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QA: N/A
Project No. WM-00011

JUL 02 2004

OVERNIGHT MAIL

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**TRANSMITTAL OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT (OCRWM) QUALITY ASSURANCE REQUIREMENTS AND
DESCRIPTION (QARD), REVISION 15 – REVISION**

On April 29, 2004, the U.S. Department of Energy (DOE) transmitted Revision 15 of the QARD; letter serial number OLA&S:DCH-1181.

Subsequent to the original transmittal, the DOE determined that additional changes to Revision 15 were necessary. The changes involve removing the information that was inserted as part of Revision 15 regarding the relationship between OCRWM and the Naval Nuclear Propulsion Program, (i.e., it is not necessary to include this information in the QARD). Additionally, the Naval Nuclear Propulsion Program is not considered to be an "affected organization," as defined in QARD Revision 15. Also included are minor editorial corrections/clarifications. The details of these changes and corrected pages are included in Enclosure 1. These changes are not considered as reductions in commitment, but are included to assure that the copy of the QARD, Revision 15, which the U.S. Nuclear Regulatory Commission (NRC) is reviewing, is accurate in all respects.

Additionally, the DOE discovered that Enclosure 2, Attachment 1 (Proposed Changes - Reduction in commitment), pages 3 and 4, as submitted with the April 29, 2004, letter, did not contain the appropriate information regarding change #3 of Revision 15 of the QARD. Specifically, the columns "Proposed change" and "Basis for change" were not included as intended. Additionally, since the date of the original transmittal, DOE has determined that the "Basis for change" for change #3 required revision. Specifically, the last paragraph of the "Basis for change" for change #3:

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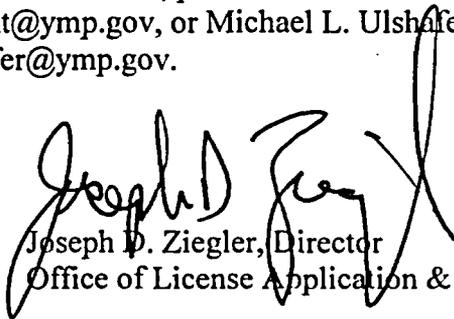
Additionally, the programs/process of the existing Section 2.2.2, listed below which are not considered within the scope of the 10 CFR Part 63 QA program requirements are to be conducted in accordance with the provisions of the "Augmented Quality Assurance Program."

The DOE has decided to delete this paragraph, notwithstanding the fact that it was inadvertently left out of the April 29, 2004, submittal. The deletion is based on a determination that:

1. It is not necessary to include those activities which are not within the scope of the 10 CFR 63.142 Quality Assurance program in the QARD.
2. It was determined sufficient mechanisms exist to provide the necessary controls to assure the quality of these other programs.

Accordingly, pages 3 and 4 of Enclosure 2, Attachment 1 of the April 29, 2004, letter, should be replaced with the revised pages 3 and 4 contained within the enclosure of this letter.

If you have any questions or require additional information, please contact David C. Haught at (702) 794-5474 or by e-mail at david_haught@ymp.gov, or Michael L. Ulshafer at (702) 794-5085 or by e-mail at michael_ulshafer@ymp.gov.


Joseph D. Ziegler, Director
Office of License Application & Strategy

OLA&S:DCH-1542

Enclosures:

1. QARD Revision 15 changes
2. Revised pages 3 and 4

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ENCLOSURE 1
REVISED QARD REVISION 15

Details of Changes

1. The REVISION HISTORY, page 8 of 9, 5th bullet currently indicates a new subsection 1.3.3C. It has been determined that this new subsection should be deleted from Revision 15 of the QARD. Based on this determination, this bullet is to be deleted.

A corrected page 8 of 9 is attached.

2. The REVISION HISTORY, page 9 of 9, 4th bullet currently refers to an incorrect Subsection 16.3.3. Specifically, it reads:
“Section 16.0 Revised Subsections 16.3.3, 16.2.4, 16.2.5, and 16.2.6 to delete the Quality Assurance Organization from all corrective action related activities.”

This item should read:

“Section 16.0 Revised Subsections 16.2.3, 16.2.4, 16.2.5, and 16.2.6 to delete the Quality Assurance Organization from all corrective action related activities.”

A corrected page 9 of 9 is attached.

3. The TABLE OF CONTENTS (TOC), page 1 of 8 requires a revision to be consistent with the deletion described in item 1 above. Specifically, the TOC information provided on Subsection 1.3.3 which currently states:
“OCRWM Affected Organizations, Direct Support Organizations, and Naval Nuclear Propulsion Program”

This is revised to read:

“OCRWM Affected Organizations and Direct Support Organizations”

A corrected page 1 of 8 is attached.

