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Quality Assurance	Program Requirements Document	For Additional Info: http://EDMS	Effective Date: 09/18/13
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Manual: 13— Quality Assurance Program

Change Number: 339226

*The current revision can be verified on EDMS.

1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for ensuring that *conditions adverse to quality* (see def.) are promptly identified and corrected as soon as practical through the company's Corrective Action System.

2. APPLICABILITY

This PRD applies to company organizations and subcontractors responsible for achieving, maintaining, and verifying the quality of items, services, and activities of facilities, programs, and projects; and to those corresponding conditions that may be adverse to safety, health, operations, quality, security (except as noted below), and the environment.

This PRD applies to conditions identified by external agencies or by employees during internal independent assessments; *management assessments* (see def.), and *surveillances* (see def.); manufacturing, installation, and *testing* (see def.) activities; operations and maintenance activities; and normal work assignments.

NOTE: *The Issue Communication and Resolution Environment system is the approved company system for tracking conditions adverse to quality.*

This PRD does not apply to reporting and resolving *employee concerns* (see def.); protective services' assessments, other than those involving environmental, safety, health and quality aspects; or processing improvement suggestions.

3. RESPONSIBILITIES

3.1 Senior Management

Senior management is responsible for the following:

- A. Ensuring that *corrective action* (see def.) system requirements are implemented
- B. Establishing and communicating the standards for regulatory compliance.

3.2 Quality Assurance Organization

The Quality Assurance (QA) organization is responsible for providing overall leadership for the company's QA program and corrective action/issues management process.

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3.3 Performance Assurance Organization

The Performance Assurance organization is responsible for definition, development, implementation, and oversight of the Issues Management Program and Corrective Action System.

3.4 Cognizant Director or Designee (Site-Area, Functional, and Program)

The cognizant director, or designee, is responsible for the following:

- A. Ensuring company-level procedures and systems relating to the Issues Management Program and Corrective Action System are effectively implemented
- B. Promoting an open environment and culture to support identification and resolution of issues and *conditions adverse to quality* (see def.)
- C. Being accountable and responsible for ensuring that conditions adverse to quality affecting the site-area, program, or functional areas under their purview are identified, documented, and resolved in an effective and timely manner
- D. Using designees to implement many of the activities to resolve conditions adverse to quality and ensuring that adequate priority and resources are allocated for effective program implementation
- E. Performing categorization and classification evaluations to determine their type and significance
- F. Approving corrective action plan (CAPs), schedules, and revisions thereto, which involve *significant conditions adverse to quality* (see def.)
- G. Ensuring that applicable lessons learned information is shared as appropriate, follow-up assessments are performed, and trend analysis is conducted to identify other conditions adverse to quality or recurrence of previously closed conditions.

3.5 Responsible Manager or Designee

The *responsible manager* (see def.), or designee, is responsible and accountable to the cognizant director to ensure that the following elements of the program are implemented:

- A. Proper notification or reporting is completed

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- B. Appropriate cause analysis is performed and documented by a qualified analyst
- C. CAPs address identified causes
- D. CAPs, revisions, and schedules for conditions adverse to quality are approved
- E. Corrective actions are implemented as scheduled or, rescheduled, if necessary
- F. All necessary documentation supporting corrective action closure is maintained as a quality record
- G. Appropriate *verification* (see def.) activities are performed
- H. Status of the item in the Issue Communication and Resolution Environment tracking system is current.

3.6 Lessons Learned Coordinators (Site-Area, Functional, and Program)

The lessons learned coordinators are assigned by their respective cognizant directors and are responsible for providing an interface between the local lessons learned activities and the company-level Lessons Learned System Office. Site-area coordinators also serve as points of contact for site-area operations safety boards on lessons learned items.

3.7 Cognizant Quality Engineers

Cognizant quality engineers are responsible for conducting concurrence reviews of all CAPs, including *remedial action* (see def.) and performing verification of CAP implementation for all Department of Energy/Office of Civilian Radioactive Waste (DOE/RW) -0333P conditions.

3.8 Independent and Knowledgeable Persons

Assigned independent and knowledgeable persons are responsible for verifying implementation of CAPs for non-DOE/RW-0333P significant conditions adverse to quality.

3.9 Validation/Effectiveness Assessor

The Project Evaluation Board performs corrective action validation/effectiveness assessments consistent with DOE O 226.1B or ensures trained and qualified personnel perform validation/effectiveness assessments for significant conditions adverse to quality.

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3.10 Employees

Employees are responsible for identifying and reporting potential conditions adverse to quality.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection meet the requirements in “Quality Assurance Requirements for Nuclear Facility Application,” American Society of Mechanical Engineers (ASME) NQA-1-2008 with Addenda through NQA-1a-2009, Department of Energy (DOE) O 414.1D, “Quality Assurance,” and the other standards listed in FWD-7, “Foreword.” These requirements apply to the entire company as defined by FWD-7.

