

U. S. Department of Energy
Carlsbad Field Office

MANAGEMENT PROCEDURE

CBFO MP 10.5, Rev. 7

Effective: July 25, 2007

Expires: July 25, 2009

SUBJECT: PEER REVIEW

Manager, Carlsbad Field Office:

Date:

1.0 PURPOSE

This management procedure (MP) prescribes the responsibilities, requirements, and methodologies to be used for the performance of peer reviews conducted for the Carlsbad Field Office (CBFO) in support of the Waste Isolation Pilot Plant (WIPP) compliance demonstration and applications. This procedure was developed in accordance with and implements the guidance in NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories (see attachment 1).

2.0 SCOPE

This procedure applies to the performance of peer reviews prescribed in the Code of Federal Regulations (CFR), Title 40 Part 194 (40 CFR Part 194), and conducted under the responsibility of the CBFO. The peer reviews may be applied to repository performance demonstrations as specified in 40 CFR §194.27, to qualify waste characterization data as specified in 40 CFR §194.22(b), and to other applications requiring the use of NUREG-1297. This procedure supersedes MP 10.5, Revision 6.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 40 CFR Part 191, Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes
- 40 CFR Part 194, Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations
- NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories, published February 1988
- Carlsbad Field Office *Quality Assurance Program Document* (QAPD) (DOE/CBFO-94-1012)
- MP 4.2, *Document Review*

3.2 Definitions

Refer to the CBFO QAPD Glossary of Terms for general quality assurance terms. For the purposes of this procedure, the following terms are defined:

AVAILABLE ONLINE AT:

<http://bellview/cbfo/Procedures/ProcedureManualTOC.htm>

INITIATED BY:

CBFO Compliance Certification Manager

- **Contractor Technical Representative** – A person who is authorized to represent their organization and first tier contractual responsibilities with CBFO for performance of the peer review.
- **Independence** – The peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed and, to the extent practical, has sufficient freedom from funding considerations to ensure that the work is impartially reviewed.
- **Peer** – A person with technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work (subcontractor position as specified in attachment I).
- **Peer review** – A documented, critical review performed by peers who are independent of the work being reviewed. The review shall include (as appropriate) in-depth analysis and evaluation of assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions reached in the original work. It will assess the adequacy of the original work and determine its acceptability for use per 40 CFR Part 194.
- **Peer review panel** – An assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed (service provider as specified in Attachment I).
- **Peer review manager** – The administrative manager of the peer review process (service provider as specified in Attachment I).
- **Peer Review Panel Selection Committee** – A committee, headed by the peer review manager, which selects the peer review panel members (as specified in Attachment I).
- **Peer review chairperson** – A peer review panel member designated by the peer review manager to provide technical leadership to the peer review panel and to determine the manner in which the required peer review evaluations and reporting are conducted (service provider as specified in Attachment I).
- **Peer review observer protocol** – Documented instructions for observer interaction with the peer review panel.
- **Peer review observers** – Representatives of regulatory entities, stakeholders, CBFO, and CBFO participant organizations with the express need to observe the peer review process.
- **Peer review plan** – Documents the approach, purpose, and scope of a peer review.
- **Peer review procedure** – Documents responsibilities and methods for conducting a peer review. Meets the criteria established in NUREG-1297 and in attachment I of this procedure.
- **Peer review report** – In-depth documentation of the proceedings and findings of a peer review.

