



Environmental Management
Office of Standards and Quality Assurance

Quality Procedure

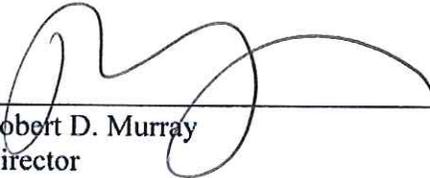
Subject Area: *Document Review*

QP-4.2, Revision 0

Effective Date: 8/31/2015

Preparer: 
Robert A. Toro
Office of Standards and Quality Assurance

8/25/2015
Date

Approved: 
Robert D. Murray
Director
Office of Standards and Quality Assurance

8/31/2015
Date

1. PURPOSE

This procedure establishes the process for the review and approval of Environmental Management (EM) Quality Assurance (QA) program documents as performed by the Office of Standards and Quality Assurance. This procedure also establishes the process for review and approval of other EM documents external to the EM Headquarters Office of Standards and Quality Assurance.

2. SCOPE

The scope of this procedure is to provide a systematic approach for the review and approval of Quality Assurance Plans (QAPs), Quality Implementation Plans (QIPs), Quality Procedures (QPs), Quality Implementing (QI) Documents, reports, and other documents subject to review by EM Headquarters (HQ) Office of Standards and Quality Assurance, which may include documents generated by EM Headquarters and Field Offices as well as its facilities, programs, and projects.

3. APPLICABILITY

This procedure applies to EM HQ Office of Standards and Quality Assurance personnel and contractors participating in document review activities of programs related to EM-QA-001, *Environmental Management Quality Assurance Program*.

4. REQUIREMENTS & REFERENCES

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

Requirements

- 4.1 DOE Order O 226.1B, *Implementation of Oversight Policy*
- 4.2 DOE Order O 414.1D, *Quality Assurance* (including Administrative Change 1)
- 4.3 ASME NQA-1-2008/2009a, *Quality Assurance Requirements for Nuclear Facility Applications*
- 4.4 EM-QA-001, Revision 1, *Environmental Management Quality Assurance Program*
- 4.5 DOE-EM-SRP-2010, 2nd Edition, *Standard Review Plan (SRP) - Protocol for EM-HQ Review/Field Self-Assessment of Site Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*; March 2010

References

- 4.6 DOE Environmental Management Correspondence Guidance Handbook
- 4.7 QP-4.1, *Document Control*
- 4.8 QP-4.3, *Records Management*

5. DEFINITIONS

- 5.1. Approval – The act of approving a document to release for use.

- 5.2. Concurrence – The act of indicating, in writing, that a document is suitable for use and review comments have been satisfactorily resolved.
- 5.3. Document Review - Any review that meets the requirements stated in this procedure, or clearly demonstrates a comprehensive review process involving experienced and knowledgeable individuals of the subject matter. Document reviews are identified as either internal or external reviews.
- 5.4. Document Review and Comment Resolution Form – A record documenting review comments and their resolution that is retained as a record.
- 5.5. External Reviews - Reviews of documents (reports, etc.) requested by organizations outside of the Office of Standards and Quality Assurance. The review is performed by the Office of Standards and Quality Assurance. Approval authority lies with the Deputy Assistant Secretary, Safety, Security and Quality Programs. Example of this type of review is the review of QA Programs (QAPs) and QA Implementation Plans (QIPs) received from the DOE EM Field Offices, facilities, programs, and projects.
- 5.6. Internal Reviews - Reviews of documents generated by the Office of Standards and Quality Assurance that require approval by the Director, Office of Standards and Quality Assurance. Example of this type of review is the review of implementing documents, such as the Quality Procedures (QPs) and Quality Implementing Documents (QIs).

6. RESPONSIBILITIES

- 6.1. Deputy Assistant Secretary (DAS) for Safety, Security, and Quality Programs
 - 6.1.1. Direct the Offices within the Safety, Security, and Quality Programs to implement this procedure in accordance with the Oversight Policy.
 - 6.1.2. Approve QAPs/QIPs upon review by the Office of Standards and Quality Assurance.
- 6.2. Director, Office of Standards and Quality Assurance
 - 6.2.1. Maintain overall responsibility for implementation of the process described in this procedure.
 - 6.2.2. Responsible for the preparation, revision, and approval of this procedure.
 - 6.2.3. Responsible for the approval of the document under internal review.
- 6.3. Document Owner, Office of Standards and Quality Assurance
 - 6.3.1. Responsible for coordinating the document review.
 - 6.3.2. Responsible for selecting appropriate reviewers.
 - 6.3.3. Responsible for developing criteria based upon the applicable standards and requirements to which the review is being conducted.

