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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

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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for identifying, administrating, and storing documents designated as *quality assurance (QA) records* (see def.).

## 2. APPLICABILITY

This PRD applies to company organizations that prepare or process documents designated as QA records.

## 3. RESPONSIBILITIES

### 3.1 Quality Assurance Organization

The QA organization is responsible for developing, maintaining, and interpreting the requirements of this PRD.

### 3.2 Support Services Organization

The support services organizations are responsible for developing and maintaining *procedures* (see def.) that implement these requirements, and for developing and executing the corrective actions associated with any deficiencies.

### 3.3 Company Organizations

Company organizations are responsible for carrying out requirements set forth in this PRD, authentication of records, and for developing implementing procedures that control QA records.

### 3.4 Records Control Personnel

Records control personnel are responsible for identification, receipt control, retention, maintenance, storage, and disposition of QA records in accordance with company procedures.

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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) 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**

**NOTE:** *The term “records,” used throughout this PRD, is to be interpreted as QA records.*

4.1.1.1 Records will furnish documentary evidence that *items* (see def.) or activities meet specified quality requirements.

4.1.1.2 Records will be identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities will be documented.

**4.1.2 Generation of Records**

4.1.2.1 Records will be legible.

4.1.2.2 Records will be traceable to associated items and activities and accurately reflect the work accomplished or information required.

4.1.2.3 Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures.

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### 4.1.3 Authentication of QA Records

- 4.1.3.1 Documents will be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated as complete. This authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (such as magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted.
- 4.1.3.2 Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.
- 4.1.3.2.1 Electronic documents shall be authenticated with comparable information as in Step 4.1.3.1., with identification on the media or with authentication information contained within or linked to the document itself.

### 4.1.4 Classification of QA Records

- 4.1.4.1 Records will be classified as *lifetime* (see def.) or *nonpermanent* (see def.).
- 4.1.4.2 Lifetime records are those that meet one or more of the following criteria:
- A. Those which would be of significant value in demonstrating capability for safe operation
  - B. Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item
  - C. Those which would be of significant value in determining the cause of an accident or malfunction of an item
  - D. Those which provide baseline *data* (see def.) for *in-service inspections* (see def.).

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#### **4.1.5 Receipt Control of Quality Assurance Records**

- 4.1.5.1 Each organization responsible for the receipt of records will designate a person or organization responsible for receiving records.
- 4.1.5.2 The designee will be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage, including a method for *verifying* (see def.) that the records are those designated.
- 4.1.5.3 Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.
- 4.1.5.4 Records will be protected from damage, deterioration, or loss when received.

#### **4.1.6 Permanent Storage of Quality Assurance Records**

- 4.1.6.1 Records will be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:
  - A. Natural disasters, such as winds, floods, or fires
  - B. Environmental conditions, such as high and low temperatures and humidity
  - C. Infestation of insects, mold, or rodents.
  - D. Dust or airborne particles.
- 4.1.6.2 There are two equally satisfactory methods of providing storage, single or dual.
  - 4.1.6.2.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault, room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

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- 4.1.6.2.2 Dual storage facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Facilities used for dual storage are not required to meet the requirements of single storage facilities, but must meet the general storage requirements above.
- 4.1.6.3 The storage arrangement will provide adequate protection of special processed records (e.g., radiographs, photographs, negatives, microform, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored.
- 4.1.6.4 Activities detrimental to the records shall be prohibited in the storage area.
- 4.1.6.5 Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.
- 4.1.6.6 Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.
- 4.1.6.7 Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.
- 4.1.6.8 Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:
- A. Duplication or transfer is appropriately authorized
  - B. Record content, legibility, and retrievability are maintained.
- 4.1.7 Temporary Storage of QA Records**
- 4.1.7.1 Storage of records by the authenticating organization before transfer to a central file location will minimize the risk of loss, damage, or destruction. As a minimum, records will be stored in a facility or container that provides a one-hour fire rating unless dual storage requirements are met.

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#### **4.1.8 Retention and Disposition of Quality Assurance Records**

- 4.1.8.1 Record retention periods will be documented.
- 4.1.8.2 Records shall be maintained for their retention periods.
- 4.1.8.3 Lifetime records are required to be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use.
- 4.1.8.4 The disposition and destruction of records whose retention period has expired will be controlled.

**NOTE:** *Nonpermanent records are those records required to show evidence that an activity was performed in accordance with the applicable requirements, but need not be retained for the life of the item, because they do not meet the criteria for lifetime records.*

- 4.1.8.5 Nonpermanent records shall be maintained for the identified retention period.

#### **4.1.9 Retrieval of Quality Assurance Records**

- 4.1.9.1 Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

#### **4.1.10 Correcting Information in Quality Assurance Records**

- 4.1.10.1 The methods for hardcopy and electronic record changes shall be documented.

#### **4.1.11 Replacement of Quality Assurance Records**

- 4.1.11.1 Lost or damaged records will be replaced or restored. When replacement or restoration cannot be achieved, the owning organization will conduct and document an evaluation of the impact.

