



Department of Energy

Washington, DC 20585

QA: QA


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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) AUDIT OBSERVER INQUIRY FORM AUDIT EM-ARC-02-01

As a result of the OCRWM Office of Quality Assurance (OQA) audit EM-ARC-02-01 of the Office of Environmental Management, Office of Safety, Health and Security, High-Level Waste, performed on December 11-14, 2001, an Audit Observer Inquiry related to a QA issue was generated. Enclosed is the OQA response to the inquiry initiated by U.S. Nuclear Regulatory Commission Observer, Larry L. Campbell.

It is anticipated that the response provided herein will be acceptable to your staff. If you have any questions or desire further information, please contact me at (702) 794-1460.


Ram Murthy, Acting Director
Office of Quality Assurance

OQA:RM-0565

Enclosure:
OCRWM Audit Observer Inquiry Form
Audit EM-ARC-02-01

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Audit No. EM-ARC-02-01

Sequence No. 1

Name (Observer) LARRY L. CAMPBELL

Larry Campbell 12/14/01

Organization U.S. NUCLEAR REGULATORY COMMISSION

Requirement Reference

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION (QARD), REV 10

SECTIONS 2.2.1.4, 2.2.1.C.1 (a, b, and c), 2.2.1.C.4, and 2.2.10

Question/Concern:

SEE ATTACHED PAGE 2 of 2.

Response:

See Attached

Audit Team Leader: J. M. Dwyer, Jr.

Acknowledgement of Receipt: Larry Campbell

Observer Signature

Date: 12/14/01

ENCLOSURE

Audit Observer Inquiry EM-ARC-02-01, Sequence No.1
Question/Concern (Continued from Page 1)

During Audit No. EM-ARC-02-01, OQA and EM-5 audit personnel stated that their present practice for reviewing the Quality Assurance Requirements and Description (QARD) Requirements Matrixes was to review the matrixes during their annual audits of the Affected Organizations responsible for the matrixes.

Reviewing QARD Requirements Matrixes, including any exceptions taken by the Affected Organizations and any requirements identified as not applicable, once a year during the conduct of an audit is a concern. This practice may result in an unacceptable exception or a requirement incorrectly identified as not applicable being implemented for almost a year.

Further, the OQA audit checklist for Audit EM-ARC-02-01 and several FY 2001 EM-5 audit checklists, used for reviewing QARD Requirements Matrixes, do not appear to meet applicable review provisions contained in Section 2.2.10 of the QARD. For example, QARD Section 2.2.10.A requires that a review criteria be established before performing the QARD Requirements Matrix review and that the criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. The checklists reviewed did not appear to address or identify acceptance criteria to be used by the audit team when reviewing the matrixes.

Therefore, as required by QARD Section 2.2.10.A, the audit checklist should contain acceptance criteria or guidance to evaluate the acceptability of exceptions or alternatives to QARD requirements. Although not provided, this criteria may include considerations such as the following: applicable regulations are not violated; applicable DOE policies and practices are met; equivalent level of quality assurance is provided; are not within the Affected Organization's work scope; obtain guidance from the OQA Director of Quality Assurance; etc. Further, it is not clear to the observers if the review provisions contained in Section 2.2.10 are entirely applicable for reviewing exceptions, alternatives, or requirements not within the scope of the Affected Organization's work scope. Because some exceptions or alternatives may result in a reduction of a QARD requirement, it is suggested that OQA evaluate the review provisions contained in QARD Section 2.2.10 and determine if they need to be revised or supplemented when they are used for the review of QARD Requirements Matrixes.

Recommendations

It appears that the review and acceptance of exceptions or alternatives to QARD requirements, and the review of QARD Matrixes, as presently performed during OQA and EM-5 audits, is an area requiring improvement. It is recommended that, as a minimum, OQA evaluate the need for the QARD be revised to require formal approval of exceptions or alternatives to QARD requirements (as applicable by OQA or EM-5) before they are implemented by the Affected Organizations. Further, it is recommended that OQA evaluate the review requirements contained in QARD Section 2.2.10 and determine if they are acceptable when used for the review of QARD Requirements Matrixes. If QARD Section 2.2.10 is determined to be acceptable for this review, then applicable OQA and EM-5 audit checklists, used to review QARD Requirements Matrixes, need to be revised to address QARD Section 2.2.10 review requirements.

**Response to Nuclear Regulatory Commission
Observer Inquiry EM-ARC-02-01**

There appears to be confusion relative to the review requirements delineated in QARD Section 2.2.1C for QARD requirements matrices and the requirement to perform internal audits of work to verify QA program compliance in accordance with QARD Section 18.0.

1. **Subsection 2.2.1.C2** - Affected Organizations (AOs) initial QARD requirements matrices are reviewed by OQA in accordance with Subsection 2.2.10. The requirements of QARD Subsection 2.2.10 have been incorporated into Administrative Procedure (AP) 6.28Q, *Document Review*. This procedure provides the review criteria for QARD requirements matrices.
2. **Subsection 2.2.1.C3 and 2.2.1.C4** – These Subsections requires the AO to revise their QARD matrices as changes are made to procedures and the AO QA organization to review these changes in accordance with QARD Subsection 2.2.10. The intent of these requirements are to have the QARD requirements associated with this process imbedded into the AOs procedure governing procedure development/revision so that the QARD matrix changes and QA concurrence of the changes occur concurrent with procedure development/change. It is not intended that the QA concurrence of the QARD matrix changes be performed annually via the annual compliance audit
3. **Section 18.0** - The purpose of the annual compliance audit relative to QARD Subsection 2.2.1C is to verify that the requirements of this Subsection have been implemented effectively via the review of objective evidence related to the procedure development/revision process. The audit process is not intended to perform the review delineated in Subsection 2.2.10 for each new or revised procedure.
4. **Subsection 2.2.1.C1.1b and 2.2.1C.1c** - Relative to QARD requirements that are not applicable to an AO based on work scope and exceptions/alternatives to QARD requirements as permitted by these subsections, the QARD will be revised to require OQA to concur with all non-applicability determinations, and exceptions/alternatives prior to implementing the exception/alternative. If the exception/alternative results in a reduction in the NRC accepted quality assurance program description, NRC approval will be obtained prior to implementation as required by 10CFR63.144(b).