4. Section 1.3.2.C.2.d, page 5 of 10, provides a description of the responsibilities of the Office of Project Management and Engineering. Included in these responsibilities is:
“Providing overall direction and approving the basis for placement of items on the “Q-List””

This is the first use of the “Q-List.” In order that a user of the QARD understands the concept of the “Q-List,” and what it contains, the responsibility is to be revised to refer the user to Section 2.2.3. The responsibility is revised to read:

“Providing overall direction and approving the basis for placement of items on the “Q-List”” (See subsection 2.2.3)

A corrected page 5 of 10 is attached.

Details of Changes

5. The title of Section 1.3.3, page 8 of 10, requires revision to be consistent with items 1 and 3 above. Specifically, the title of Section 1.3.3 states:
“OCRWM Affected Organizations, Direct Support Organizations, and Naval Nuclear Propulsion Program”

This is revised to read:

“OCRWM Affected Organizations and Direct Support Organizations”

A corrected page 8 of 10 is attached.

6. Section 1.0, subsection 1.3.3C “Naval Nuclear Propulsion Program,” on page 9 of 10, is to be deleted.

A corrected page 9 of 10 is attached.

7. As a result of the above changes, a replacement QARD approval page is included.



Office of Civilian Radioactive Waste Management

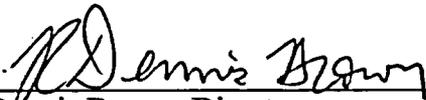
QA: QA

***QUALITY ASSURANCE REQUIREMENTS AND
DESCRIPTION***

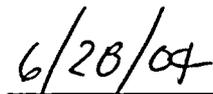
DOE/RW-0333P

Revision 15

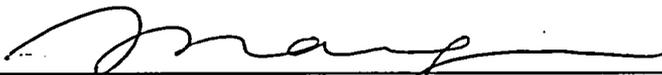
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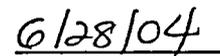
R. Dennis Brown, Director
Office of Civilian Radioactive Waste Management
Office of Quality Assurance



Date



Dr. Margaret S.Y. Chu, Director
Office of Civilian Radioactive Waste Management



Date

OCRWM

Title: Quality Assurance Requirements and Description

DOE/RW-0333P Rev. 15 Effective Date:

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REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	Incorporated Document Action Request D11228.	
15	Revised the following sections to incorporate changes as noted: <ul style="list-style-type: none">• Introduction–Delete QARD applicability, Items A through F (Item B of the Introduction is deleted since the QARD does not apply to the off-repository transport of spent nuclear fuel and high-level waste, except as provided in Appendix B).• Introduction (Figure Intro-1)–Deleted reference to 10 CFR 73.• Section 1.0–Changed Subsection 1.3.2C.2d 3rd bullet from “classification list” to “Q” List. Inserted reference to Subsection 2.2.3• Section 1.0–Subsection 1.3.3A.1 deleted EM NSNFP and HLW Programs.• Section 2.0–Subsection 2.1 changed to be consistent with changes made to the Introduction and Subsections 2.2.2 and 2.2.3.• Section 2.0–Incorporated new Subsection 2.2.2 to address QA Program Applicability and Related Activities.• Section 2.0–Revised old Subsection 2.2.2 (new 2.2.3) to describe system, structure, and component classification. Deleted the following:<ul style="list-style-type: none">- Items required for the control and management of site generated radioactive waste other than spent fuel and high-level waste.- Items required for the protection of items important to safety and waste isolation from the hazards of fire.	

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REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	<ul style="list-style-type: none">- Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function.- Items required to control occupational radiological exposure.- Items required for physical protection as defined by 10 CFR 73.	
	<ul style="list-style-type: none">• Section 2.0–Deleted Subsection 2.2.4 (old 2.2.3) incorporated activities in Subsection 2.2.2 (new).• Section 15.0–Revised Subsection 15.2.5 to delete the Quality Assurance Organization.• Section 16.0–Revised 16.2.2B to delete the number of classification categories.• Section 16.0–Revised Subsections 16.2.3, 16.2.4, 16.2.5, and 16.2.6 to delete the Quality Assurance Organization from all corrective action related activities.• Section 18.0–Revised Subsection 18.2.9 to address internal and external responses, and deleted notification of the auditing organization for internal audits.• Section 18.0–Revised Subsection 18.2.10 and 18.2.11 to delete evaluation in accordance with Section 16.0.• Section 18.0–Revised Subsection 18.2.14 to delete Lead Auditor evaluation of corrective actions and planned and taken corrective actions. Added requirement for auditor to be qualified to initiate conditions adverse to quality.• Supplement III, Scientific Investigation–Revised Subsection III.2.6F.2 – Changed the “and” proceeding “independent” to “or.”• Glossary–Revised definition of “Condition Adverse to Quality” to be consistent with NQA-1. Incorporated the following definitions: Important to Safety, Important to Waste Isolation, and Preclosure Safety Analysis. Clarified that definition of “Performance Assessment”	

