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Quality Assurance	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 09/18/13
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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for specifying, planning, performing, and reporting *inspections* (see def.) used to *verify* (see def.) the *acceptance* (see def.) of *items* (see def.) or activities.

## 2. APPLICABILITY

This PRD applies to company organizations involved with the evaluation of conformance to specified requirements and acceptability of items and activities by inspection.

## 3. RESPONSIBILITIES

### 3.1 Design Organization

The design organization is responsible for the identification of and selective application of inspection requirements and appropriate *acceptance criteria* (see def.) in implementing *documents* (see def.) and specifications. They are to interface with Quality Assurance (QA), area/project managers, facility managers/custodians, and *system engineers* (see def.).

### 3.2 Cognizant Quality Engineer

*Cognizant quality engineers* (see def.) are responsible for the preparation and/or review of working documents that establish inspection requirements. Cognizant quality engineers will interface with the design organization, facility managers/custodians, and system engineers.

### 3.3 Inspector

The *inspector* (see def.) is responsible and authorized to perform, document, accept, and report specified independent inspections.

### 3.4 Line Organization

The *line organization* (see def.) is responsible for ensuring that the appropriate level of inspection is performed, as specified. It will also interface with the design organization, QA, facility managers/custodians, and system engineers.

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## 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 Inspections required to verify conformance of an item or activity to specified requirements or the continued acceptability of items in *service* (see def.) will be planned and executed.
- 4.1.1.2 *Characteristics* (see def.) subject to inspection and inspection methods will be specified.
- 4.1.1.3 Inspection results will be documented.
- 4.1.1.4 Inspection for acceptance will be performed by qualified persons other than those who performed or directly supervised the work being inspected.

#### 4.1.2 Inspection Requirements

- 4.1.2.1 Inspection requirements and acceptance criteria will include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

#### 4.1.3 Inspection Hold Points

- 4.1.3.1 If mandatory inspection *hold points* (see def.) are required beyond which work will not proceed without specific consent of the designated representative, the specific hold points will be indicated in appropriate documents.
- 4.1.3.2 Consent to waive specified hold points will be recorded prior to continuation of work beyond the designated hold point.

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#### 4.1.4 Planning

4.1.4.1 Identification of characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. During the inspection planning process, *process* (see def.) monitoring methods to be employed and when shall be identified. .

4.1.4.2 Selection and identification of the *measuring and test equipment* (M&TE) (see def.) to be used to perform the inspection shall be identified. M&TE to be used shall be verified as to its calibration status and that it is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

4.1.4.3 When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method will be based on recognized standard practices.

4.1.4.4 Periodic inspections or surveillances during operation shall be planned and executed to ensure the continued performance to operational requirements.

**NOTE:** *Guidance (see def.) and considerations for the preparation of inspection planning are provided in Appendix A.*

#### 4.1.5 In-Process Inspection and Monitoring

4.1.5.1 Inspection of items under construction or otherwise *in-process* (see def.) will be performed as necessary to verify quality.

4.1.5.2 If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel will be provided.

4.1.5.3 Both inspection and process monitoring will be provided when control is inadequate without both.

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#### **4.1.6 Final Inspections**

4.1.6.1 Completed items will be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance to the specific requirements.

##### **4.1.6.1.1 Item Acceptance**

4.1.6.1.1.1 Final inspections will include a records review of the results and resolution of *nonconformances* (see def.) identified by prior inspections. Documentation not previously examined shall be examined for adequacy and completeness.

##### **4.1.6.1.2 Modifications, Repairs, or Replacements**

4.1.6.1.2.1 Any modifications, *repairs* (see def.), or replacements of items performed subsequent to final inspection will require reinspection or retest, as appropriate, to verify acceptability.

##### **4.1.6.1.3 Inspection Documentation**

4.1.6.1.3.1 Inspection documentation will identify:

- A. The item inspected
- B. The date of inspection
- C. The name of the inspector or the inspector's unique identifier who documented, evaluated, and determined acceptability; name of data recorder as applicable

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- D. The type of observation or method of inspection
- E. Results indicating acceptability of characteristics inspected
- F. Reference to information on actions taken in connection with nonconformances
- G. M&TE used during inspection and calibration data.

**NOTE:** *Guidance and considerations for the review of inspection records and other documentation generated as a result of or directly associated with the inspection activity are provided in Appendix A.*

#### 4.1.7 Qualifications of Inspection and Test Personnel

- 4.1.7.1 Personnel performing inspections to verify conformance of an item to specified acceptance criteria or as described in this section and personnel performing *tests* (see def.) as described in PRD-5082, “Test Control,” will be qualified and certified according to the *indoctrination* (see def.), *training* (see def.), education, experience, and physical requirements of this PRD and PRD-5072, “Personnel Training and Qualification.”

