

AUDIT OBSERVER INQUIRY FORM

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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:

Audit Team Leader: *John M. Day, Jr.*

Acknowledgement of Receipt: *Larry Campbell* Date: 12/14/01  
Observer Signature

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 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.