- 6.3.4. Responsible for resolving comments associated with the document review.
- 6.3.5. Responsible for documenting the results of the review in accordance with this procedure.

6.4. Document Reviewer

- 6.4.1. External review of QAPs/QIPs submitted by EM Field Offices, facilities, programs, and projects: As delegated by the Deputy Assistant Secretary for Safety, Security, and Quality Programs, the Office of Standards and Quality Assurance assigns a document reviewer. Conducts the review by:
 - using the specific lines of inquiry or checklist defined for Phase 1 or Phase 2 review of QAPs/QIPs; and
 - providing timely comments to the Office Director for concurrence who will forward the Office recommendation (including comments) for QAP/QIP approval, conditional approval, or rejection to the Deputy Assistant Secretary for approval and issuance to the EM Field Office. This process is defined in DOE-EM-SRP-2010.
- 6.4.2. Internal review of Office documents: Conducts the review by:
 - preparing for the review by reading applicable plans, procedures, or review specific LOIs or checklists as specified by the Document Owner.
 - providing timely comments to the Document Owner; and
 - conducting the review in accordance with this procedure.

7. GENERAL INFORMATION

DOE-EM-SRP-2010, 2nd Edition, *Standard Review Plan (SRP) - Protocol for EM-HQ Review/Field Self-Assessment of Site Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)* establishes the requirement for EM Headquarters technical review and approval of site-specific QAPs/QIPs. The EM-HQ review and approval of site-specific QAP/QIP consists of two distinct phases. Phase 1 is focused on Approval for Implementation of QAP/QIP. Phase 2 is focused on the annual submittal of EM Field Office QAP/QIP including an onsite Verification and Validation (V&V) of QAP/QIP implementation.

This procedure also establishes requirements for conducting internal Office document reviews by the EM-HQ Office of Standards and Quality Assurance and documenting the resolution of comments using Form 4.2-1, Document Review and Comment Resolution Form. Comments resulting from the review are resolved to the satisfaction of the Document Owner.

8. DOCUMENT REVIEW, COMMENT RESOLUTION, and APPROVAL PROCESS

8.1. Selecting Document Reviewers

- 8.1.1. For QAP/QIP reviews performed by the Office of Standards and Quality Assurance and review of Office documents, the Office Director selects the Document Reviewer(s) knowledgeable in the area being reviewed.
- 8.1.2. For QAP/QIP Phase 1 or Phase 2 reviews, the Document Reviewers are identified using the SRP lines of inquiry.
- 8.1.3. For internal Office document reviews, the Document Reviewers are identified on the Form 4.2-1, Document Review and Comment Resolution Form (Attachment A).

8.2. Document Review

- 8.2.1. An electronic or hard copy of the document is provided for review and Form 4.2-1, Document Review and Comment Resolution Form with items 1-9 is completed once Document Reviewer(s) are selected.
- 8.2.2. For QAP/QIP reviews and internal Office document reviews, the Office Director provides additional background information as requested by the Document Reviewer.
- 8.2.3. For QAP/QIP reviews, the Document Reviewer reviews the document as defined in the review process of the SRP. The Document Reviewer provides timely comments to the Office Director for concurrence who forwards the Office recommendation (with comments) for QAP approval, conditional approval, or needs significant revision to the Deputy Assistant Secretary (DAS) for Safety, Security, and Quality Programs. The DAS issues a memorandum to the EM Field Office, facility, program, or project on the HQ Office review of and recommendation on the QAP/QIP.
- 8.2.4. For QAP/QIP reviews, the Document Reviewer documents the review of the QAP/QIP using the process described in the SRP for Phase 1 and 2 reviews.
- 8.2.5. For internal Office document reviews, the Document Reviewer reviews the document for adequacy, compliance, correctness, and completeness ensuring that the document represents the governing requirements accurately, the current organization responsibilities are up to date, the technical content is free of error, and the instructions are presented clearly to reduce or eliminate misunderstanding.
- 8.2.6. For internal review of Office documents, the Document Reviewer documents their comments on Form 4.2-1, Document Review and Comment Resolution Form items 17-19. The Document Reviewer also completes items 10-12 and submits Form 4.2-1 to the Document Owner.

8.3. Comment Resolution

- 8.3.1. For QAP/QIP reviews, The Deputy Assistant Secretary for Safety, Security, and Quality Programs forwards the formal response with the revised QAP/QIP received from the EM Field Office, facility/ program, or project to the Office of Standards and Quality Assurance to determine whether the comments are addressed and resolved. Once comments are resolved, Step 8.2.3 is repeated.
- 8.3.2. For internal Office document reviews, the Document Owner documents resolution of comments using Form 4.2-1, Document Review and Comment Resolution Form item 20. The Document Owner completes items 13-14 and provides the Document Reviewer with Form 4.2-1 containing the responses to the comments and a concurrence draft document that incorporates those responses to comments.
- 8.3.3. The Document Reviewer reviews the responses that address the comments and ensures that the responses are adequately incorporated into the concurrence draft document.
- 8.3.4. If acceptable, the Document Reviewer completes and signs Form 4.2-1, Document Review and Comment Resolution Form items 15-16 and returns it and the concurrence

draft document to the Document Owner.