**NOTE:** *PRD-5082, “Test Control,” Subsection 4.1.7.2 contains the qualification (see def.) requirements of personnel who operate systems/subsystems during testing (see def.) and the qualification requirements for test engineers and others who prepare and direct testing activities.*

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4.1.7.2 The initial capabilities of a candidate will be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The evaluation will be performed in accordance with the requirements of the applicable functional level and education and experience requirements of this document.

#### **4.1.7.3 Indoctrination and Training Qualification Requirements**

4.1.7.3.1 Personnel performing or managing *activities affecting quality* (see def.) will receive indoctrination in their job responsibilities and authority; general criteria, including technical objectives and requirements, applicable codes and standards, regulatory commitments, company procedures, and QA program requirements.

4.1.7.3.2 Indoctrination and training will be commensurate with scope, complexity, importance of the activities, special nature of the inspections or tests, and the education, experience, and proficiency of the person.

4.1.7.3.3 The need for a formal training program for personnel performing or managing activities affecting quality will be determined. Training will be provided if necessary to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

#### **4.1.7.4 Physical Qualification Requirements**

4.1.7.4.1 The responsible organization will identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent visual acuity and other physical examinations.

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#### **4.1.7.5 Certification of Qualifications**

4.1.7.5.1 The qualification of inspection and test personnel will be certified in writing by the responsible organization and will document the following information:

- A. Employer's name
- B. Identification of the person being certified
- C. Activities, qualified inspection and test categories, or class the individual is certified to perform
- D. Basis of qualification, such as:
  - 1. Education, experience, indoctrination, and training
  - 2. Test results, where applicable
  - 3. Capability demonstration results.
- E. Results of periodic evaluations
- F. Results of visual acuity and other physical examinations, when required
- G. Signature of the employer's designated representative who is responsible for such certification
- H. Date of certification or recertification and certification expiration.

#### **4.1.7.6 Periodic Evaluation of Inspection and Test Personnel Qualifications**

4.1.7.6.1 The job performance of inspection and test personnel will be reevaluated at periodic intervals not to exceed 3 years.

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- 4.1.7.6.2 Reevaluation will be verified by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of this PRD. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person will be removed from that activity until such time as the required capability has been demonstrated.
- 4.1.7.6.3 Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year will be reevaluated.
- 4.1.7.7 Maintaining Qualification Documentation for Inspection and Test Personnel**
- 4.1.7.7.1 Records of qualification, including requalification for inspection and test personnel, will be established and maintained by the employer and for indoctrination and training.
- NOTE:** *Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.*
- 4.1.7.7.2 Integrity of the examination will be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examination. Copies of the objective evidence regarding the type(s) and content of the examination(s) will be required by the employer in accordance with the requirements of PRD-5072, “Personnel Training and Qualification.”

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## 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 (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.

### 4.2.1 Planning

4.2.1.1 Inspection planning will be performed and documented. Inspection plans may be separate documents governed by procedural controls, or an integral part of approved implementing documents.

4.2.1.2 Representatives of the interested technical organizations and individuals trained and qualified in QA practices and concepts shall participate in planning activities

**NOTE 1:** *Individuals performing a QA function will be qualified in accordance with PRD-5072, "Personnel Training and Qualification."*

**NOTE 2:** *Guidance and considerations for the preparation of inspection planning are provided in Appendix B.*

### 4.2.2 Selecting Inspection Personnel to Perform Inspection

4.2.2.1 Inspections performed by personnel during on-the-job training shall be performed under the direct observation and supervision of a qualified person and *verification* (see def.) of conformance shall be by the qualified person until proper certification is achieved.

4.2.2.2 *Data* (see def.) recorders, equipment operators, or other inspection team members who are supervised by a qualified inspector will not be required to be qualified inspectors.

4.2.2.3 Inspections for acceptance shall be performed by individuals other than those who performed or directly supervised the work being inspected, and those individuals shall not report directly to the supervisor immediately responsible for performance of the work.

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**NOTE:** *Inspection personnel will be qualified and/or certified in accordance with PRD-5072, "Personnel Training and Qualification." See PRD-5082, "Test Control," for the qualification requirements of personnel who operate systems/subsystems during testing and the qualification requirements for test engineers and others who prepare and direct testing activities.*

#### **4.2.3 Statistical Sampling**

4.2.3.1 When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method shall be based on recognized standard practices and shall be in accordance with PRD-5074, "Design Control."

