



***Environmental Management***  
**Office of Standards and Quality Assurance**

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**Quality Procedure**

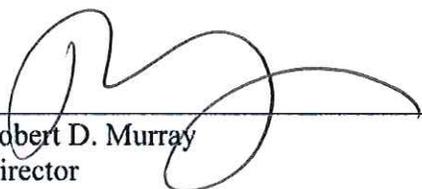
**Subject Area: *Document Control***

**QP-4.1, Revision 0**

Effective Date: 8/31/2015

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8/31/2015  
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1. PURPOSE

This procedure establishes the responsibilities and process for preparing, managing, and revising EM Headquarters Office of Standards and Quality Assurance controlled documents in accordance with EM-QA-001, *Environmental Management Quality Assurance Program*.

2. SCOPE

The scope of this procedure is to guide the development of controlled documents, such as quality assurance (QA) programs, quality procedures (QPs), Quality Implementing (QI) documents, and other controlled documents generated by the EM Headquarters Office of Standards and Quality Assurance.

3. APPLICABILITY

This procedure applies to EM Headquarters Office of Standards and Quality Assurance personnel and contractors participating in document control activities related to the EM Corporate QA Program activities as conducted by the Office of Standards and Quality Assurance.

4. REQUIREMENTS & REFERENCES

The most current version of the following requirements and references are applicable to this procedure.

Requirements

- 4.1 ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*
- 4.2 DOE Order O 414.1D, *Quality Assurance* (including Administrative Change 1)
- 4.3 EM-QA-001, *EM Quality Assurance Program*

References

- 4.4 QP-4.2, *Document Review*
- 4.5 QP-4.3, *Records Management*

5. DEFINITIONS

- 5.1. Controlled Document – Documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, drawings, management plans, technical reports (audit/assessment plans and reports), and performance reports. Documents are controlled to ensure that the correct documents are being used, are controlled during the review and approval

phase and issued by designated individuals or organizations in accordance with approved procedures. Controls are established and maintained to identify the current status or revision of controlled documents and forms. Controls are provided for identification of documents to be controlled and their distribution. Effective dates are established and identified on the approved and controlled documents.

5.2. Major Changes – Major changes to controlled documents are changes that are prompted by changes to input requirements or standards (e.g., DOE Orders); or result in changes to work processes, scope, or responsibilities.

5.3. Minor Changes – Minor changes to controlled documents are changes that do not result in changes to work processes, scope, or responsibilities. Minor changes include inconsequential editorial changes, format changes, and correction of typographical or grammatical errors.

## 6. RESPONSIBILITIES

### 6.1. Deputy Assistant Secretary (DAS) for Safety, Security and Quality Programs

6.1.1 Directs the Office of Standards and Quality Assurance to implement this procedure in accordance with the Oversight Policy.

### 6.2. Director, Office of Standards and Quality Assurance

6.2.1. Responsible for assigning Document Owners to all controlled documents as defined in this procedure.

6.2.2. Responsible for the preparation, revision, and approval of this procedure.

6.2.3. Responsible for providing the necessary resources needed to develop and manage controlled documents in accordance with this procedure.

6.2.4. Ensures that controlled documents governed by this procedure are implemented at EM Headquarters Office of Standards and Quality Assurance.

6.2.5. Approves controlled documents as specified in this procedure.

### 6.3. Document Owner

6.3.1. Prepares a controlled document in accordance with this procedure as assigned by the Director, Office of Standards and Quality Assurance.

6.3.2. Revises the controlled document as needed if major changes are needed as precipitated by changes to applicable DOE Orders or QA standards or if the activity processes, scope, or responsibilities are changed. (*Note: a minor change may be made to a controlled document for clarity.*)

- 6.3.3. Maintains all changes to documents between controlled document revisions to ensure that changes are incorporated into the next revision of the controlled document.
- 6.3.4. Reviews the controlled document as directed by the Office Director or on an annual basis to determine if revision is required.
- 6.3.5. Ensures that the original controlled document and its revisions are reviewed by qualified and knowledgeable personnel to ensure that the controlled document is consistent with actual work practices and complies with applicable DOE Orders and QA standards.

#### 6.4 EM Office of Standards and Quality Assurance and Contractor Staff

- 6.4.1 Responsible for reading and understanding controlled documents applicable to their work activities. Also responsible for ensuring that they use the current version of controlled documents available on the Office of Standards and Quality Assurance website in the EM Portal.
- 6.4.2 Brings any errors or inconsistencies in the procedure to the attention of the Document Owner.