4.0 RESPONSIBILITIES

- 4.1 Assistant Manager (AM), Office Director (OD), or designee shall:
- 4.1.1 Request CBFO Office of Business or designated contractor to acquire services for the conduct of a peer review consistent with this procedure.
 - 4.1.2 Concur with the peer review manager candidate nominated by the service provider prior to initiation of the peer review process.
 - 4.1.3 Ensure that information and data required to support the peer review are assembled and complete.
 - 4.1.4 Ensure that the service provider peer review procedure and peer review plan are reviewed by the appropriate CBFO staff in accordance with MP 4.2, *Document Review* as needed.
 - 4.1.5 Provide the required interfaces to ensure effective flow of information and logistic support for the peer review process.
 - 4.1.6 Ensure necessary communications, including regulatory reporting requirements, with the Environmental Protection Agency, the New Mexico Environment Department, and other interested stakeholders as appropriate.
- 4.2 CBFO Quality Assurance (QA) Manager
- Responsible for the overall assessment of the peer review process including QA records.
- 4.3 If the service acquisition action is performed by a designated contractor, the Contractor Technical Lead shall perform the duties of the responsible AM, OD or designee on behalf of the designated contractor.

5.0 PROCEDURE

5.1 Peer Review Process

Peer reviews shall be used as a management tool to achieve confidence in the validity of certain technical and programmatic judgments. The intent of a peer review is to pass judgment on the technical adequacy of the work or data submitted for review, to identify aspects of the work on which technical consensus exists, to identify aspects on which technical consensus does not exist, and to identify aspects of the reviewed work which the peer review panel believes to be incorrect or which need amplification. A peer review process provides assurance in cases where scientific uncertainties and ambiguities exist but in which technical and programmatic judgments and decisions still must be made. In general, peer reviews should be used in a confirmatory sense. Peer reviews shall not be used as a substitute for readily collectable data. Conclusions based on inadequate or limited data cannot be improved by subjecting those conclusions to the peer review process and peer reviews shall not be confused with technical reviews

5.2 Peer Review Process Initiation

- 5.2.1 Upon request for a peer review in accordance with 40 CFR Part 194, the AM, OD, or designee shall request an appropriate service acquisition action from the Office of Business or designated contractor that includes:

- A. Development of a peer review procedure that incorporates the NUREG-1297 requirements established in attachment I and includes forms equivalent to those in attachments II through VI. Attachment I may be used in lieu of development of a new procedure, with appropriate service provider documentation (e.g., cover sheet with approvals) provided to the CBFO.
- B. CBFO review and approval of the peer review procedure and peer review plan, if attachment I is not used.
- C. A request that the service provider submit the identification and qualification documentation of the nominated peer review manager for concurrence by the responsible AM, OD, or designee prior to initiation of the peer review process.
- D. The specific scope of the peer review to be conducted, including a schedule for review activities and delivery of the final report.
- E. The requirement that the peer review process be conducted in accordance with this procedure.
- F. The requirement for the peer review manager to transfer all QA records to the contract technical representative who then submits them to the responsible AM, OD, or designee.

5.2.2 If the service provider develops a peer review procedure, the AM, OD, or designee shall initiate the CBFO document review process in accordance with MP 4.2, *Document Review*. If attachment I of this procedure is used, no further CBFO review is required.

5.3 Peer Review Process Support

5.3.1 The AM, OD, or designee shall:

- A. Evaluate the qualifications of the candidates for peer review manager submitted by the service provider and communicate concurrence or non-concurrence until a peer review manager is selected.
- B. Verify that information and data required to support the peer review are assembled, complete, and provided to the peer review manager.
- C. Process requests for information, including any additional information required by the peer review panel, in a timely manner.
- D. Provide required interfaces to ensure effective flow of information and logistic support for the peer review process.
- E. Initiate the CBFO document review process if changes are made to the peer review plan will affect the implementation of this procedure.
- F. Ensure that changes to the peer review procedure are reviewed by CBFO in accordance with MP 4.2.

5.3.2 The AM, OD, or designee will serve as the interface with internal and external observers and will coordinate logistics between the peer review manager and observers.

5.3.3 The AM, OD, or designee will review and approve/disapprove requests for information from observers as deemed appropriate.

5.4 Peer Review Process Conclusion

- 5.4.1 The AM, OD, or designee shall review the final peer review report and any supplemental information for impacts and further actions required.
- 5.4.2 The AM, OD, or designee shall notify the affected organizations (if any) and the appropriate regulatory agencies of the conclusions of the peer review.

