

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

INTERIM CHANGE NOTICE

AFFECTED DOCUMENT (Including Revision): Quality Assurance Requirements Document (QARD) Revision 4	EFFECTIVE DATE: September 3, 1991	ICN NO. 4.1
INTERIM CHANGE AND RATIONALE: I QARD Main Body The following changes are made for clarity and correctness or to add additional requirements. 1.0 Paragraph 2.5.1 Change title to "Classification". Change first sentence to read: "Items shall be classified to determine applicability of the quality assurance (QA) program to the items and their related activities. The QA program shall apply to items important to radiological safety and waste isolation." 2.0 Paragraph 2.5.2 Add "(Grading)" to title after the word "Controls". 3.0 Section 2.8, Personnel Selection, Indoctrination, Training, and Qualification Add new paragraph between existing paragraphs 4 & 5 to identify the need to collect and maintain certain records as privileged records: "Records on individuals generated by affected organization training and qualification programs shall be collected and maintained as privileged records according to the Privacy Act of 1974 as defined in Section 17." 4.0 Subsection 2.12 and Paragraph 2.12.1 Add new Subsection 2.12 and Paragraph 2.12.1 as follows: "2.12 QUALIFICATION OF DATA OF INDETERMINATE QUALITY Data that will be needed to be qualified to support a license application and that was not collected under the control of a QA program meeting the QA program requirements of 10 CFR 60, 71, 72 or this document, shall be qualified in accordance with the approach provided in NUREG-1298, prior to use in support of license application activities.		PAGES AFFECTED 2-2 2-3 2-4 2-6
TYPE OF CHANGE: Major <input checked="" type="checkbox"/> Minor <input type="checkbox"/>		REQUIRED TRAINING: Read <input checked="" type="checkbox"/> Classroom <input type="checkbox"/>
<u><i>R White</i></u> PREPARER OF ICN	<u><i>[Signature]</i></u> DIRECTOR, OQA	
<u><i>[Signature]</i></u> DIRECTOR, OQA	<u><i>John N. Bartlett</i></u> DIRECTOR, OCRWM	
8/7/91 DATE	8/8/91 DATE	
8/8/91 DATE	8/9/91 DATE	

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INTERIM CHANGE NOTICE (Continuation Sheet)

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INTERIM CHANGE AND RATIONALE:

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4.0 Subsection 2.12 and Paragraph 2.12.1 (continued)

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- a. Data may include information collected from such sources as professional journals, technical reports, and symposia proceedings; such data does not include design reference codes and standards, for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks.
- b. The organization using the data shall define the data qualification process that describes how data will be assessed for quality characteristics, such as accuracy, precision, completeness, representativeness, and comparability.
- c. Acceptable qualification methods include any one, or a combination of, peer review, corroborating data, or confirmatory testing.
- d. Consideration shall be given to the following factors when available and measurable:
 1. Qualifications of personnel or organizations generating the data.
 2. Technical adequacy of the equipment and procedures used in the scientific investigation.
 3. Laboratory conditions.
 4. Confidence level associated with the corroborating data based upon the quality and reliability of the measurement control program under which the data was generated.
 5. Amount of corroborating data or confirmatory testing.
 6. Extent to which data demonstrates properties of interest (for example; physical, chemical, geologic, mechanical).
 7. Extent to which conditions generating the data may partially meet requirements of this document.
 8. Prior uses of the data and associated verification process.
 9. Prior professional reviews of the data.
 10. Extent and reliability of the documentation associated with the data.
 11. Degree to which data-generating processes were independently audited.
 12. Importance of the data to show that performance objectives were met.
- e. The results of data qualification activities shall be documented.

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4.0 Subsection 2.12 and Paragraph 2.12.1 (continued)		
2.12.1 Qualification of Data by Use of Corroborating Data Reports of data qualification by use of corroborating data shall include the following elements:		2-6
a. Identification of the corroborating data source. b. Tabulation of the corroborating data. c. Description of the corroborating data relationship to the data being qualified. d. Technical justification for use of the corroborating data. e. Identification of the corroborating data reviewers. f. Test results."		
5.0 Subsection 3.5		3-2
Add "new" Subsection 3.5 as follows: "3.5 PEER REVIEWS Peer Reviews shall be performed in accordance with the approach provided in NUREG-1297"		
6.0 Section 17, Quality Assurance Records		17-1
Add new Section 17.2 to identify the requirements for compliance with the Privacy Act of 1974 using DOE System 80:		
"17.2 QA TRAINING AND QUALIFICATION RECORDS (DOE SYSTEM 80)		
17.2.1 QA records that contain personnel training and qualification information, including certification records, shall be collected and maintained as a special system of records in accordance with the requirements of the <i>Privacy Act of 1974; Proposed Establishment of a New System of Records</i> , 55 FR 32288, August 8, 1990 (DOE System 80).		
17.2.2 DOE System 80 shall be managed by the Director, Office of Quality Assurance, OCRWM. The system manager shall delegate responsibility for management of DOE System 80 at PROGRAM Participant locations.		
17.2.3 DOE System 80 records shall be processed, maintained, and controlled at OCRWM Headquarters and PROGRAM Participant locations as privileged records with appropriate restrictions on availability and distribution, according to each affected organization's Quality Assurance Program Description and established procedures for processing QA records.		
17.2.4 Access to DOE System 80 records is restricted to authorized personnel and those provided access under a routine use as defined in DOE System 80. Requests for access to DOE System 80 records shall be directed to the appropriate system manager."		

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II <u>QARD, Appendix A</u>		
<u>Appendix A, Subsection 2.1</u> Change to read: "The classification process to determine the applicability of the QA program to items and their related activities and the grading process shall be consistent with the guidelines provided in NUREG 1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," April 1988."		A-1
<u>Appendix A, Subsections 3.0 and 3.1</u> Delete.		A-1
<u>Appendix A, Subsection 20.10 and Paragraph 20.10.1</u> Delete.		A-13 & A-14
III <u>QARD, Appendix B</u>		
<u>Appendix B, Subsection 2.5</u> Change reference from Section "2.8" to "2.10".		B-2
<u>Appendix B, Sections 3.1, 3.2, and Paragraphs 3.2.1, 3.2.2, 3.2.3, and 3.2.4</u> Delete existing Section 3.1 and renumber remaining sections and paragraphs as 3.1, 3.1.1, 3.1.2, 3.1.3 and 3.1.4		B-2 & B-3
<u>Appendix B, Paragraph 3.2.5, 3.2.6 and Section 3.3</u> Delete existing Paragraph 3.2.5 and renumber existing paragraph 3.2.6 as 3.1.5. Renumber Section 3.3 as 3.2.		B-3, B-4 & B-5

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The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

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