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Companywide	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

Change Number: 339215

\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for ensuring that *procurement documents* (see def.), and changes thereto, contain appropriate technical and *quality assurance* (QA) (see def.) requirements

## 2. APPLICABILITY

This PRD applies to company organizations and employees involved in the processing of documents for the procurement of *items* (see def.) and *services* (see def.).

## 3. RESPONSIBILITIES

### 3.1 Cognizant Quality Engineer

The *cognizant quality engineer* (see def.) is responsible for:

- A. Reviewing and approving the quality provisions of purchases
- B. Ensuring that appropriate quality requirements and administrative controls for the specified items or services have been properly specified.

### 3.2 Technical Support Organization

The *Technical Support Organization* (see def.) is responsible for:

- A. Establishing the technical provisions of purchase requisitions
- B. Ensuring that appropriate technical requirements and administrative controls for the specified items or services have been properly specified.

### 3.3 Requesting Organization

Organizations requesting procurement of items or services are responsible for documenting the requirements for the specified items or services by providing requisite ordering information and by ensuring adequacy of the documentation used to initiate procurement and any subsequent changes. The manager of the requesting organization verifies that any requisitions and attached documents have been properly reviewed and approved and meet the requirements specified in this PRD for initiating a procurement.

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**3.4 Procurement Organization**

The Procurement organization has the overall responsibility for developing and approving *procedures* (see def.) and documents that implement the procurement *process* (see def.). The Procurement organization is responsible for ensuring that requirements specified in the procurement documents are accurately transcribed into the final purchase document. It is responsible for solicitation and receipt of proposals and is the only company organization authorized to commit the company to contracts (purchase orders or contracts) for the acquisition of goods and services that involve the expenditure of project funds.

**3.5 Procurement Quality Organization**

The Procurement Quality organization is responsible for:

- A. Evaluating and qualifying suppliers
- B. Developing and controlling receipt inspection instructions for the acceptance of procured items
- C. Maintaining the Qualified Suppliers List.

**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, and Department of Energy Order (DOE O) 414.1D, “Quality Assurance.” These requirements apply to the entire company as defined by FWD-7, “Foreword.”

**4.1.1 Basic**

- 4.1.1.1 Applicable *design basis* (see def.) and other requirements necessary to ensure adequate quality will be included or referenced in documents for procurement of items and services.
- 4.1.1.2 To the extent necessary, procurement documents will require *suppliers* (see def.) to have a QA program consistent with the applicable requirements.

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- 4.1.1.3 When deemed appropriate, the purchaser will permit some or all supplier work to be performed under the purchaser's or another *affected organization's* (see def.) QA program provided the work is adequately addressed. In these cases, procurement documents will specify that the purchaser's or another organization's implementing documents are applicable to the supplier, and that the purchaser will provide these applicable documents to them.
- 4.1.1.4 Procurement processes and controls will include provisions for preventing the procurement of suspect and counterfeit items per the requirements of PRD-5095, "Suspect/Counterfeit Items."
- 4.1.1.5 Each procurement document issued for a facility or a basic component subject to 10 Code of Federal Regulations (CFR) 21 will specify, when applicable, that the provisions of 10 CFR 21 apply.

**4.1.2 Procurement Document Contents**

**NOTE:** *PRD-5092, "Software Quality Assurance," also contains further requirements that apply to the procurement of computer software.*

Procurement documents issued at all tiers of procurement will include provisions for the following, as deemed necessary by the *purchaser* (see def.), and identify the revision level or change status on each document.

**4.1.2.1 Scope of Work**

- 4.1.2.1.1 Procurement documents will include a statement of the scope of work to be performed by the supplier.

**4.1.2.2 Technical Requirements**

- 4.1.2.2.1 Technical requirements (such as manufacturer name and part number) will be specified in the procurement documents. These requirements will be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished.

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4.1.2.2.2 The procurement documents will identify appropriate *test* (see def.), *inspection* (see def.), and *acceptance criteria* (see def.) for determining acceptability of the item or service.

4.1.2.2.3 QA program requirements will be specified in procurement documents. These requirements will be consistent with the importance and/or complexity of the item or service being procured.

4.1.2.2.4 The procurement documents will require the supplier to incorporate the appropriate QA requirements in subtier procurement documents.

4.1.2.3 **Right of Access**

4.1.2.3.1 The procurement documents will provide for access to the supplier's and subtier supplier's facilities and records for *surveillance* (see def.), inspection, or *audit* (see def.) by the purchaser, its designated representative, or others authorized by the purchaser.

4.1.2.4 **Documentation Requirements**

4.1.2.4.1 The procurement documents will identify the documentation required to be submitted for information, review, or *approval* (see def.) by the purchaser. The time of submittal will also be established.

