NRC on a case-by case basis."</p> <p>The use of the technical assessment was discussed between the DOE and the NRC during the May 12, 1997 exchange. This is not a reduction in commitment.</p>
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EVALUATION OF QARD, REVISION 8 CHANGES

<p>III.2.4 Data Review, Adequacy, and Usage III.2.5 Technical Report Review (continued)</p>	<p>Section III.2.5D.2 of Revision 7 stated, "Qualification shall be planned and documented. The documentation shall include the following:</p> <ul style="list-style-type: none"><li>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,</li><li>b. A documented review to determine the quality of data when qualification methods (a), (b) , or (c) are used."</li></ul> <p>Section III.2.4C (second paragraph) of Revision 8 restructures the requirements as follows: "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."</p>	<p>The requirement to document the factors used at arriving at the choice of qualification methods has been changed to document the rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process. This clarification is supported by discussions on pages 3 and 4 of the Enclosure to NRC Letter dated December 26, 1995, D. M. Gillen to R. A. Milner, Subject: Minutes of the September 27, 1995, Technical Exchange on Data Qualification. This is not a reduction in commitment.</p>
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<p>C.2.1 Modification of QARD Section 2.0, Quality Assurance Program</p>	<p>These are new requirements for conducting expert elicitation in support of the Mined Geologic Disposal System (MGDS). NUREG-1563 was used as guidance in developing these requirements.</p> <p>Section C.2.1D states, "Software which has not been qualified in accordance with Supplement I and existing data may be used in the expert elicitation process. The results of the expert elicitation are considered qualified; however, the expert elicitation is not considered a method for the qualification of software or existing data used as input."</p> <p>This change is a reduction in commitment to the following requirements:</p> <ol style="list-style-type: none"> <li>1. Supplement I.1 (first sentence) of Revision 7, "This supplement establishes requirements for the development, modification, control, and use of software."</li> <li>2. Supplement III.2.5A (first sentence) of Revision 7, "Unqualified data may be used in scientific investigation and design activities provided traceability to its status as unqualified is maintained."</li> </ol> <p>The MGDS expert elicitation process allows the use of software which has not been qualified in accordance with Supplement I.</p> <p>The use of existing data has been expanded beyond design and scientific investigation activities to MDGS expert elicitation.</p> <p>(continued)</p>	<p>As discussed in the analysis of change, Section C.2.1D is a reduction in commitment to the requirements of Supplement I.1 (first sentence) and Supplement III.2.5A (first sentence); however, this section still addresses the pertinent requirements of the regulatory and commitment documents.</p>
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EVALUATION OF QARD, REVISION 8 CHANGES

<p><b>C.2.1 Modification of QARD Section 2.0, Quality Assurance Program</b></p>	<p><b>This reduction in commitment is necessary because the scope of expert elicitation is to consider all relevant data and interpretations, not just those collected or developed under a Quality Assurance Program. Much of the existing data to be used may have been developed using software that was not controlled under a Quality Assurance program. In expert elicitation the experts are provided access to available data. They are expected to use their own judgement concerning the merits of the data sets and to decide which data sets to use.</b></p> <p><b>Finally, the results of the MGDS expert elicitation are considered qualified even though software which was not qualified in accordance with Supplement I and existing data may have been used. The expert elicitation process is roughly equivalent to a peer review and provides a method for the qualification of its results.</b></p>	<p>See above</p>
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<p><b>Glossary</b></p>	<p>The following definitions were added to clarify discussion in Supplement III and Appendix C: accepted data, acquired data, developed data, technical assessment, technical report, expert elicitation, generalist, normative expert, subject-matter expert.</p> <p>The term “unqualified data” was changed to “existing data” and its definition was modified as follows:</p> <p>“Existing data (formerly designated as “Unqualified Data” ) - Data that were not acquired or developed in accordance with an approved Quality Assurance program that meets 10 CFR Part 60 Subpart G, and do not meet the definition of accepted.”</p> <p>This change clarifies that existing data include all data that are not qualified or accepted.</p> <p>The definition of qualified data was modified as follows:</p> <p>Qualified Data - Data acquired or developed under an approved Quality Assurance program that meets the requirements of 10 CFR Part 60 Subpart G (i.e., qualified from origin), or data that have undergone the qualification process.</p> <p>This definition was modified to change “collected” to “acquired” because the term “acquired” is used in Supplement III and has been defined. “Qualified from origin” is used to distinguish these from data which have undergone the qualification process.</p>	<p>This is not a reduction in commitment.</p>
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