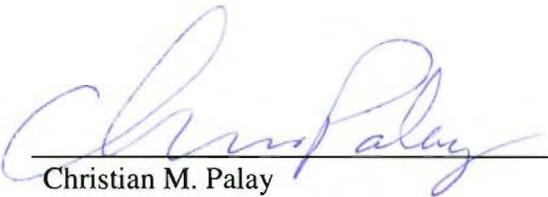


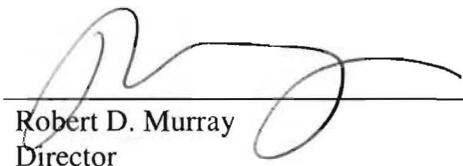


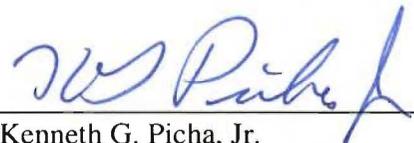
Office of Environmental Management (EM)

Subject: Document Review

Administrative Procedure

Preparer:  4/26/2011
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Office of Standards and Quality Assurance

Approval:  4-27-2011
Robert D. Murray Date
Director
Office of Standards and Quality Assurance

Concurrence:  4-27-2011
Kenneth G. Picha, Jr. Date
Acting Deputy Assistant Secretary
Safety and Security Program

1.0 PURPOSE

- 1.1 This procedure describes the EM process and responsibilities for reviewing documents that relate to the oversight of High-Level Waste (HLW) or Used Nuclear Fuel (UNF) programs. These HLW and UNF programs are based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P).

2.0 SCOPE

- 2.1 This procedure applies to EM personnel and contractors that participate in the review of documents related to high-level waste (HLW) and used nuclear fuel (UNF) programs.

3.0 APPLICABILITY

- 3.1 This procedure applies to EM personnel and contractors that are directly or indirectly involved in document review of Program Descriptions, Plans, Implementing Procedures, and Forms to conduct oversight of the EM HLW and UNF Independent Oversight Program.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

- 4.1.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20
- 4.1.2 EM-QA-002, Quality Assurance Program Plan (QAPP)

4.2 References

- 4.2.1 AP-2.2Q, Surveillances
- 4.2.2 AP-5.1Q, Preparing Implementing Documents
- 4.2.3 AP-16.1Q, Corrective Action
- 4.2.4 AP-17.1Q, Quality Assurance Records
- 4.2.5 AP-18.1Q, Audits

5.0 DEFINITIONS

- 5.1 Author and/or Subject Matter Expert (SME) – an individual who writes or originates the Controlled Document.
- 5.2 Controlled Document – A document that is prepared, reviewed, and formally approved by the Director, Office for Standards and Quality Assurance or designee. In particular, these documents are identified as Policy Statements, Program Descriptions, Plans, Implementing Procedures, Forms, and Departmental Technical Instructions. An approved Controlled Document describes how an activity is to be performed and the responsibility of those personnel required performing the activity. The document may include methods, equipment, materials to be used, and the sequence of operations to complete the activity.
- 5.3 EMCBC Controlled Document Coordinator (CDC) – is located within the Office of Logistics Management and is responsible for managing this Controlled Document Program.
- 5.4 Form – A printed or PDF'd document with spaces in which to write or fill-in information. All forms will have the series identifier, controlled document number, form number in sequential order, and revision number applied to the form.
- 5.5 Implementing Procedures – A procedure is a specified series of actions or operations which have to be executed in the same manner in order to always obtain the same result under the same circumstances.
- 5.6 Plan – A plan is used to achieve an objective, but does not have a series of actions which have to be executed in the same manner in order to receive the same result. It is a set of intended actions, through which one expects to achieve a goal.
- 5.7 Policy Statement – A written statement that communicates management's intent, objectives, requirements, responsibilities, and standards.
- 5.8 Program Description – A program description is used to develop, maintain and administer a formal, comprehensive document stating the aims and principles of a particular program.

6.0 GENERAL RESPONSIBILITIES

- 6.1 Director, Office of Standards and Quality Assurance
- 6.1.1 Ensures that a QA program that meets regulatory management requirements is established, maintained, and implemented.

