

**U. S. Department of Energy
Carlsbad Field Office****MANAGEMENT PROCEDURE****CBFO MP 4.2, Rev. 4**

Effective: 20 July 05

Expires: 20 July 07

SUBJECT: DOCUMENT REVIEW

Manager, Carlsbad Field Office: Signature on File

Date: 07/20/05

1.0 PURPOSE

The purpose of this procedure is to describe the process for reviewing documents and documenting reviews and to define the types of reviews performed for documents prepared by or for the Carlsbad Field Office (CBFO).

2.0 SCOPE

This procedure applies to the review of documents that specify requirements, prescribe processes, or establish design for quality level I and II activities as determined by Management Procedure (MP) 1.2, *Selection of Quality Levels*. Organizations performing work for the CBFO may use this procedure as guidance. This procedure supersedes MP 4.2, Revision 3, *Document Review*.

3.0 REFERENCES AND DEFINITIONS**3.1 References**

- DOE/CBFO-94-1001, *Information Management Plan*
- DOE/CBFO-94-1012, *Quality Assurance Program Document*
- MP 1.2, *Selection of Quality Levels*

3.2 Definitions

- **Document Review** - Any review that meets the requirements stated in this procedure, or clearly demonstrates a comprehensive review process involving a minimum of qualified individuals with adequate experience in the subject matter to determine where flaws may exist in a document.
- **Management Review** – All documents require a management review by at least one representative of management to ensure agreement with CBFO policies.
- **Preparer** – The individual responsible for drafting a document for review, coordinating the review, ensuring that the review comments are resolved, and ensuring the records package for the document review is complete.
- **Quality Assurance Review** – A review to determine if a document addresses requirements contained in the CBFO Quality Assurance Program Document (QAPD) and establishes procedures or work processes to fulfill those requirements.

AVAILABLE ONLINE AT:<http://bellview/cbfo/Procedures/ProcedureManual/TOC.htm>**INITIATED BY:**

CBFO Chief Information Officer

- **Technical Review** - A review to determine if a document adequately addresses system requirements and applicable design basis or reports, experimental data, performance assessments, study plans, technical specifications or reports, test reports or plans, or analysis results.

4.0 **RESPONSIBILITIES**

4.1 CBFO Manager

- 4.1.1 Review and approve all CBFO management procedures.
- 4.1.2 Review recommendations from the QA Manager and provide final approval for technical issues relating to quality assurance.
- 4.1.3 Provide final approval of resolution of technical issues when necessary.

4.2 Deputy Manager/Assistant Manager for Operations/Office Directors

Ensure that reviews applicable to their area of responsibility are conducted in accordance with this procedure, and decide a comment's final disposition when the preparer and reviewer cannot reach agreement.

4.2 Document preparer

- 4.2.1 Conduct reviews in accordance with this procedure.
- 4.2.2 Work with reviewers to ensure that all comments are resolved.
- 4.2.3 Ensure technical accuracy and data integrity.
- 4.2.4 Ensure that the Comments Received column of the review/approval matrix is complete (Y/N) for each reviewer and the document review records (CBFO Form 4.2-2) are included in the records package.
- 4.2.5 Ensure the records package is complete prior to submitting the document for signature or publication.

4.3 Document reviewer

- 4.3.1 Use the document review record to record comments.
- 4.3.2 Coordinate with the document preparer to resolve comments.

4.4 Chief Information Officer

- 4.4.1 Perform editorial reviews for CBFO procedures and other internal documents. Editorial reviews are only done AFTER all other comments have been incorporated.
- 4.4.2 Facilitate posting of documents to appropriate web pages or printing (as necessary for CBFO documents) when reviews have been completed and the document is approved for issue.
- 4.4.3 Ensure electronic notice of document updates is sent to appropriate organizations.