#### 6.5 EM Office of Standards and Quality Assurance Records Coordinator

- 6.5.1 Responsible for ensuring current versions of controlled documents are available to EM Office of Standards and Quality Assurance Federal and contractor staff on the Office of Standards and Quality Assurance website in the EM Portal.
- 6.5.2 Responsible for ensuring new and revised procedures are provided to EM HQ Records Management as quality records.

### 7. GENERAL INFORMATION

Document Control is achieved by following the procedural instructions contained within this procedure.

### 8. CONTROLLED DOCUMENT PROCESS

#### 8.1. Identification of Controlled Documents

- 8.1.1 The following categories of controlled documents are prepared by the Office of Standards and Quality Assurance:

- 8.1.1.1 Quality Assurance Program (QAP, EM-QA-001) – The *EM Quality Assurance Program* (EM-QA-001) is the QAP applicable to all EM activities.

- 8.1.1.2 Quality Implementation Plan (QIP) – The QIP is the document that specifies how the *EM Quality Assurance Program* is implemented within the EM Headquarters Office of Standards and Quality Assurance. The QIP specifies the programmatic

and implementing documents, including Quality Procedures (QPs) that are used to implement the *EM Quality Assurance Program*.

8.1.1.3 Quality Procedures (QPs) – QPs specify the scope, responsibilities, and processes used to complete quality-affecting activities performed by the Office of Standards and Quality Assurance staff and contractors.

8.1.1.4 Quality Implementing Documents (QIs) – QI documents specify work instructions for completing specific quality affecting tasks that are associated with a quality affecting activity performed by EM Headquarters Office of Standards and Quality Assurance staff and contractors. QI documents are not required for all tasks but may be developed for certain tasks that have a high degree of importance, a high degree of complexity, or are performed routinely. An example of a QI document is the Standard Review Plan Review Module which describes the process for reviewing QA programs submitted to EM Headquarters.

## 8.2 Content of Controlled Documents

8.2.1 The content of controlled documents noted above is provided in Attachment A of this procedure.

## 8.3 Format of Controlled Documents

8.3.1 Formatting requirements for controlled documents are provided in Attachment B of this procedure.

## 8.4 Numbering Controlled Documents

8.4.1 All controlled documents have a unique document number that is assigned using the formats found in Attachment C.

## 8.5 Revision Control for Controlled Documents

8.5.1 Original version: The first or original version of a controlled document is issued as Revision 0 of the document.

8.5.2 Major Revisions: Major revisions to controlled documents are made when any of the following occurs:

- Changes when the DOE QA Order, other DOE Orders, and applicable regulatory standards on which controlled documents are based are changed.
- Changes required correcting findings or observations identified as a result of management or independent assessments of the EM Headquarters Office of Standards and Quality Assurance QA Program.
- Changes correcting corrective actions identified in the Issues Management System.
- Changes made based on the annual review of controlled documents to include the accumulation of minor changes noted, and self-identified procedural inconsistencies to the actual scope, responsibilities, and processes of the activities performed.

Major revisions are documented on the updated revisions of controlled documents as follows:

Revision 0 → Revision 1.0

Revision 1.0 → Revision 2.0

- 8.5.3 Minor Revisions: Minor changes typically consist of inconsequential editorial corrections, misspelled words, minor format changes and other changes that do not impact the scope, responsibilities, and processes of the activities associated with the controlled document.

The Document Owner maintains all minor changes identified since the effective date of the most current revision of a controlled document. The Document Owner maintains the changes using an approach that captures minor changes. Approaches may include keeping a track change electronic version of the document, maintaining a marked-up hard copy of the current version of the document, or maintaining a log of changes.

## 8.6 Controlled Document Review

- 8.6.1 Reviews of controlled documents are performed in accordance with QP-4.2, *Document Review*.

## 8.7 Controlled Document Issuance

- 8.7.1 The Document Preparer (staff member or contractor staff) provides the following to the Document Owner:

- Approved hard-copy of the document in its entirety;
- Electronic version of the approved document in Microsoft Word;
- Any applicable support documentation.

- 8.7.2 The Document Owner reviews the approved document package for legibility, correctness, and completeness. For example:

- Approval signatures (document changes, other than those defined as editorial changes, shall be reviewed and approved by the same organization that performed the original review and approval).
- Editorial changes (approval is only required by the organization responsible for preparing the document).
- Document completeness (document type, number and revision, and place to fill in effective date, correct pagination, change bars, and electronic copy).