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b. Office of Facility Operations

The Director, Office of Facility Operations is responsible for:

- Managing site operations
- Managing site support infrastructure
- Ensuring that site construction and operations activities comply with applicable federal, state, local, and Indian tribe statutes
- Managing the construction of facilities and structures associated with the Project, including underground construction of the Exploratory Studies Facility, surface-based testing facilities, and general support facilities and drilling operations
- Managing and integrating all aspects of field operations including engineering, design, construction, and site testing activities
- Ensuring ORD compliance with radiological protection standards and regulations
- Managing the ORD Safeguards and Physical Security Program.

c. Office of Business Support

The Director, Office of Business Support is responsible for:

- Ensuring execution of procurement documents
- Developing the ORD federal employee training program
- Overseeing contractor training programs
- Verifying education and experience of applicable ORD employees
- Overseeing contractor records management system.

d. Office of Project Management and Engineering

The Director, Office of Project Management and Engineering is responsible for:

- Establishing requirements to ensure that the design meets all repository nuclear safety and performance requirements
- Monitoring contractor design activities including the development of designs for individual features as well as adequacy of design products
- Providing overall direction and approving the basis for placement of items on the "Q-List." (See Subsection 2.2.3)

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1.3.3 OCRWM Affected Organizations and Direct Support Organizations

A. OCRWM Affected Organizations

1. OCRWM Affected Organizations include: OCRWM, specific programs within the DOE that have material planned for disposition at a monitored geologic repository, U.S. Geological Survey (USGS), OCRWM Management and Operating Contractor (M&O), and National Laboratories performing work for OCRWM (i.e., Los Alamos National Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Sandia National Laboratories).
2. The QARD requirements for each OCRWM Affected Organization are identified in the appropriate procurement documents. When a Memorandum of Understanding, Memorandum of Agreement, Program Guidance Memorandum, or other document serves as a procurement document, it shall include the scope of work and appropriate technical and QA requirements.
3. OCRWM Affected Organizations perform work subject to the QARD in accordance with implementing documents developed and maintained by OCRWM Affected Organizations. For certain tasks and when agreed to by involved organizations, an implementing document may apply to more than one OCRWM Affected Organization.
4. OCRWM Affected Organizations, with the exception of the USGS and National Laboratories, evaluate and verify implementation of their activities through reviews; surveillance; audits (compliance and performance based) and inspection of systems, structures and components; or other means of verification, as appropriate. The M&O QA organization performs the evaluation and verification of the M&O, M&O subcontractors and suppliers, USGS, and National Laboratories' activities.
5. The OCRWM Affected Organization's position responsible for evaluation and verification activities shall be occupied by an individual with appropriate knowledge and experience in management and QA. The position shall:
 - a. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to the QARD.
 - b. Be sufficiently independent from cost and schedule considerations.
 - c. Have the organizational freedom to effectively communicate with other senior management positions.

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- d. Have no other assigned responsibilities that would prevent full attention to QA matters.
 - e. Be responsible for identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying solutions to quality problems.
 - f. Have the authority to stop work when significant conditions adverse to quality warrant such action.
 - g. Be responsible for providing guidance and direction to organizations responsible for performing activities subject to the QARD on QA matters relating to the OCRWM Affected Organization's activities.
6. OCRWM Affected Organizations ensure lines of communication are established and maintained between their QA organizations and the OQA.

B. OCRWM Direct Support Organizations

OCRWM Direct Support Organizations perform work subject to the QARD in accordance with the appropriate OCRWM Affected Organization's implementing documents. OCRWM Direct Support Organizations are not required to develop and maintain implementing documents.

