

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086
	Revision*: 16
	Page: 1 of 9

Quality Assurance	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 09/18/13
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Manual: 13—Quality Assurance Program

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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for controlling *items* (see def.) that do not conform to specified requirements to prevent their inadvertent installation or use.

## 2. APPLICABILITY

This PRD applies to all company organizations; all items related to facility safety, reliability, or operation; and all items that are determined to be *suspect/counterfeit items* (S/CI) (see def.).

The requirements identified in this PRD are optional for the following items unless S/CIs are involved:

- A. Operational deficiencies controlled by operation or maintenance deficiency tracking systems that are reworked as normal *corrective maintenance* (see def.) to meet existing design requirements
- B. Nonconforming items discovered while in an *in-process* (see def.) status under work *process* (see def.) control *procedures* (see def.) that are reworked within the scope of the work process control to meet existing design requirements
- C. Items not related to facility safety, reliability, or operation (e.g., drinking water and sewage systems and office heating, cooling, electrical, and lighting systems).

## 3. RESPONSIBILITIES

### 3.1 Quality Assurance Organization

The Quality Assurance (QA) organization is responsible for establishing the procedures for definition, implementation, and maintenance of the company's process for the control of nonconforming items.

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

The cognizant director or designee is responsible for:

- A. Ensuring company-level procedures relating to the nonconforming item process are effectively implemented

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 2 of 9
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- B. Promoting an open environment and culture to support the identification and resolution of nonconforming items so that employees may report *nonconformances* (see def.) without fear of reprisal
- C. Ensuring that nonconforming items 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 nonconforming items and to ensure that adequate priority and resources are allocated for effective process implementation
- E. Performing categorization and ensuring the completion of applicable reportability reviews and operability evaluations, as required, for nonconforming items
- F. Ensuring nonconforming items are properly tagged or segregated to prevent inadvertent installation or use
- G. Ensuring that nonconforming items that pose a threat to employee safety or health or represent an imminent threat to the environment, the public, or property are placed in a safe condition, and that an evaluation is conducted to determine if stopping work is warranted.

### 3.3 Responsible Manager

The *responsible manager* (see def.) is responsible and accountable to the cognizant director for ensuring that:

- A. Investigation and evaluation of nonconforming items are conducted to determine the disposition of nonconforming items
- B. Appropriate cause analysis is performed and documented by a qualified analyst
- C. Conditional use evaluations are done, if needed
- D. Appropriate engineering change control measures are implemented for nonconforming items that are under *configuration control* (see def.)
- E. Corrective action plans address the identified cause, and that *technical justifications* (see def.) are documented for *use-as-is* or *repair* (see defs.) dispositions

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 3 of 9
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- F. Corrective action plans are reviewed and approved, and implemented as scheduled, or rescheduled, as necessary, with approval from the cognizant director
- G. All necessary documentation supporting nonconforming item closure is maintained as a *quality assurance record* (see def.)
- H. Appropriate *verification* (see def.) activities are performed
- I. Status of the nonconforming item in the Issue Communication and Resolution Environment (ICARE) tracking system is kept current.

### 3.4 Cognizant Quality Engineers

*Cognizant quality engineers* (see def.) are responsible for:

- A. Reviewing and concurring with conditional use evaluations, nonconforming item dispositions
- B. Performing verification *inspections* (see def.) of implemented *corrective actions* (see def.)
- C. Ensuring quality nonconformance control status tags are applied and removed as appropriate.

### 3.5 Employees

Employees are responsible for identifying and reporting items that could be categorized as nonconforming.

### 3.6 Suspect/Counterfeit Items Subject Matter Expert

The S/CI *subject matter expert* (see def.) is responsible for:

- A. Evaluating items for suspect/counterfeit determination and providing for their disposition
- B. Consulting with the Inspector General for the disposition of S/CI.

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 4 of 9
---------------------------------------	---

## 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) Order 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 Items that do not conform to specified requirements will be controlled to prevent inadvertent installation or use of the item. Controls will provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to relevant organizations.

#### 4.1.2 Documentation and Evaluation

- 4.1.2.1 Nonconformance documentation will clearly identify and describe the *characteristics* (see def.) that do not conform to specified criteria.
- 4.1.2.2 Nonconforming items will be evaluated; and recommended dispositions will be proposed, evaluated, and approved.
- 4.1.2.3 The review will include determining the need for corrective action according to the requirements of PRD-5087, “Corrective Action.”
- 4.1.2.4 Documentation of a nonconformance in a nonconformance report is required when an item:
  - A. Fails to meet required technical or quality requirements
  - B. Is of indeterminate quality
  - C. Is an SC/I

**CONTROL OF NONCONFORMING ITEMS**

Identifier: PRD-5086

Revision\*: 16

Page: 5 of 9

- D. Has documentation deficiencies (i.e., missing, incomplete, illegible, or damaged documents; improper revisions; or documents having unauthorized changes) which render the quality of the item indeterminate.

**4.1.3 Notification**

- 4.1.3.1 Organizations affected by the nonconformance will be notified.