5.5 Quality Assurance Assessments

- 5.5.1 The QA Manager shall assess the peer review process to ensure that it conforms to this procedure.
- 5.5.2 The QA Manager shall present any assessment findings to the responsible AM, OD, or designee, and the contract technical representative who in turn submits them to the peer review manager.
- 5.5.3 The QA Manager will review the resolution of any findings to ensure that they include an assessment of the impact of the findings on completed and ongoing peer reviews, as
- 5.5.4 Attendance requests for individuals performing peer review QA oversight activities must be coordinated through the peer review manager or chairperson.

6.0 **RECORDS**

6.1 QA Records

- 6.1.1 Upon completion of the peer review process and receipt of the QA records from the contract technical representative (via the peer review manager), the AM, OD, or designee, with the assistance of the QA Manager, shall verify that the following are assessed and retained, including the peer review report with the following specific appendices:
- A. Peer review panel manager qualification documentation
 - B. Peer review plan(s) including peer review procedures (identify if different from Attachment I of MP 10.5)
 - C. Documentation for appointment of the peer review panel member selection committee.
 - D. Peer review panel member qualification and selection documentation including:
 - Verification of education/employment documentation and
 - Determination of peer review panel member independence documentation
 - E. Service acquisition documents (beginning with request for peer review from CBFO Office of Business through peer review panel member service provider contracting documentation)
 - F. Peer review panel orientation documentation and attendance form(s)
 - G. Written minutes of meetings, deliberations and activities

H. Observer inquiry forms and/or relevant information that is within the scope of the peer review submitted by an observer to the panel.

6.1.2 Upon the successful completion of the verification that appropriate QA records were provided, the QA records shall be processed by the responsible AM, OD, or designee, in accordance with CBFO MP 4.9, *Quality Assurance Records*.

7.0 ATTACHMENTS

Attachment I. Typical WIPP Protocol for Implementation of NUREG-1297 Peer Review Process

Attachment II. Example of Peer Review Panel Member Verification of Education/Employment Form

Attachment III. Example of Determination of Peer Review Panel Member Independence Form

Attachment IV. Example of Peer Review Panel Selection Justification/Decision Form

Attachment V. Example of Peer Review Panel Orientation Form

Attachment VI. Example of Observer Inquiry Form

Typical WIPP Protocol for Implementation of NUREG-1297 Peer Review Process

Note: Refer to Section 3.2 of MP 10.5 for definitions of terms.

- A1.0 Establishment of the peer review panel selection committee
 - 1.1 The peer review manager shall head the peer review panel selection committee and shall document the selection of two individuals to serve on the selection committee using the following criteria:
 - 1.1.1 Knowledge of the peer review process
 - 1.1.2 Knowledge of the potentially qualified peer review candidates
 - 1.1.3 Impartiality and no organizational conflict of interest
- A2.0 Selection of peer review panel members
 - 2.1 Peer Review Panel Size and Composition
 - 2.1.1 Peer review panel size and composition shall be determined by the peer review panel selection committee. The committee may utilize technical advisors to assist in the selection process. The committee may select an alternate Peer Review Panel Member who will serve in the event that a selected panel member is unable to participate in the peer review.
 - 2.1.2 The number of peers comprising a peer review panel varies with the complexity of the work to be reviewed, its importance to meeting safety or waste isolation performance goals, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.
 - 2.1.3 The collective technical expertise and qualifications of peer review panel members shall span the issues and areas involved in the work to be reviewed, including any differing bodies of scientific thought. Technical areas more central to the work to be reviewed shall receive proportionally more representation on the peer review panel. The peer review panel should represent the major schools of scientific thought and the potential for technical or organizational partiality should be minimized by the formation of a balanced peer review panel.
 - 2.2 Peer Review Panel Member Qualifications
 - 2.2.1 The acceptability of any peer review panel member is based on technical qualifications and independence, both of which shall be satisfied.
 - 2.2.2 The requirement for technical qualifications of a panel member shall be satisfied by meeting all of the following:
 - A. Recognized and verifiable technical qualifications at least equivalent to those needed for the original work under review (the primary

consideration in the selection process) in the technical area the panel member has been selected to cover. The technical qualifications of each panel member, and of the peer review panel as a whole, shall relate to the importance of the subject matter to be reviewed.