#### **4.1.12 Vendor/Subcontractor Quality Assurance Records**

- 4.1.12.1 The requisitioner is required to define in the *procurement documents* (see def.) the records to be controlled and turned over. This includes specifying that the *supplier* (see def.) will inventory and index the records to be provided to CH2M-WG Idaho, LLC (CWI).

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- 4.1.12.2 Records maintained by a supplier, vendor, or subcontractor at their facility or other locations for items and activities contracted by or for CWI will be controlled in a manner that provides adequate protection. These records will be made accessible to individuals designated by CWI.

## **4.2 Specific Requirement 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 (Department of Energy/Office of Civilian Radioactive Waste [DOE/RW] -0333P) that are specific to the spent nuclear fuel and high-level waste activities as defined in FWD-7, "Foreword."

### **4.2.1 Quality Assurance Records**

- 4.2.1.1 Specific QA records types include , but are not limited to:
- 4.2.1.1.1 Scientific, engineering, and operational data and logs; laboratory and field notebooks; and data reduction documents.
  - 4.2.1.1.2 QA program changes that reduce commitments.
  - 4.2.1.1.3 Computer software supporting a safety or waste isolation function.
  - 4.2.1.1.4 Qualification of special process procedure.
  - 4.2.1.1.5 Documents that provide evidence of the quality of items and activities associated with the characterization of spent nuclear fuel (SNF) and conditioning through Office of Civilian Radioactive Waste Management (OCRWM) acceptance of the SNF.
  - 4.2.1.1.6 Documents that provide evidence of the quality of high-level waste (HLW) waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance by OCRWM).
  - 4.2.1.1.7 Records required by 10 CFR 71.91 and 10 CFR 71.135.

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4.2.1.1.8 Records required by 10 CFR 72, Subpart D, and 10 CFR 72.174.

#### **4.2.2 Creating Valid Quality Assurance Records**

- 4.2.2.1 Individuals creating records will ensure that the records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.
- 4.2.2.2 Individuals handling records will protect them from damage or loss until the records are submitted to the records management system (refer to PRD-111, “Records Management”).
- 4.2.2.3 Handwritten signatures shall not be required if the document is clearly identified as a statement of the reporting individual or organization.
- 4.2.2.4 Records may be originals or copies.

#### **4.2.3 Storing and Preserving Quality Assurance Records**

- 4.2.3.1 The storage arrangement shall provide adequate protection of special processed QA records (i.e., radiographs, photographs, negatives, microfilm, and electronic and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored. The guidance provided in NRC Regulatory Issue Summary 2000-18, Guidance on Managing Quality Assurance Records in Electronic Media, shall be complied with in the development of procedures governing the management of electronic media records.

#### **4.2.4 Retention of Quality Assurance Records**

- 4.2.4.1 Lifetime QA records shall be retained and maintained until the license is amended for permanent closure. QA records including those directly related to waste form or other items that will be supplied to OCRWM (such as standard canister). These records shall be transferred to OCRWM for retention and maintenance.

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- 4.2.4.2 QA records shall be classified as lifetime as follows:
- A. Documents that provide evidence of the quality of items on an items/activities list
  - B. Documents that provide evidence of the quality of activities related to items on an items/activities list
  - C. Documents that provide evidence of the quality of site characterization data and samples
  - D. Documents that provide evidence of the quality of those activities that provided data used to assess the potential dispersion of radioactive materials from the licensed facility
  - E. Documents that provide evidence of the quality of the production process for the HLW waste form and acceptance of the HLW waste form product
  - F. Documents that provide evidence of the quality of those activities associated with the characterization of SNF, and conditioning of SNF through acceptance of DOE SNF
  - G. Personnel training and qualification documents for individuals executing QA program requirements.

**4.2.5 Temporary Storage Facility**

- 4.2.5.1 Temporary storage shall provide for the storage of QA records during processing, review, or use until turnover to the OCRWM for disposition according to the following requirements:
- 4.2.5.1.1 QA records shall be temporarily stored in a container or facility with a fire rating of 1 hour, or dual storage shall be provided.
  - 4.2.5.1.2 Single storage containers or facilities shall bear an Underwriters' Laboratories Label (or equivalent) certifying 1 hour fire protection or be certified by a person competent in the technical field of fire protection.

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- 4.2.5.1.3 Procedures shall specify the maximum allowable time for the temporary storage of QA records.

**5. RECORDS**

All records generated by this document that are designated in implementing documents as QA records 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:

*data*

*in-service inspection*

*items*

*lifetime records*

*nonpermanent records*

*procedure*

*procurement document*

*quality assurance record*

*supplier*

*verifying*

**7. REFERENCES**

10 CFR 71.91, “Records”

10 CFR 71.135, “Quality Assurance Records”

10 CFR 72, Subpart D, “Records, Reports, Inspections, and Enforcement”

10 CFR 72.174, “Quality Assurance Records”

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”

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

FWD-7, “Foreword”

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

PRD-111, “Records Management”