- 6.1.2 Verifies that activities subject to the QARD have been correctly performed by reviews, surveillances, and/or audits.
- 6.2 QA Lead, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for development, review and approval of implementing procedures and plans.
 - 6.2.2 Selects independent and peer reviewers.
- 6.3 EMCBC Office of Logistics Management
 - 6.3.1 EMCBC Office of Logistics Management personnel shall be responsible for Procedural Control of Activities, including developing, implementing, and maintaining policies, plans, and procedures that control the quality of the work consistent with applicable upper-tier requirements.
 - 6.3.2 EMCBC Records Management personnel shall be responsible for the maintenance/use, storage, protection, retrieval and final disposition of QA records.
- 6.4 Document Authors
 - 6.4.1 Responsibility for the content of the document.
- 6.5 Each individual is responsible for the quality of his/her work. All individuals are responsible for identifying potential and existing conditions adverse to quality, and reporting them through the appropriate program outlined in AP-16.1Q, Corrective Action.

7.0 GENERAL INFORMATION

- 7.1 This procedure prescribes the Office for Standards and Quality Assurance process for reviewing documents. It establishes requirements for, conducting all types of reviews, including independent technical, quality assurance, and management reviews, and documenting the resolution of comments using Form 6-1-1, Document Review and Comment (DRC) Form.
 - 7.1.1 The requirements in this procedure apply to the review process for the controlled documents which must be processed through the EMCBC document control process.

8.0 PROCEDURE

8.1 Document Preparation

8.1.1 Prior to submitting the document for review, the author shall ensure that it has been written according to the procedure which specifies the requirements for that document type.

8.2 Identifying the Reviewers

8.2.1 The author of the document, or the QA Lead, shall select individuals to review the document based on the required reviews specified in the governing procedure for the document type. For the purposes of this procedure, the author who initiates the review process is the Review Requester. The Review Requester can delegate an appropriate individual to respond to comments of the reviewer. This delegation is implied and does not need to be documented.

8.2.2 The review requester shall ensure that those individuals selected to review a document are qualified to perform the specified type of review. The review requester shall ensure that at least one of the reviewers of any controlled document is in an organization or technical discipline affected by the document. The originator of the document shall not be a reviewer of the document.

8.2.3 Note: Technical reviews shall be performed by someone who is independent. In order for an individual to qualify as an independent technical reviewer, the individual shall not have performed, contributed to, or directed the work being reviewed, and the individual must not stand to either gain or be adversely affected by the results of the work, or the success of the reviewed document.

8.2.4 Document control shall determine the effective date and is responsible for placing the document on the EMCBC document website. The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work. The Controlled Documents database will be used to identify the current status of each document.

8.3 Conducting the Review

8.3.1 The review requester shall provide the reviewer an electronic or hard copy of the document to be reviewed, and if required by the procedure, a Document Review and Comment (DRC) form with items 1-6 completed.

8.3.2 Minimum criteria for document review are included on the form. The review requester may provide additional criteria as deemed appropriate to the DRC form (see item 5) or as a memo.

8.3.3 When asked, the reviewer requester shall provide additional background information or data to the reviewer.

8.4 Documenting the Review

8.4.1 (1) Use of the DRC is optional for individuals whose signatures are incorporated in the document.

8.4.2 (2) Use of the DRC is mandatory for reviewers who are not signatories.

8.4.3 Note: Completed DRC's are required from all technical, QA, and management reviewers. If the report has references, a Reference Review may be required, and is entered on line 5 of the DRC form.

8.5 Comment Resolution

8.5.1 The author has ultimate responsibility for the content of the document.

8.5.2 The review requester shall evaluate comments made by the reviewer(s), document acceptance/rejection of the comments of the DRC form, and return the form to the reviewer(s).

8.5.3 When comment resolution is complete, the reviewer(s) shall sign the DRC form in the concurrence field (DRC item 10), and return the DRC and copy of the document to the review requester. If comments cannot be resolved, resolution shall be determined by the next level of management.

8.5.4 Implementing documents require history of changes to QA program documents. This document history shall be reviewed each time a QA document is revised.

8.5.5 Comments shall be resolved before the document is approved.

8.6 Approval and Distribution

8.6.1 Changes/revisions to a document shall be reviewed and approved by the same organizations (e.g., functional areas) that performed the review/approval of the original document. Implementing documents require

a history of changes to QA program documents, and this history shall be reviewed each time a QA document is revised.