- B. The peer review manager shall ensure that the education and pertinent experience of each panel member is verified and documented on a peer review panel member verification of education/employment form or equivalent (see attachment II).

2.2.3 The requirement for independence shall be satisfied by meeting all of the following:

- A. Peer review panel members shall be independent of the original work to be reviewed.
- B. Because of the Department of Energy's (DOE's) extensive effort in the waste management area, the unavailability of other technical expertise in certain areas, and the possibility of reducing the technical qualifications of the reviewers in order to maintain total independence, it may not be possible to exclude all DOE or DOE contractor personnel from participating in a peer review. In cases where total independence requirements cannot be met, a documented rationale as to why someone of equivalent technical qualifications and greater independence, if applicable, was not selected shall be documented in a memo to file and included in the QA record package.
- C. The peer review panel member shall document the rationale for independence on a determination of peer review panel member independence form or equivalent (see attachment III). The documented rationale shall be reviewed, verified, and approved by the peer review manager. The form shall be maintained as a QA record.

2.3 Peer Review Panel Selection

- 2.3.1 The peer review panel selection committee shall eliminate potential peer review panel members from consideration based on information provided on the list and the following criteria: 1) equally or more qualified individuals are available, 2) the candidate is not available, and/or 3) the candidate has a potential or perceived organizational conflict of interest.
- 2.3.2 The peer review panel selection committee shall document the rationale for selection and nonselection of peer review panel members on a peer review panel selection justification/decision form, or equivalent (see attachment IV). This form shall be maintained as a QA record.
- 2.3.3 The peer review manager shall ensure the services of the selected peer review panel members are retained. Service acquisition documents are to be included with the QA records.

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- 2.3.4 If an appointed peer review panel member is unable to continue as a standing member, the member shall formally resign. The peer review manager will reconvene the peer review panel selection committee to select an alternate member in accordance with the applicable sections of this protocol, or opt to continue the peer review with the remaining panel members, as appropriate. The basis for the decision shall be formally documented.
- 2.3.5 The peer review manager shall select and appoint a peer review panel chairperson for each peer review panel from among the peer review panel members.

A3.0 Peer Review Panel Member Orientation

- 3.1 The peer review manager shall ensure that all peer review panel members have received adequate orientation prior to performing their assigned work. Orientation may take the form of reading assignments, briefings, or classroom training as appropriate. Orientation shall be documented as to content and scope.
- 3.2 At a minimum, assigned reading or orientation shall be facilitated by the peer review manager and shall include the applicable sections of the following:
 - 3.2.1 40 CFR Part 191, Environmental Radiation Protection Standards For Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes
 - 3.2.2 40 CFR Part 194, Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance With the 40 CFR Part 191 Disposal Regulations
 - 3.2.3 NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories
 - 3.2.4 Carlsbad Field Office *Quality Assurance Program Document* (QAPD) (DOE/CBFO-94-1012) sections 1.1.2.5 and 5.4
 - 3.2.5 Carlsbad Field Office Management Procedure (MP) 10.5, *Peer Review*
 - 3.2.6 Applicable peer review plans
 - 3.2.7 Peer review procedure(s)
 - 3.2.8 The peer review process, including the administrative requirements
 - 3.2.9 A brief summary of the peer review technical subject matter, which may include a briefing by the scientist or engineer responsible for the study being reviewed
- 3.3 Attendance at orientation shall be documented on the peer review panel member orientation form or equivalent (see attachment V), and shall be maintained as a QA record.