ENCLOSURE 2
REVISED PAGES 3 AND 4

Attachment 1

Proposed changes-Reduction in commitment

Change #	Existing Requirement	Proposed change	Basis for change
1	<p>Introduction: The QARD applies to the following:</p> <ul style="list-style-type: none"> A. Acceptance of spent nuclear fuel and high-level waste. B. Transport of spent nuclear fuel and high-level waste. C. Storage of spent nuclear fuel through receipt of storage cask certification or a facility operating license. D. Monitored Geologic Repository, including the site characterization activities Exploratory Studies Facility (ESF) and surface based testing], through receipt of an operating license. E. High-level waste form development through qualification, production, and acceptance. F. Characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel. 	Delete the "QARD Applicability" statement in the Introduction. QARD applicability will be contained in Sections 2.2.2, as shown in change 4 below.	<p>Remove duplicate information. The Introduction and Section 2.2 contained duplicate QARD applicability information.</p> <p>Additionally, the applicability of the QARD to the A-C items is not included in the revised Section 2.2. It has been determined that these activities did not/will not occur during the site characterization phase or the construction authorization phase. Since one of the purposes of this revision is to clearly state the applicability of the QARD, it is appropriate to delete them during this revision</p>
2	Figure INTRO-1 includes as a Source Document- 10CFR73, (Current)-Physical Protection of Plants and Materials.	Delete the reference to Source Document-10CFR73, (Current)-Physical Protection of Plants and Materials	<p>Section 2.2.2. B had previously stated that the QA program applied to the items required for physical protection as defined in 10 CFR 73. It has been determined that items in this category are not required to be controlled in accordance with the Quality assurance requirements of 10 CFR 63.142.</p> <p>Also, the change basis for change #4 provides additional discussion of this change.</p>
3	<p>2.2.2 Classifying Items</p> <p>A. The QA program shall apply to the following, which shall be included on a <i>Q-List</i>.</p> <ul style="list-style-type: none"> 1. Items important to public radiological safety as described in 10 Code of Federal Regulations (CFR) Parts 60, 71, and 72. 2. Items and natural barriers important to waste isolation as described in 10 CFR Part 60. 3. Items required for the control and management of site-generated radioactive waste other than spent 	<p>2.2.2 QA Program Applicability and Related Activities</p> <p>The QA program shall be applied to:</p> <ul style="list-style-type: none"> A. All structures, systems and components (SSCs) important to safety or waste isolation, B. Design and characterization of barriers important to waste isolation and 	<p>Section 2.2.2 is retitled "QA Program Applicability and Related Activities." It combines information, from the Introduction, Sections 2.2.2, and 2.2.3, into one section, which now addresses the applicability of the QARD.</p> <p>1.The revision is a restatement of the applicability statement contained in 10 CFR 63.142, as follows: (paraphrased)- "Quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers</p>

	<p>fuel and high-level waste.</p> <p>4. Items required for the protection of items important to safety and waste isolation from the hazards of fire.</p> <p>5. Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function.</p> <p>6. Items required to control occupational radiological exposure.</p> <p>B. The QA Program shall apply to the items required for physical protection as defined by 10 CFR Part 73.</p>	<p>to,</p> <p>C. Related activities.</p> <ol style="list-style-type: none"> 1. Performance of the pre-closure safety analysis (PCSA), total system performance assessment (TSPA), and their inputs. 2. Characterization related activities (i.e., acquisition, control, and analysis of samples and data), tests and experiments, and scientific studies that provide data to support pre-closure safety analysis, performance confirmation and total system performance assessment. 3. Activities that are important to waste isolation and important to the safety functions of those SSCs (i.e., design, purchasing, fabricating, handling, packaging, shipping, storing, cleaning, erecting, installing, inspecting, maintaining, repairing, and modifying SSCs). 4. Activities related to U.S. Department of Energy (DOE) high-level waste form from development through qualification, production, and acceptance. 5. Activities related to the characterization of DOE spent nuclear fuel, and its conditioning, treatment, and/or canisterization through acceptance. 	<p>important to waste isolation, and to related activities.”</p> <p>2. The revision also relocates and revises “related activities” from Section 2.2.3, Controlling Activities” to section 2.2.2. The paragraph is based on the criteria of 10 CFR 62, 142(a) which states, in part : “These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities.”</p> <p>It should be noted that “permanent closure, decontamination, and dismantling are not included at this time. These are activities that will be addressed at the appropriate time in the life cycle of the repository.</p> <p>3. The applicability to high-level waste and DOE characterization are applicability requirements that were previously addressed in the INTRODUCTION section of the QARD. These are considered necessary due to the activities on going by DOE Environmental Management.</p> <p>4. Based on the criteria of 10 CFR 63 and the acceptance criteria established in the Yucca Mountain Review Plan, NUREG-1804, Rev 2, the applicability of the QARD to items in 2.2.2 A- 1, 3-6, and B is no longer necessary (Item 2.2.2. A-2 remains). However, if any of the items that would have been included in one of these categories is determined to meet the criteria to be classified as Important to Safety or Important to Waste Isolation, the item will be included on the “Q” list.</p>
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