5.0 PROCEDURE

5.1 General Requirements

- 5.1.1 The preparer shall use the review/approval matrix (attachment I) to identify potential reviewers. The CBFO Manager or appropriate approving authority shall review and approve or modify the matrix before the preparer sends the document out for review. If the document originator is a senior staff member, s/he may approve the review/approval matrix for the document.
- 5.1.2 Technical and QA reviews shall be performed by individuals who are independent of the original work. Individuals from the same team may be assigned to review different parts of a final document, provided they were not involved in the development of that part.
- 5.1.3 The following groups should be considered as reviewers:
- A. All office directors
 - B. Quality Assurance Manager or representative
 - C. CBFO Deputy Manager or representative
 - D. CBFO Chief Information Officer (for editorial review of internal documents)
 - E. CBFO Chief Legal Counsel or representative (for legal review)

NOTE: Revised documents shall be reviewed by the team that performed the original review unless other organizations are specifically designated.

- 5.1.4 Three types of reviews shall be done for all documents: management, technical, and quality assurance. (See attachment III for guidance. All reviewers may use this guidance for document review.)
- 5.1.5 A legal review shall be conducted on certain significant programmatic documents, including all applications to regulators and all draft documents and certifications received from regulatory entities. The preparer should consult with the Office of the Chief Counsel if they are uncertain whether a legal review is required. The following is a list that includes, but is not limited to, documents requiring legal review:
- A. Documents related to the State of New Mexico hazardous waste permit, including, but not limited to, permit modification requests, notices of deficiency, notices of violation and other enforcement actions and responses thereto, and any inquiries from/responses to stakeholders and regulators.
 - B. Documents regarding Environmental Protection Agency (EPA) compliance certification, recertification, and modifications, revocations, or suspensions of the WIPP compliance certification determination.
 - C. EPA biennial reports.
 - D. Nuclear Regulatory Commission packaging certification applications.
 - E. Major programmatic operational reports such as the Waste Acceptance Plan, Waste Acceptance Criteria, and documents related to the Quality Assurance Program Document and the National Environmental Policy Act.

5.1.6 When all other reviews are complete, an editorial review by a technical editor must be performed on all documents. The comments and resolution of the editorial review shall be documented on a document review record.

5.2 Document Review

5.2.1 A document review record (attachment II), shall be included with any document sent out for review under this procedure.

5.2.2 If the person chosen for the review wishes to distribute the document for group review, all review comments may be compiled on one form. The assigned or delegated reviewer will be responsible for signing the form after all comments have been resolved.

A. If a review is delegated to one person, the first comment should denote to whom the review was delegated.

B. If a review is delegated to a group of individuals and the responses are compiled on one document review record, each comment may be followed by the name or initials of the individual who made it.

5.2.3 The reviewer(s) shall document comments on the document review record.

A. Comments should be preceded by the page and paragraph to ensure that the preparer can locate the corresponding text in the document.

B. When the review is completed, the reviewer shall return the document review record to the preparer for comment resolution.

C. The reviewer shall sign the document review record when all comments have been resolved.

5.2.4 The preparer shall compile all comments and make corrections to the document as necessary.

A. Where comments require extensive revision of a document, making it difficult for a reviewer to determine whether the comment has been resolved, the preparer may include a cross-reference to where in the document the comment has been addressed.

B. The preparer may provide this information in the response column of the document review record. This process is sometimes referred to as a "crosswalk."

5.2.5 The reviewer should be provided a minimum of ten working days from the date the document is sent/distributed for review to permit adequate time to review the document.

A. Reviewers who require more time must request an extension via e-mail or other written documentation. The document preparer decides whether or not to grant the extension. Requests that are not granted must contain justification for the denial.

B. For reviewers who did not request an extension, the preparer shall determine if comments returned after the deadline are significant or relevant, and incorporate them (or not) based on that determination.

C. Documents requiring review and response in less than 10 working days shall clearly state the date by which the comments are due, and note that the review period is less than 10 days.