A4.0 Interface Requirements

- 4.1 The observer protocol shall be maintained during the peer review process. Observers are not active participants in the peer review process. Observer communication with peer review panel members during formal panel sessions is disallowed unless requested by a peer panel member or when prior approval is obtained from the peer

review chairperson. The peer review manager is responsible for the conduct of the peer review and will maintain administrative control of the peer review process.

- 4.2 The peer review manager or chairperson will ensure that all observers are introduced in the pre-review meeting and initial review sessions.
- 4.3 Prior to starting the panel session, the peer review manager or chairperson will provide a brief introduction, summary of review objectives, and expectations for observer conduct.
- 4.4 Observers may submit questions in writing to the peer review manager or chairperson during breaks or other designated times unless otherwise requested by peer review panel members or approved by the peer review manager. Observers should limit questions to issues directly related to the information/data being reviewed. Observer questions and peer review panel responses will be addressed only if prior approval is obtained from the peer review manager and the approved questions are documented and retained as QA records.
- 4.5 Observers shall be permitted copies of information distributed to peer review panel members during the peer review process. Such requests shall be made to the peer review manager and shall be documented.
- 4.6 Observers are permitted to submit to the panel relevant information that is within the scope of the peer review. The information must first be given to the peer review manager for documentation as a QA record before it is submitted to the panel.
- 4.7 Handbooks provided to peer review panel members will be made available for observers to review in the panel conference room.

A5.0 Schedule/Status

- 5.1 The peer review manager will provide status updates to the assistant manager, office director or designee, and the CBFO QA manager.
- 5.2 The peer review manager or chairperson will ensure observers are informed daily of schedule and room changes.
- 5.3 The peer review manager will provide the assistant manager, office director, or designee with a detailed peer review schedule and updates, as required. This information will be provided to observers as requested.

A6.0 General Peer Review Process

6.1 Peer Review Plan

The peer review manager shall ensure that a peer review plan has been prepared and approved by the CBFO prior to each peer review. The peer review plan shall contain, at a minimum:

- A. The scope of the peer review and description of the work to be reviewed

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- B. The intended use of the work in performance assessment (if applicable)
- C. The composition of the peer review panel
- D. Suggested methods (e.g., the method used to document observations, comments, and conclusions)
- E. The schedule to complete the peer review report
- F. The frequency of status reports

6.2 Subject Matter Peer Review Process

- 6.2.1 Peer reviews shall be conducted in accordance with the requirements of the peer review procedure(s) and the peer review plan. Major changes to the peer review procedure(s) or the plan shall be submitted to the responsible assistant manager, office director, or designee for review and concurrence. The peer review manager may approve minor changes (e.g., editorial, renumbering sections, reformatting forms, updating organization titles, and clarifications that do not change intent) to the peer review plan.
- 6.2.2 The peer review process shall consist of an in-depth analysis and evaluation of (a) validity of assumptions; (b) alternate interpretations; (c) uncertainty of results and consequences if wrong; (d) appropriateness and limitations of methodology and procedures; (e) adequacy of application; (f) accuracy of calculations; (g) validity of conclusions; and (h) adequacy of requirements and criteria, in accordance with approved technical and quality assurance requirements and the applicable peer review plan(s).
- 6.2.3 Peer review panel members shall interact to ensure that sufficient consideration is given to interdisciplinary and coupled data and information.
- 6.2.4 Each peer review panel member shall support the peer review chairperson in the preparation of peer review report(s) on their specific review areas.
- 6.2.5 The peer review chairperson shall provide technical leadership of the peer review panel members and determine the manner in which the required peer review evaluations and reporting are conducted.
- 6.2.6 The peer review chairperson shall delegate, with the assistance of the peer review manager, the assignments of specific review tasks and activities among peer review panel members.
- 6.2.7 The peer review manager shall coordinate peer review panel activities in accordance with applicable procedures and the peer review plan.
- 6.2.8 The peer review manager shall provide the required coordination between the peer review panels and the responsible assistant manager, office director, or designee to ensure that an effective and responsible flow of information and logistic/technical support are provided.
- 6.2.9 The peer review manager shall provide the assistant manager, office director, or designee with periodic progress reports on the status of the peer review, as specified within the peer review plan.
- 6.2.10 The peer review manager shall ensure that all required forms and documentation are complete prior to the start of the peer review process.