8.7 Editorial Corrections

8.7.1 Editorial corrections (See AP-5.1Q) may be made to documents without being subject to review requirements. However, editorial corrections shall be distributed as a revision to the document. Editorial corrections shall be approved by the Director, Office for Standards and Quality Assurance.

9.0 RECORDS MAINTENANCE

9.1 QA Records

The forms and Controlled Documents generated through implementation of this procedure shall be prepared and submitted to the EMCBC Records Management Center in accordance with AP-17.1Q, Quality Assurance Records.

9.1.1 Document Review and Comment Form (Form 6.1-1)

9.1.2 Review drafts/attachments (as applicable when review comments are contained in draft document)

9.1.3 Final Document

10.0 FORMS USED

Form 5.1-1, Record of Revision

Form 6.1-1, Document Review and Comment (DRC) Sheet

11.0 ATTACHMENTS

N/A

Form 6.1-1 – Document Review and Comment (DRC)

	Document Review and Comment (DRC)	Form Number: 6.1-1 Page 1 of _____			
<p>REVIEW REQUESTER (e.g., author/Sandia contact) Complete items 1-6 Provide the DRC and review documents to the reviewer.</p> <p>REVIEWER Review the document applying the criteria specified below and completes items 7 and 8. Return DRC to review requester.</p> <p>REVIEW REQUESTER If there are comments requiring response, prepare response to each comment on following page(s); complete item 9, and return to reviewer</p> <p>REVIEWER Review response to comments. Indicate acceptance or rejection on the DRC and complete item 10.</p>					
<p>1. Document Title _____ 2. Rev # _____ (if applicable)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> <p>3. Document Desc ↑ Technical (Technical adequacy, accuracy completeness) -Are objectives clearly stated and fulfilled?</p> <p>4. Type of Review & Criteria -Is the technical activity clearly described? -Are equations/calculations accurate? -Does logic lead to reasonable conclusions? -Are the results drawn from the data supported by data present? Data/tables/figures: Are they easily understood? Are legends complete?</p> <p>↑ Other type of review (please specify or leave blank if not applicable) _____</p> </td> <td style="width: 33%; vertical-align: top;"> <p>↑ QA (Compliance and completeness) -Are applicable AQ requirements adequately cited/incorporated and met (content, reviews)? <u>-Has the technical review been performed by someone who is "independent"?</u></p> </td> <td style="width: 33%; vertical-align: top;"> <p>↑ Management (Completeness and correctness) -Is report consistent with policy? -Is there consensus with other program documents? -Does the document meet applicable criteria?</p> </td> </tr> </table>			<p>3. Document Desc ↑ Technical (Technical adequacy, accuracy completeness) -Are objectives clearly stated and fulfilled?</p> <p>4. Type of Review & Criteria -Is the technical activity clearly described? -Are equations/calculations accurate? -Does logic lead to reasonable conclusions? -Are the results drawn from the data supported by data present? Data/tables/figures: Are they easily understood? Are legends complete?</p> <p>↑ Other type of review (please specify or leave blank if not applicable) _____</p>	<p>↑ QA (Compliance and completeness) -Are applicable AQ requirements adequately cited/incorporated and met (content, reviews)? <u>-Has the technical review been performed by someone who is "independent"?</u></p>	<p>↑ Management (Completeness and correctness) -Is report consistent with policy? -Is there consensus with other program documents? -Does the document meet applicable criteria?</p>
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<p>5. Additional criteria (if applicable) _____ 6. Review Requester _____ Date: _____ (Printed Name)</p> <p>7. Review Prepared by: _____ <i>Reviewer's Printed Name</i> <i>Reviewer's Signature</i> <i>Org.</i> <i>Date</i></p> <p>8. <input type="checkbox"/> No comments <input type="checkbox"/> Mandatory Comments; record on following pages.</p>					
<p>(This section to be left blank if there are no comments requiring a response)</p> <p>9. Response to comments prepared by: _____ <i>Review Requester's/Delegate's Printed Name</i> <i>Review Requester's/Delegate's Signature</i> <i>Org.</i> <i>Date</i></p> <p>10. Response concurrence: _____ <i>Reviewer's Signature</i> <i>Date</i></p>					

RECORD OF REVISION

DOCUMENT: AP-6.1Q, Document Review

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

<u>Rev. No.</u>	<u>Description of Changes</u>	<u>Revision on Pages</u>	<u>Date</u>
0	Original	All	04/27/2011