4.1.1 Basic

- 4.1.1.1 Conditions adverse to quality will be identified promptly and corrected as soon as practicable.
- 4.1.1.2 In the case of a significant condition adverse to quality, the cause of the condition will be determined and corrective action will be taken to preclude recurrence.
- 4.1.1.3 Managers responsible for an activity will evaluate significant conditions adverse to quality and initiate a *stop work order* (see def.) if warranted.
- 4.1.1.4 The QA management will retain a right to initiate a stop work order for significant conditions adverse to quality in any company operation.

4.1.2 Classification of Conditions Adverse to Quality

- 4.1.2.1 Conditions adverse to quality will be classified in regard to their significance, and corrective actions will be taken accordingly.
- 4.1.2.2 Two categories of classification will be established:
 - A. Conditions adverse to quality
 - B. Significant conditions adverse to quality.

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4.1.3 Conditions Adverse to Quality

- 4.1.3.1 Conditions adverse to quality will be documented and reported to the appropriate levels of management responsible for the conditions and to the QA organization for tracking.
- 4.1.3.2 Responsible management will perform investigative action to determine the extent of the adverse condition and complete remedial action as soon as practical.

4.1.4 Significant Conditions Adverse to Quality

- 4.1.4.1 Criteria for determining a significant condition adverse to quality will be established.
- 4.1.4.2 The identification, cause, and corrective action for significant conditions adverse to quality will be documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking.
- 4.1.4.3 Responsible management will:
 - A. Perform investigative action to determine the extent and impact of the condition, and document the results.
 - B. Determine, document, and complete *remedial action* (see def.) as soon as practical.
 - C. Determine the *root cause* (see def.) of the problem and take corrective action to prevent recurrence as soon as practical.

4.1.5 Follow-up and Closure Action

- 4.1.5.1 Completion of corrective actions will be verified.
- 4.1.5.2 For significant conditions adverse to quality an independent, knowledgeable person will concur with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure that QA program requirements are satisfied.

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4.1.6 Quality Trending

- 4.1.6.1 The QA organization will establish criteria for determining adverse quality trends.
- 4.1.6.2 Reports of *nonconformances* (see def.) and conditions adverse to quality will be evaluated to identify adverse quality trends and help identify root causes.
- 4.1.6.3 Trend evaluation will be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.
- 4.1.6.4 Trend evaluations will be distributed to impacted organizations management.
- 4.1.6.5 Identified adverse trends will be reported to the management of the organization responsible for corrective action.

4.2 Specific Requirements for DOE/RW-0333P, Quality Assurance Requirements and Description, Applications

This subsection contains additional requirements from the Quality Assurance Requirements and Description (DOE/RW-0333P), which are specific to spent nuclear fuel and high-level waste activities as defined in FWD-7.

4.2.1 Identifying Conditions Adverse to Quality

- 4.2.1.1 A condition adverse to quality shall be identified and documented when a failure, malfunction, deficiency, defective item, or nonconformance is identified.

4.2.2 Classification of Conditions Adverse to Quality

- 4.2.2.1 Conditions adverse to quality shall be evaluated for reportability in accordance with 10 CFR 21 and 10 CFR 63.73.

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4.2.3 Significant Conditions Adverse to Quality

- 4.2.3.1 Significant conditions adverse to quality will be evaluated for a stop work condition by the QA organization to determine whether stopping work is warranted.
- 4.2.3.2 QA management will issue *stop work orders* (see def.) to responsible management after a stop work condition has been identified.
- 4.2.3.3 QA management will take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.
- 4.2.3.4 For significant conditions adverse to quality, the QA organization will concur with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure that QA program requirements are satisfied.

5. RECORDS

All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

6. DEFINITIONS

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for definitions of the following terms:

condition adverse to quality
corrective action
employee concern
management assessments
nonconformance
quality assurance records
remedial action
responsible manager
root cause
significant condition adverse to quality
stop work order

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surveillances

testing

verification

7. REFERENCES

10 CFR 21, “Reporting of Defects and Noncompliance”

10 CFR 63.73, “Reports of Deficiencies”

ASME NQA-1-2008 with Addenda through NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications,” American Society of Mechanical Engineers

DOE O 414.1D, “Quality Assurance”

DOE O 226.1B, “Implementation of Department of Energy Oversight Policy”

DOE/RW-0333P, *Quality Assurance Requirements and Description*, Rev. 20, Office of Civilian Radioactive Waste Management

FWD-7, “Foreword”

LST-199, “Quality Assurance Program Requirements Document Definitions”

PRD-5088, “Quality Assurance Records”