4.1.2.4.2 When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements will be prescribed.

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4.1.2.4.3 All *quality level* (QL) (see def.) -1, QL-2, and QL-3 engineered item procurements will include a procurement specification, drawing, or Design Data Sheet, as applicable, with or attached to the purchase requisition. A specification, drawing, or Design Data Sheet is also required for items that are for QL-2 *mission critical* (see def.) *structures, systems, and components* (SSCs) (see def.). A line item description may be adequate for nonengineered commodities. Manufacturers' part numbers are permissible as specifications for QL-3 Part Number Verification (PNV) and QL-4 items if ordering information is complete.

4.1.2.4.4 All QL-1, QL-2, and QL-3 services procurements will include a Statement of Work (SOW) or clearly describe the requested service on the requisition. Vendor data requirements will be included with the requisition.

4.1.2.5 **Nonconformances**

4.1.2.5.1 For QL-1, -2, and -3, the procurement documents will specify the purchaser's requirements for the supplier's reporting of *nonconformances* (see def.), and the requirement for purchaser's approval of all nonconformance report "use-as-is" and "repair" dispositions.

4.1.2.6 **Spare and Replacement Parts**

4.1.2.6.1 The procurement documents will specify the supplier's requirements to identify spare and replacement parts or assemblies, and the related *data* (see def.) required for ordering these parts and assemblies.

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#### **4.1.3 Procurement Document Review and Approval**

- 4.1.3.1 A review of the procurement documents, and changes thereto, will be made and documented before award to ensure that documents transmitted to prospective supplier(s) include all appropriate technical and QA provisions to ensure that items or services will meet the specified requirements.
- 4.1.3.2 Technical or QA program changes made as a result of bid evaluations or negotiations will be incorporated into the procurement documents before their issuance to the supplier.
- 4.1.3.3 Procurement document review will be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

#### **4.1.4 Procurement Document Changes**

- 4.1.4.1 Changes to the scope of work, technical requirements, QA program requirements, *right of access* (see def.), documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents will be subject to the same degree of control as used in the preparation of the original documents.

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

This subsection contains additional requirements from the *Quality Assurance Requirements and Description* (QARD) (see def.) (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 Procurement Document Preparation**

- 4.2.1.1 Specific documents (such as drawings, codes, standards, regulations, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be specified. The revision level or change status of those documents shall also be identified.

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- 4.2.1.2 Tests, inspections, and *acceptance* (see def.) requirements that the purchaser will use to monitor and evaluate the *performance* (see def.) of the supplier will be specified.
- 4.2.1.3 To the extent necessary, procurement documents shall require suppliers to have a QA program consistent with applicable requirements of the QARD. The extent of the program shall depend upon the type and use of the item or service being procured. A principal contractor shall comply with the QARD. A supplier QA program description document shall comply with the purchaser QA program description document. The extent of the QA program shall depend on the scope, nature, type and use, or complexity of the item or service being procured.
- 4.2.1.4 As an alternative to requiring a documented QA program for the procurement of analytical services to support scientific investigation, procurement of data, or commercial calibration services, the procurement may be controlled in accordance with PRD-5078, “Control of Purchased Items and Services,” Subsection 4.2.6.

#### **4.2.2 Procurement Document Review and Approval**

- 4.2.2.1 When specified by controlling procedures, procurement documents shall be reviewed by individuals or groups other than the one who generated the document, that are trained and qualified in QA practices and concepts, and concur with these documents with respect to the QA-related aspects. The training and qualification of individuals or groups performing reviews shall be in accordance with PRD-5072, “Personnel Training and Qualification.”
- 4.2.2.2 NQA-1 or other QA program requirements invoked for procurements subject to DOE/RW-0333P will be evaluated and verified to meet or exceed the applicable requirements of DOE/RW-0333P.

**NOTE 1:** *For DOE/RW-0333P Revision 10 procurements, PRD-5076, “Instructions, Procedures, and Drawings,” Step 4.2 addresses review requirements.*

**NOTE 2:** *Personnel training and qualification requirements are addressed in PRD-5072, “Personnel Training and Qualification.”*

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**5. RECORDS**

All records 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*

*affected organization*

*approval*

*audit*

*cognizant quality engineer*

*data*

*design bases*

*inspection*

*item*

*mission critical*

*nonconformances*

*performance*

*procedure*

*process*

*procurement document*

*purchaser*

*quality assurance*

*quality assurance record*

*Quality Assurance Requirements and Description*

*quality level*

*right of access*

*service*

*structures, systems and components*

*supplier*

*surveillance*

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*Technical Support Organization**test***7. REFERENCES**

10 CFR 21, “Reporting of Defects and Noncompliance”

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/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-5072, “Personnel Training and Qualification”

PRD-5076, “Instructions, Procedures, and Drawings”

PRD-5078, “Control of Purchased Items and Services”

PRD-5088, “Quality Assurance Records”

PRD-5092, “Software Quality Assurance”

PRD-5095, “Suspect/Counterfeit Items”