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6.2.11 The peer review manager shall ensure that the peer review is accomplished and documented in accordance with approved procedures, or with this attachment, and in an effective and timely manner.

6.3 Peer Review Daily Caucus

6.3.1 When peer review activities are conducted, the peer review panel chairperson shall schedule and conduct daily caucuses of the peer review panel to address issues, concerns, questions, conflicts, etc. The peer review manager will assist the chairperson in resolution of the issues, as necessary.

6.3.2 The peer review manager shall ensure that written caucus minutes are developed, shall initial the minutes to signify that they have been reviewed and reasonably represent the work of the peer review panel, and shall ensure the minutes are maintained as QA records.

6.3.3 Authorization for observers to attend the caucus meetings shall be obtained through the peer review manager prior to admittance.

6.4 Peer Review Report

6.4.1 The peer review chairperson, with assistance from the peer review manager as needed, shall ensure that the peer review panel findings are documented and that the peer review report is prepared.

6.4.2 The peer review report shall:

- A. Be signed by each peer review panel member
- B. Describe the work or issue that was reviewed
- C. Describe the conclusions reached by the peer review panel and the conclusions reached by the peer review process (Section 6.2.2)
- D. Provide individual statements by the peer review panel members reflecting dissenting views or additional comments, as appropriate
- E. List the peer review panel members and provide acceptability information (i.e., technical qualifications and independence) for each member including any potential technical and or organizational partiality

6.5 Supplemental Information and Data

In the event that issues affecting the defined purpose of the peer review are identified in the peer review report, the panel may be reconvened to review supplementary information provided to resolve such issues. If the panel is reconvened, the review of the supplementary data and information shall be conducted in accordance with this procedure. The results of the supplementary peer review shall be documented in a supplementary peer review report.

A7.0 Retention and Maintenance

7.1 QA records shall be retained by the peer review manager until completion of the peer review process. Upon completion of the peer review process, the peer review manager shall transfer all QA records to the responsible AM, OD, or designee.

7.2 QA records to be retained include:

- A. Peer review plans
- B. Peer review procedures (if different from attachment I of MP 10.5)
- C. Service acquisition documents
- D. Peer review panel member verification of education/employment documentation
- E. Determination of peer review panel member independence documentation
- F. Peer review panel selection justification/decision documentation
- G. Peer review panel member service provider contracting documentation
- H. Observer inquiry forms
- I. Peer review panel manager qualification documentation
- J. Peer review panel member selection documentation
- K. Peer review panel orientation documentation and attendance form
- L. Written minutes of meetings, deliberations, and activities
- M. Peer review reports

Example of Determination of Peer Review Panel Member Independence Form

Are you currently employed by DOE or a DOE contractor? Yes/No

Were you employed by DOE or a DOE Contractor previously? Yes/No

(If yes, give dates, location, organization, position, and type of work performed.)

Do you have or have you had any direct involvement or financial interest in the work under review? Yes/No

(If yes, describe.)

Is there any reason why you cannot perform an impartial peer review? Yes/No

(If yes, describe.)

Is there any aspect of your past that may lead to a perception of bias in the results of your peer review? Yes/No

(If yes, describe.)

I pledge that my review of this work will be completely impartial and based solely on the information available during the review.

Signature: _____

Print Name: _____

Date: _____

Example of Peer Review Panel Selection Justification/Decision Form

Selection committee members:

Peer review entitled:

Peer review panel composition:

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

Justification:

Date: _____

Selection committee signatures:

