

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 1 of 8
-------------------------	---

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

Manual: 13—Quality Assurance Program

Change Number: 339319

*The current revision can be verified on EDMS.

1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities to ensure that specified *documents* (see def.), either in hard copy or electronic media, are reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed.

2. APPLICABILITY

This PRD applies to company organizations involved in development, review, *approval* (see def.), revision, distribution, or use of *controlled documents* (see def.).

3. RESPONSIBILITIES

3.1 Information Management Services Organization

The Information Management Services organization is responsible for establishing and implementing the *Document Control* (see def.) program.

3.2 Document and Records Management Organization

The Document and Records Management organization is responsible for managing controlled documents in accordance with the requirements of this PRD.

3.3 Company Personnel

Personnel who prepare, process, or use controlled documents for *activities affecting quality* (see def.) are responsible for complying with implementing documents of the Document Control program.

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.

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 2 of 8
-------------------------	---

4.1.1 Basic

- 4.1.1.1 The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, *procedures* (see def.), and drawings, will be controlled to ensure that correct documents are being employed.
- 4.1.1.2 Such documents, including changes thereto, will be reviewed for adequacy and approved for release by authorized personnel, including the document owner.
- 4.1.1.3 The organization and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents will be identified.

4.1.2 Distribution and Use of Documents

- 4.1.2.1 The distribution and use of documents, including changes and editorial corrections to documents, include the following controls:
 - A. The documents to be controlled will be identified
 - B. Controlled documents will be reviewed for adequacy, completeness, and approved prior to distribution
 - C. A method will be established to ensure the correct controlled documents, either in hardcopy or electronic media, are distributed to, or made available to, and used at, the work location
 - D. Effective dates will be established for approved implementing documents
 - E. A method will be established to ensure the disposition of obsolete or superseded documents so they are controlled and not used to perform work
 - F. A method will be established to identify the current status of each document that is required to be controlled (e.g., being revised or obsolete).

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 3 of 8
-------------------------	---

4.1.3 Major Document Changes

- 4.1.3.1 Changes to documents, except *minor changes* (see def.), will be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.
- 4.1.3.2 The individual reviewing controlled document changes will have access to pertinent document background data or information upon which to base their changes and approval.

4.1.4 Minor Document Changes

- 4.1.4.1 Minor changes to documents, such as inconsequential editorial corrections, will not require that the revised documents receive the same review and approval as the original documents. However, such corrections will be distributed as a revision or change to the document. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision will be clearly delineated.

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), 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 Controlled Documents

- 4.2.1.1 Controlled documents shall include, but not be limited to, documents that specify technical or quality requirements or prescribe activities that are governed by the QARD (e.g., design documents, procurement documents, procedures, instructions, and drawings; QA program description documents; and safety analysis reports for distribution and use, and changes thereto).

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 4 of 8
-------------------------	---

4.2.2 Reviewing Documents

- 4.2.2.1 Implementing documents and documents that specify technical or QA requirements or prescribe activities that are governed by the QARD, including changes thereto, shall be reviewed prior to approval and issuance for correctness, adequacy, and compliance with established requirements.
- 4.2.2.2 When specified by controlling procedure, the review shall be performed by individuals other than the preparer who are trained and qualified in QA practices and concepts. The training and qualification of individuals will be performed in accordance with PRD-5072, “Personnel Training and Qualification.”
- 4.2.2.3 Comments resulting from the review shall be documented and resolved to the satisfaction of the organization responsible for the document before approving the document.
- 4.2.2.4 Implementing documents and documents that specify technical or quality requirements shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of DOE/RW-0333P:
 - 4.2.2.4.1 Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.
 - 4.2.2.4.2 Pertinent background information or data shall be made available to the reviewers by the organization requesting the review if the information is not readily available to the reviewer.
 - 4.2.2.4.3 The review shall be performed by individuals other than the preparer.
 - 4.2.2.4.4 Reviewers shall be technically competent for the subject area of the document being reviewed.
 - 4.2.2.4.5 The scope of the review shall consider all aspects of the document.

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 5 of 8
-------------------------	---

4.2.2.4.6 Each organization or technical discipline affected by the document shall review the document according to the established review criteria. Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.

4.2.2.4.7 The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes. The QA organization also shall review changes to other documents if they were required to review the previous version, unless the QA organization has concurred that its review is no longer required.

4.2.2.4.8 Mandatory comments resulting from the review shall be documented and resolved before approving the document.

4.2.3 Distribution and Use of Documents

4.2.3.1 The latest version (revision or change) of a document, either in paper copy or electronic media, shall be available for use prior to start of work at the location where the activity is performed. Documents shall be adhered to in the performance of work.

4.2.4 Changes to Documents

4.2.4.1 Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history will be reviewed each time additional changes to the document are proposed.

4.2.4.2 Changes to documents, other than editorial corrections, shall be reviewed by the same organizations that performed the original review and approval (if these organizations are affected by the change). The reviewing organizations shall have access to pertinent background data or information upon which to base their approval.

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 6 of 8
-------------------------	---

- 4.2.4.3 Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire revised controlled document as a revision, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled documents as a revision.
- 4.2.4.4 Changes to documents shall be reviewed in accordance with the requirements of Step 4.2.2.4 and the requirements listed below:
- 4.2.4.4.1 Changes shall be approved for release by the designated organizational position that is responsible for the document.
 - 4.2.4.4.2 Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.
 - 4.2.4.4.3 Implementing documents shall require that a history of changes to the QA program documents, including the reasons for the changes, be documents and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

4.2.5 Expedited Document Changes

- 4.2.5.1 If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management.
- 4.2.5.1.1 After the *expedited change* (see def.) has been authorized, the changes will be processed through the normal change process. This processing will occur in a timely manner consistent with the type and nature of the document being changed.

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 7 of 8
-------------------------	---

4.2.5.1.2 Implementing documents will describe the process to control expedited changes according to the following requirements:

4.2.5.1.2.1 The level of management with the authority to make expedited changes will be identified.

4.2.5.1.2.2 The time limits for processing expedited changes through the normal change process will be specified.

4.2.5.1.2.3 An evaluation of the work will be performed if the normal review process results in a change that is different from the expedited change.

4.2.6 Editorial Corrections

4.2.6.1 Editorial corrections that do not have a material impact on the document requirements may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document. The following are considered editorial changes:

- A. Correcting grammar or spelling
- B. Renumbering sections or attachments that do not affect the chronological sequence of work
- C. Changing the title or number of the document or the title or number of documents referenced in the procedure
- D. Updating organizational titles.

NOTE: *A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.*

4.2.6.2 The organizational position responsible for approving the document for release shall approve editorial corrections.

DOCUMENT CONTROL	Identifier: PRD-5077 Revision*: 17 Page: 8 of 8
-------------------------	---

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:

activities affecting quality

approval

controlled document

document

document control

expedited change

minor changes

procedure

quality assurance record

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 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-5088, “Quality Assurance Records”