- 8.3.5. The Document Owner prepares the issue copy of the document and provides to the Director for review and approval.

8.4. Approval

- 8.4.1. For QAP/QIP reviews, the Deputy Assistant Secretary for Safety, Security, and Quality Programs issues a memorandum to the EM Field Office, facility, program, or project noting approval of the QAP/QIP, and coordinates with the Field Office in scheduling an implementation audit/assessment of the Field Office QA program.
- 8.4.2. For QAP/QIP reviews, the Office Director or designate transmits the record package consisting of the DAS memorandum and its attachments to be processed in accordance with QP-4.3, *Records Management*.
- 8.4.3. For internal Office document reviews, the Office Director reviews the issue copy and approves the document and notifies the Document Owner of the approval. Any comments or concerns the Director may have are provided to the Document Owner for resolution in accordance with this procedure.
- 8.4.4. Upon approval of the internal Office document, the Document Owner transmits the record package consisting of the completed Form 4.2-1 and the review document to be processed in accordance with QP-4.3, *Records Management*.

9. RECORDS

Records generated during performance of this procedure are collected as quality records. Final disposition is based on the EM HQ Records Management process.

9.1 Lifetime Record: None

9.2 Nonpermanent Record:

- For QAP/QIP reviews: DAS Memoranda and completed Phase 1 and 2 lines of inquiry).
- For internal Office document reviews: Completed Form 4.2-1, Document Review and Comment Resolution Form and the document being reviewed

10. FORMS

Form 4.2-1, Document Review and Comment Resolution Form

11. ATTACHMENTS

There are no attachments generated for this procedure.

RECORD OF REVISION

DOCUMENT: QP-4.2, Revision 0; Subject Area: *Document Review*

| Revision Number | Description of Changes | Revision on Pages | Effective Date |
|------------------------|-------------------------------|--------------------------|-----------------------|
| 0 | Original | All | 8/31/2015 |
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| Form 4.2-1 - Document Review and Comment Resolution Form | | | |
|--|--------------|----------------------|----------------|
| 1) Document Number: | | 3) Revision Number: | |
| 2) Document Title | | 4) Draft Designator | |
| Review Criteria | | | |
| 5) Document Review Instructions: | | | |
| 6) Document Owner: | | | |
| 7) Total Number of Document Reviewers: | | | |
| 8) Document Reviewer: | | 9) Review Criteria: | |
| | | | |
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| | | | |
| | | | |
| Conduct of Review | | | |
| 10) Document Reviewer (print name): | | 11) Organization | 12) Date: |
| Comment Resolution and Review Concurrence | | | |
| 13) Revision Number: | | 14) Draft Designator | |
| 15) Reviewer Concurrence: | | 16) Date: | |
| 17) Comment No | 18) Location | 19) Comment | 20) Resolution |
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**Form 4.2-1, Document Review and Comment Resolution Form
INSTRUCTIONS**

- 1) The Document Owner identifies the unique number of the document being reviewed, if applicable.
- 2) The Document Owner indicates the title of the document being reviewed.
- 3) The Document Owner identifies the revision of the document being reviewed.
- 4) The Document Owner identifies the alpha-designator of the draft being reviewed (e.g., DRAFT A).
- 5) The Document Owner attaches the review criteria and identifies any specific review instructions, if applicable.
- 6) The Document Owner prints their name indicating the lead reviewer.
- 7) The Document Owner indicates the total number of the document reviewers (e.g., 1 or 2 or 3, etc.)
- 8) The Document Owner identifies the Document Reviewer(s).
- 9) The Document Owner identifies the assigned area of review.
- 10) The Document Review prints their name.
- 11) The Document Reviewer identifies their organization
- 12) The Document Reviewer fills in the date that they completed their review.
- 13) The Document Owner indicates the Document Revision Number.
- 14) The Document Owner specifies the alpha-designator of the draft that represents the concurrence draft.
- 15) The Document Reviewer Signs their signature indicating their comments have been resolved and their concurrence.
- 16) The Document Reviewer enters the date they signed their comment resolution and review concurrence.
- 17) The Document Owner assigns a Comment Number.
- 18) The Document Owner identifies the specific location of the comment in the document (e.g., section, paragraph, page number, etc.)
- 19) The Document Owner documents the comment.
- 20) The Document Owner documents the resolution to the comment