**4.1.4 Personnel**

- 4.1.4.1 Personnel performing evaluations to determine a disposition will have demonstrated competence in the specific area they are evaluating, have adequate understanding of the requirements, and have access to pertinent background information.

**4.1.5 Responsibility and Authority**

- 4.1.5.1 The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances will be defined.
- 4.1.5.2 Responsibility for the control of further processing, delivery, installation, or use of nonconforming items will be designated in writing.
- 4.1.5.3 Further processing, delivery, installation, or use of a nonconforming item will be controlled pending the evaluation and an approved disposition by authorized personnel.

**4.1.6 Identification**

- 4.1.6.1 Nonconforming items will be identified by marking, tagging, or other methods not detrimental to the item, the container, or the package containing the item. The identification will be legible and easily recognizable.
- 4.1.6.2 If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, will be identified.

**CONTROL OF NONCONFORMING ITEMS**

Identifier: PRD-5086

Revision\*: 16

Page: 6 of 9

**4.1.7 Segregation**

- 4.1.7.1 Nonconforming items will be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.
- 4.1.7.2 When segregation is impractical or impossible because of physical conditions such as size, weight, or access limitations, other precautions will be employed to preclude inadvertent use of the nonconforming item.

**4.1.8 Disposition**

- 4.1.8.1 The disposition of use-as-is, *reject* (see def.), repair, or *rework* (see def.) for nonconforming items will be identified and documented.
- 4.1.8.2 The technical justification for the acceptability of a nonconforming item that has been dispositioned repair or use-as-is will be documented.
- 4.1.8.3 Items not meeting original design requirements that are dispositioned use-as-is or repair will be subject to design control measures commensurate with those applied to the original design.
- 4.1.8.4 Required as-built records will reflect the use-as-is or repair condition.
- 4.1.8.5 If changes to the specifying document are required to reflect the as-built condition, then the disposition will require action to change the specifying document to reflect the accepted nonconformance.
- 4.1.8.6 Any document or QA record change required by the disposition of the nonconformance will be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change will identify the nonconformance documentation.
- 4.1.8.7 The disposition of an item to be reworked or repaired will contain a requirement to re-examine (i.e., inspect, *test* [see def.]), or nondestructively examine) the item to verify acceptability.

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 7 of 9
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#### **4.1.9 Reexamination**

- 4.1.9.1 Repaired or reworked items will be reexamined using the original process and *acceptance criteria* (see def.) unless the nonconforming item disposition has established alternate acceptance criteria.

#### **4.1.10 Quality Trending**

- 4.1.10.1 Nonconformance documentation will be periodically analyzed to identify quality trends in accordance with PRD-5087, “Corrective Action.”

### **4.2 Specific Requirements for DOE/RW-0333P, Quality Assurance Requirements and Descriptions, Applications**

This subsection contains additional requirements from the Quality Assurance Requirements and Descriptions (Department of Energy/Office of Civilian Radioactive Waste [DOE/RW] -0333P) that are specific to spent nuclear fuel and high-level waste activities as defined in FWD-7, “Foreword.”

#### **4.2.1 Documenting, Reporting, and Evaluating Nonconforming Items**

- 4.2.1.1 Nonconforming characteristics shall be reviewed, and recommended dispositions of the nonconforming items shall be proposed and approved. The review shall include determining the need for corrective action to the requirements of PRD-5087, “Corrective Action.”
- 4.2.1.2 Recommended dispositions shall be evaluated and approved by individuals who are independent of work that produced the disposition.

#### **4.2.2 Disposition of Nonconforming Items**

- 4.2.2.1 The disposition of “use-as-is,” “limited use” (this disposition is limited to nonconforming sample in accordance QARD Supplement II, Sample Control) “reject,” “repair,” or “rework” for nonconforming items shall be identified and documented.

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 8 of 9
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4.2.2.2 The technical justification for the acceptability of a nonconforming item that has been dispositioned “repair,” “limited use,” or “use-as-is” shall be documented.

**NOTE:** *The “Limited Use” disposition required by the QARD for nonconforming samples in accordance with Supplement II, Sample Control, does not apply because Supplement II only applies to physical samples collected at the Yucca Mountain Project site.*

## 5. RECORDS

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

## 6. DEFINITIONS

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

*acceptance criteria*

*characteristic*

*cognizant quality engineer*

*configuration control*

*corrective action*

*corrective maintenance*

*in-process*

*inspection*

*item*

*nonconformance*

*procedure*

*process*

*quality assurance record*

*reject*

*repair*

*responsible manager*

*rework*

<b>CONTROL OF NONCONFORMING ITEMS</b>	Identifier: PRD-5086 Revision*: 16 Page: 9 of 9
---------------------------------------	---

*subject matter expert*

*suspect/counterfeit item*

*technical justification*

*test*

*use-as-is*

*verification*

## 7. REFERENCES

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

DOE Order 414.1D, “Quality Assurance”

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-5087, “Corrective Action”

PRD-5088, “Quality Assurance Records”