5.2.6 The document review/approval matrix includes a column marked, "Comments Received, Y/N." For each reviewer listed on the matrix, a "Y" or "N" shall be entered in the column. Original document review records containing comments, responses, and reviewer's signature, shall become part of the records package for each document.

5.3 Comment Resolution

5.3.1 All comments received by the close of the review or approved extension period must be resolved.

5.3.2 The preparer shall clearly indicate agreement or disagreement with the comment and provide justification for disagreement.

5.3.3 If comments are not resolved to the satisfaction of the reviewer, the supervisors for the reviewer and preparer shall decide the comment's final disposition. If the two supervisors cannot resolve a comment, the CBFO Manager shall determine the final resolution.

5.3.4 Document review records from reviewers who completed the review but had no comments on a document must be signed and included in the records package.

5.3.5 A signature on the document review record by the assigned reviewer, delegated reviewer, or by a person having signature authority, constitutes acceptance of the comment resolutions.

5.3.6 Preparers shall ensure that all document review records have been signed and the records package has been assembled prior to seeking approval/release of the document.

5.4 Electronic Reviews

The review process may be performed electronically. Forms may be requested from the Chief Information Officer or downloaded from the CBFO Intranet. Once the comments have been resolved, the form can be printed out and signed by the reviewer for record purposes.

5.5 External Document Reviews

5.5.1 If a document requires review by an external organization, the approval authority or designate with responsibility for the document will prepare a packet including a letter requesting the review and indicating when it should be returned.

A. As appropriate, document packages intended for external review must be clearly marked 'Deliberative Draft Document – Do Not Quote' or 'Privileged', depending upon the nature of the document. When in doubt, contact the Office of the Chief Counsel.

B. Electronic and hard copies of the document and the document review record should be provided with the letter.

5.5.2 All other internal reviews (including editorial review) of a document should be completed, including comment resolution, before sending a review packet to an external organization.

5.5.3 The document preparer and the approval authority will review external comments to determine how they should be incorporated into the document.

5.6 Completed Document Reviews

Reviews are considered complete when document review records from the names/ organizations listed on the review and approval matrix are all signed off by the reviewer or designee.

6.0 **RECORDS**

The records packages generated for documents reviewed using this procedure will be QA records if the document specifies requirements, prescribes processes, or establishes design important to the compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, and management and operation of the WIPP facility. Such packages must be identified as QA records by the preparer. Records packages for most documents will be forwarded to Document Services, which will maintain them in appropriate file cabinets. Records packages for internal CBFO procedures are maintained in the CBFO Mail & Records Center in a locked 1-hour fire-rated file cabinet. The records packages will consist of the following records:

- 6.1 Approved Review/Approval Matrix
- 6.2 Final Draft Document (version sent for review)
- 6.3 Document Review Records
- 6.4 Requests for Extension (if received)
- 6.5 Denial of Request for Extension (if denied)
- 6.6 Final Document (signed, if a signature page is prepared)
- 6.7 Electronic Posting Notice (if prepared)
- 6.8 Interim Change Notices (if prepared)

7.0 **ATTACHMENTS**

Attachment I - Sample Document Review/Approval Matrix

Attachment II - Sample Document Review Record

Attachment III - Review Criteria

DOCUMENT REVIEW RECORD (instructions)