- 8.7.3 The Document Owner resolves any issues of legibility and completeness with the Document Preparer before posting the document on-line. After determining that the package is complete, the Document Owner updates the controlled documents folder and posts the documents on-line per Steps 8.7.4 and 8.7.5.

- 8.7.4 The Document Owner places the approved controlled document (electronic version) on-line with “read-only” access on the Office of Standards and Quality Assurance website in the EM Portal.

- 8.7.5 The Document Owner posts the following disclaimer:

– NOTE –

Documents posted on line are the most current version of the approved controlled document. Users of on-line documents are responsible to verify that printed documents are current and reflect the most recent version of the on-line document. Printed documents are not considered to

be controlled documents but are considered to be an “Information Only” copy.

#### 8.8 Use of Controlled Documents

- 8.8.1 EM Headquarters Office of Standards and Quality Assurance staff and contractor staff are responsible for ensuring that the most current revision of controlled documents is used.

### 9. RECORDS

Records listed below are collected per QP-4.3, *Records Management*, as individual records or included in a records package, as specified. Final disposition of QA records resulting from audits is based on the EM Records Disposition process.

Lifetime QA Record: None

Nonpermanent Records:

- Quality Assurance Program (EM-QA-001)
- Quality Implementation Plan (QIP)
- Quality Procedures (QPs)
- Quality Implementing Documents (QIs)

Non-QA Records: None

### 10. FORMS

There are no forms associated with this procedure

### 11. ATTACHMENTS

The following Attachments are associated with this procedure:

Attachment A - Controlled Document Content Requirements

Attachment B - Controlled Document Formatting

Attachment C – Controlled Document Numbering

**RECORD OF REVISION**

DOCUMENT: QP-4.1, Revision 0; Subject Area: *Document Control*

| <b>Revision Number</b> | <b>Description of Changes</b> | <b>Revision on Pages</b> | <b>Effective Date</b> |
|------------------------|-------------------------------|--------------------------|-----------------------|
| 0                      | Original                      | All                      | 8/31/2015             |
|                        |                               |                          |                       |
|                        |                               |                          |                       |

## Attachment A- Controlled Document Content Requirements

### Quality Assurance Program (QAP)

The *EM Quality Assurance Program* describes the EM Management System that is used to implement 10 CFR 830, Subpart A, Quality Assurance and the current version of the DOE QA Order O 414.1D, *Quality Assurance*. The *EM Quality Assurance Program* implements the DOE QA Order 414.1D by invoking the specific QA requirements of NQA-1 2008/2009a. The *EM Quality Assurance Program* contains the following sections at a minimum:

- Purpose and Objective
- Scope
- Applicability
- Requirements and References
- Definitions and Acronyms
- Responsibilities
- EM QA Program Criteria
- Attachments

### Quality Assurance Program Criteria

The Quality Assurance Program Criteria are defined in the current DOE QA Order as follows:

- Criterion 1 – Management/Program
- Criterion 2 – Management/Personnel Training and Qualification
- Criterion 3 – Management/Quality Improvement
- Criterion 4 – Management/Documents and Records
- Criterion 5 – Performance/Work Processes
- Criterion 6 – Performance/Design
- Criterion 7 – Performance/Procurement
- Criterion 8 – Performance/Inspection and Acceptance Testing
- Criterion 9 – Assessment/Independent Assessments
- Criterion 10 – Assessment/Management Assessments

### Attachments to Quality Assurance Program

Attachments to the EM Quality Assurance Program are provided for DOE activities that may not be fully defined in either DOE Orders or national consensus standards upon which the activity is based. The following are activities or programs for which attachments have been developed for the EM Quality Assurance Program:

- Certified Type B and Fissile Packaging Quality Assurance Program
- QA Program Variance/Exemption Request Form
- Quality Assurance Implementation Plans
- Graded Approach
- Integrated Safety Management System
- Suspect/Counterfeit Items Prevention
- Software Quality Requirements
- Model Development, Use, and Validation
- Revision History

### **Quality Implementation Plan (QIP)**

The Quality Implementation Plan is developed by the Office of Standards and Quality Assurance and is applicable to the EM Headquarters Offices. It is provided as a matrix which contains the following:

- DOE Order criteria
- Applicable Quality Standard Sections for each criterion
- Specific processes and activities covered by each criterion
- Applicability of criterion to organization (Not all criteria will be applicable to a particular organization)
- Procedures and Implementing Documents associated with each criteria

### **Quality Procedures (QPs)**

Quality Procedures are developed to document how quality activities are performed and documented by EM Headquarters Office of Standards and Quality Assurance staff and its contractors. The Quality Procedures include the following sections:

- Purpose
- Scope
- Applicability
- Requirements and References
- Definitions
- Responsibilities
- Procedural steps
- Records and Forms
- Attachments

Depending upon the scope and purpose of the procedure, some sections noted above may not be applicable. If a section in a procedure is not applicable, retain the appropriate section in the procedure and provide rationale in the section on why it is not applicable.

Procedural steps may be presented as a single section or in multiple sections depending upon the complexity of the process.

### **Quality Implementing Documents**

Generally, Quality Implementing Documents are adequate to perform most quality affecting activities. For some specialized, frequent, or complex activities, Quality Implementing Documents are used to provide specific work instructions that are not addressed in the associated Quality Procedures. All Quality Implementing Documents will include the following sections:

- Overview
- Purpose
- Instructions
- Records and Forms
- Attachments

Depending upon the work activity, some sections may not be applicable. If any section in a QI document is not applicable, retain the appropriate section in the document and provide rationale for why the section is not applicable.

Instructions may be presented as a single section or in multiple sections depending upon the complexity of the work activity.

An example of a QI document is the Standard Review Plan Review Module which describes the process for reviewing QA programs submitted to EM Headquarters.

## **Attachment B- Controlled Document Formatting**

### **Cover Sheets**

Cover Sheets for controlled documents must contain the following information at a minimum:

- Document Title
- Document Numbering
- Revision Number
- Implementing Organization(s)
- Effective Date (Day/Month/Year)

### **Signature Page**

Signature Pages may either be included as part of the Cover Sheet or as a separate page. The following individuals must sign and date controlled documents:

- Document Owner/Preparer
- Approver(s)

The Approver should be the highest ranking individual responsible for implementing the controlled document. The Director, Office of Standards and Quality Assurance, is the Approver for the Quality Procedures developed by and for EM Headquarters Office of Standards and Quality Assurance.

### **Revision History**

A Revision History is included for all controlled documents and include the following at the minimum:

- Document Title and Document Number
- Current and Previous Revision Numbers
- Effective Date of Revision
- Summary of Change
- Pages Revised

The Revision Log is kept in a table format starting with the current revision and working back to Revision 0. The Revision Log for Revision 0 of a controlled document will indicate that the document is original and that all pages were revised. The summary of changes does not need to be exhaustive but should identify the primary changes that were made.

Changes are typically due to one of the following reasons:

- Change in DOE Order or QA standards
- Changes in process, scope, or responsibilities

### **Page Headers**

Page Headers are included for all controlled documents and include the following at the minimum:

- Document Title
- Document Number
- Revision Number

## Attachment C- Controlled Document Numbering

### EM Quality Assurance Program

The EM Quality Assurance Program is numbered as follows: *EM-QAP-001*

### Quality Implementation Plan

The QIP for EM Headquarters Office of Standards and Quality Assurance is incorporated into the overall QIP for EM Headquarters. The QIP for EM Headquarters is numbered as follows:  
*EM-HQ-QIP-001*

### Quality Procedures

Quality Procedures developed by EM Headquarters Office of Standards and Quality Assurance for internal use are named using the following nomenclature:

*QP-x.y*

Where:

- QP is the designation for a quality procedure used by EM Headquarters.
- The small *x* designates the EM-QAP Criterion number associated with the procedure.
- The small *y* designates the sequential procedure number within a Criterion number.

For example, the Audits procedure is the first sequential quality procedure within Criterion 10 of the EM Quality Assurance Plan. Therefore the number is:

*QP-10.1*

### Quality Implementing Documents

QI Documents developed by EM Headquarters Office of Standards and Quality Assurance for internal use are named using the following nomenclature:

*QI-x.y.z*

Where:

- *QP* is the designation for a quality implementing document used by EM Headquarters.
- The small *x.y* designates the QP number that associated with the QI document.
- The small *z* designates the sequential QI document number associated with a particular QP.

For example, the second QI document associated with QP-10.1 will have the following document number:

*QI-10.1.2*