### **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 the definitions of the following terms:

*acceptance*

*acceptance criteria*

*activities affecting quality*

*characteristics*

*cognizant quality engineer*

*data*

*design output*

*document*

*guidance*

*hold point*

*indoctrination*

*in-process*

*inspection*

*inspector*

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*item*

*line organization*

*measuring and test equipment*

*nonconformance*

*personnel qualification*

*process*

*qualification (personnel)*

*quality assurance record*

*repair*

*service*

*system engineer*

*test/testing*

*training*

*verify*

*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/RW-0333P, *Quality Assurance Requirements and Description*, Revision 20, Office of Civilian Radioactive Waste Management Program

DOE O 414.1D, "Quality Assurance"

FWD-7, "Foreword"

LST-199, "Quality Assurance Program Requirements Document Definitions"

PRD-5072, "Personnel Training and Qualification"

PRD-5074, "Design Control"

PRD-5082, "Test Control"

PRD-5088, "Quality Assurance Records"

## 8. APPENDIXES

Appendix A, "Inspection Documentation Guidance"

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Appendix B, "Inspection Planning Guidance"

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## Appendix A

### Inspection Documentation Guidance

Inspection records and other documentation generated as a result of or directly associated with the inspection activity should, as a minimum, be reviewed for the following:

- All documents are complete and accurate and appropriately signed off
- The required inspections were performed and completed in accordance with inspection planning documents
- Inspection results, including the accept/reject status, were recorded for each inspection requirement/attribute
- Processes, activities, and items were found to be in compliance with specified requirements, including those that were initially rejected and required resolution
- Nonconformances, including those discovered during final review and acceptance, were properly recorded and have been resolved
- Inspection activities were performed by individuals with the appropriate qualifications.

If process monitoring was required in conjunction with the inspection activity, the documentation should be reviewed to ensure performance and completion of the activity, that required items and activities were observed and evaluated, and that any discovered nonconformances were properly recorded and have been resolved.

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## Appendix B

### Inspection Planning Guidance

The basis for the assignment, level, and intensity of inspection applied to processes, activities, and items are driven by *design output* (see def.) documents. The basis should be commensurate with the importance of a process, activity, or item's function to human health, safety, nuclear safety, effect on the environment, reliability, maintainability, and operability. Factors that should be addressed in establishing inspection activities are:

- Consequence of malfunction or failure
- Design and fabrication complexity or uniqueness
- Need for special controls and surveillance over processes and equipment, including in-service inspection (ISI) of specified structures, systems, and components and related activities
- Degree to which functional compliance can be demonstrated by inspection or test
- History of an item indicating it is subject to being supplied as a suspect/counterfeit item
- Quality history and degree of standardization
- Difficulty of correction, repair, or replacement
- Requirements of applicable instructions, procedures, drawings, specifications, codes, and standards.

The type of inspection (in-process, final, in-service, etc.) to be performed should be determined and identified in the appropriate document during the inspection planning process.

Inspection personnel should be provided with adequate information, direction, and criteria for performing inspection activities as required to verify quality and conformance to specified requirements. As a minimum, this should include:

- Measurable and verifiable acceptance criteria, including tolerances
- Identification of the organization performing the work or otherwise responsible for the process, activity, or item
- Identification of the organization responsible for performing the inspection.

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When applicable, the following also should be incorporated into inspection plans:

- Special requirements, such as environmental conditions, prerequisite safety inspections, notification to (or confirmation of the availability of) other organizations, simulation of normal or abnormal operating conditions, equipment lockout, and personnel to contact for access
- Reference to associated documents
- Selection and identification of the measuring and test equipment or installed process instrumentation
- Set-up and operation of test equipment
- Equipment necessary to support the inspection (such as ladders, scaffolding, water supply, compressed air, cleaning equipment, and safety equipment)
- Inspection tools required, such as mirrors, flashlights, levels, and rulers
- Material preparation requirements, such as the removal of insulation for a leak test
- Instructions for performing any required calculations (for example, torque wrench settings using extensions and/or multipliers)
- Specific instruction for process monitoring or sampling activities.

When sampling inspection is used, alternate sampling inspection criteria may be developed and implemented in cases where the use of recognized industry statistical sampling standards is not practical or possible. The design organization should provide technical justification for the alternate criteria when so specified. The sampling criteria used (industry standard or alternate) should be documented.

The QA organization should:

- Ensure that inspection personnel are provided adequate inspection information, direction, and criteria in documentation provided by other organizations (such as work packages) that will be readily available during inspection activities

OR

- Provide the information, direction, and criteria in inspection documents, such as inspection checklists or inspection procedures.

Inspection checklists and reports may be combined, stand-alone, or incorporated with other documents that specify inspection.