Instructions for Completing the Document Review Record

1. The document preparer will provide the following information on the document review record:
 - a. Document title
 - b. Document number and revision
 - c. Name of the assigned reviewer (from the review/approval matrix)
 - d. Date comments are due
2. The assigned reviewer may elect to perform the review or delegate the responsibility to someone else. If the review is delegated, the first comment should denote to whom the review was delegated. The assigned reviewer is still ultimately responsible for the performance and documentation of the review.
3. The reviewer will enter the page number in the first column, marked "PAGE."
4. The reviewer will enter the paragraph number in the second column, marked "PARA." If the document is formatted into sections, enter the section number in this column (i.e., section 4.1, 4.1.1, etc.).
5. The reviewer will enter all comments in the third column marked "COMMENT." Comments should address the point clearly and precisely. Long comments should be avoided where possible, but clarity is the governing factor. The reviewer will then return the form to the document preparer for resolution of comments. Electronic forms are preferred to facilitate responding to comments without having to re-enter them on another form, or write in responses by hand.
6. The document preparer will respond to each comment on the form and return it to the reviewer.
7. The reviewer marks the reject (REJ) block for each comment where resolution is not satisfactory.
8. If the reviewer accepts all responses, s/he prints the form and signs and dates it under "Comment Resolution Approved" and returns it to the document preparer.
9. If the reviewer rejects a response, s/he returns the form (unsigned, with the rejected comments noted) to the document preparer. If the reviewer and the preparer cannot negotiate a resolution, the appropriate approving authority will decide the final disposition of the comment.
10. The completed document review records will accompany the original document and become part of the records package for that document. Reviewers who have no comments must sign a document review record with "No comments" in the comment block.

MANAGEMENT REVIEW CRITERIA

1. Does the document conflict with established CBFO policy?
2. Will implementation of this document place undue financial and schedule burdens on the CBFO or applicable participants?
3. Is the document suitable and appropriate for its intended use?
4. Are the purpose and scope of work clearly specified?
5. Are processes as straightforward and simple as possible?
6. Is the document user friendly?
7. Are the activities, documents, materials, or data and the individuals and organizations to which the document applies adequately described?
8. Are all individual or organizational responsibilities for implementing the document clearly delineated?
9. Are terms defined adequately to ensure consistent understanding of the document?
10. Does the document use the required standard format if applicable?
11. Are all the exhibits and attachments consistent with the document being reviewed?
12. Are the necessary requirements of the source documents incorporated?

TECHNICAL REVIEW CRITERIA

1. Are inputs and input sources current, correct, and useable under the requirements for qualified data?
2. Are the assumptions used in the development of the technical document stated clearly?
3. Are the assumptions used in the development of the technical document reasonable?
4. In the case of a design document, is the design approach compatible with design objectives and constraints and with prescribed systems engineering requirements?
5. Do calculations provide sufficient detail so that a technically qualified person can understand the analysis?
6. Have the computer programs required by the technical document been verified?
7. Are potential interactions with other technical activities adequately addressed?
8. Are analytical and design approaches and results reasonable?
9. Are analytical and design approaches and results appropriate?
10. Was technical input correctly incorporated?
11. If the technical document is for design purposes, are the following requirements addressed:
 - functions of items?
 - performance?
 - regulatory?
 - technical?
 - security?
 - safety?
12. Are applicable interfaces identified and documented (i.e., work performed in sequence, or for a product received from another affected organization)?
13. Are the responsibilities for interface requirements delineated?
14. Are constraints on required interfaces adequately described?

QUALITY ASSURANCE REVIEW CRITERIA

1. Has the document been prepared under a QA program approved by the CBFO?
2. Are all QA records to be generated during the implementation of the document identified?
3. Is the document process defined adequately and completely?
4. Does the document meet QA requirements applicable to the controls it addresses?
5. Does the document contain qualitative and quantitative data?
6. Are tolerances and parameters provided for this data?
7. Does the document include or reference appropriate quantitative and qualitative acceptance criteria for determining that prescribed processes have been satisfactorily accomplished?
8. Is there adequate traceability of information used as input to the document?
9. For unqualified inputs, do controlled steps exist for qualification of the input specified?
10. Are technical requirements identified where appropriate (i.e., drawings and specifications; codes, standards, and regulations; technical acceptance criteria; and traceability requirements)?
11. Are the technical and QA program deliverables clearly specified?
12. Is the document content consistent with applicable regulatory requirements?
13. Are there any contradictions between DOE orders and regulatory requirements or commitments that require resolution?