

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

INTERIM CHANGE NOTICE (Continuation Sheet)

AFFECTED DOCUMENT (Including Revision): Quality Assurance Program Description (QAPD) Revision 3	EFFECTIVE DATE: September 3, 1991	ICN NO. 3.1
INTERIM CHANGE AND RATIONALE: 5.0 Paragraph 2.1.13 Add new Paragraph 2.1.13 to read as follows: "2.1.13 Qualification of Data Data that will be needed to be qualified to support a license application and that was not collected under the controls 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." 6.0 Paragraph 3.1.10 Add new Paragraph 3.1.10 to read as follows: "3.1.10 Peer Review Peer reviews are required when adequacy of the information (e.g., data, interpretations, test results, design assumptions, etc.) or suitability of essential procedures and methods cannot be confirmed by testing, alternate calculations, or reference to previously established standards and practices. OCRWM establishes and implements, when appropriate, procedures in accordance with approach specified in NUREG 1297. Documents generated during the peer review process are quality assurance records." 7.0 Section 8.0 Change to read: "The identification and control of materials, parts, components, and samples are implemented in accordance with approved procedures." 8.0 Section 12.0 Change to read as follows: "12.0 GENERAL This section applies the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in activities that affect quality are properly controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. OCRWM Managers are responsible for the implementation of an effective calibration program in accordance with approved procedures.		PAGES AFFECTED 2-7 3-4 8-1 12-1

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INTERIM CHANGE AND RATIONALE:

8.0 Section 12.0 (continued)

12.1 APPLICABILITY AND SCOPE OF THE M&TE CONTROL PROGRAM

Controls noted in this section apply to M&TE (tools, gages, instruments, etc.). However, controls of M&TE are also applied to activities used to calibrate, measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known. The methodology for control of M&TE is described in approved procedures.

12.2 M&TE REQUIREMENTS

12.2.1 Selection

Selection of M&TE is controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Each device has a unique identification number. The type, range, accuracy and tolerance of a measuring device is specified in approved procedures. This number is recorded on the data sheet, log, or equivalent, along with the measurement taken, to ensure traceability of the measurement to the device used to take the measurement.

12.2.2 Calibration

Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Institute of Standards and Technology or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the acceptability of the calibration standard used is justified. Calibrating standards have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible PROGRAM personnel.

12.2.3 Control

The method and interval of calibration for each M&TE item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE is labeled, tagged, or otherwise documented in a manner that indicates the due date of the next calibration and provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on acceptability of items previously inspected or tested or on data gathered since the last calibration. Out of calibration devices require the condition be documented in accordance with Section 15 of this QAPD, tagged or segregated, and not used until they have been dispositioned and corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, it is repaired or replaced. Calibration is performed when the accuracy of equipment is suspect.

PAGES AFFECTED
12-1

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INTERIM CHANGE AND RATIONALE:		PAGES AFFECTED
<p>13.2.3 Inspection and Testing of Special Tools and Equipment</p> <p>When used, special handling tools and equipment are controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals, to verify that the tools and equipment are adequately maintained.</p> <p>13.2.4 Operators of Special Equipment</p> <p>Operators of special handling and lifting equipment are experienced or trained to use the equipment; related training activities are conducted and documented in accordance with procedures.</p> <p>13.2.5 Procedures</p> <p>Procedures used for marking, labeling, packaging, shipping, handling, and storage of items or samples include provisions addressing adequate identification, maintenance, and preservation of the items, including indication of the need for special environments or the need for special controls."</p>		13-1
<p>10. <u>Section 17, Quality Assurance Records</u></p> <p>Add new section 17.9 to identify the requirements for compliance with the Privacy Act of 1974 using DOE System 80:</p> <p>*17.9 QA TRAINING AND QUALIFICATION RECORDS (DOE SYSTEM 80)</p> <p>A special system of records is established for QA training, qualification, and certification records. Requirements for this records system are described in the Federal Register notice, <i>Privacy Act of 1974; Proposed Establishment of a New System of Records</i>, 55 FR 32288, August 8, 1990 (DOE System 80).</p> <p>DOE System 80 is managed by the Director, OQA at OCRWM Headquarters. Responsibility for maintaining the system is delegated to the QA Training Officer at Headquarters and to the Training Officer at the Project Office.</p> <p>DOE System 80 records are turned over to the LRCs and subsequently to the CRFs for processing, control, and maintenance in accordance with approved QA records management procedures.</p> <p>DOE System 80 records are classified as privileged records in the OCRWM records management system. Appropriate restrictions on availability and distribution of privileged records are described in approved procedures and instructions.</p>		17-3

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INTERIM CHANGE AND RATIONALE: <p>Access is limited to authorized supervisory, QA, records management processing personnel, and those provided access under a routine use. DOE System 80 permits disclosure of records to state and local agencies, the NRC, and other Federal agencies for audit purposes. Requests for access to DOE System 80 records are directed to the Director, OQA, OCRWM."</p> <p>II <u>QAPD, Appendix A</u></p> <p><u>Appendix A, Section 2.0 first sentence and Paragraphs 2.0.c, -d and -f</u></p> <p>Change "items and activities" (1st sentence); "activities" (paragraphs c&d); "items or activities" (paragraph f)</p> <p>to "... items and their related activities..."</p> <p><u>Appendix A, Paragraph 3.2.1</u></p> <p>"Delete" first paragraph on the top of page A-8.</p> <p><u>Appendix A, Paragraphs 12.0 through 12.3.6</u> Delete in its entirety.</p> <p><u>Appendix A, Paragraphs 13.0 through 13.3.5</u> Delete in its entirety.</p> <p><u>Appendix A, Paragraph 20.4.2</u></p> <p>Delete.</p> <p>III <u>QAPD, Appendix B</u></p> <p><u>Appendix B, Subsection 1.0</u></p> <p>Change the word "shielding" in Paragraph 1.0.a to "scheduling".</p> <p>Revise Paragraph immediately following Paragraph 1.0.d by inserting the word "and" between "Systems" and "Compliance".</p>		PAGES AFFECTED <p>17-3</p> <p>A-6</p> <p>A-8</p> <p>A-10 & A-11</p> <p>A-12 & A-13</p> <p>A-14</p> <p>B-1</p>

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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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