



CBFO MANAGEMENT PROCEDURE Carlsbad Field Office

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Revision 4

Title: **PEER REVIEW**

Manager, Carlsbad Field Office

Inés Triay

Effective Date:

4/12/02

1.0 PURPOSE

This procedure prescribes the responsibilities, requirements, and methodologies to be incorporated in 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.

2.0 SCOPE

This procedure applies to the performance of peer reviews prescribed in the Code of Federal Regulations, 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.

Peer review requirements which implement NUREG-1297 are detailed in Attachment 1.

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) (CAO-94-1012)
- Management Procedure (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:

- **Independence** - Independence in this case means that the peer: a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to ensure that the work is impartially reviewed.
- **Peer** – A person having 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) an in-depth analysis and evaluation of assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn 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** - A peer review panel is 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, that has the responsibility to select peer review panel members (as specified in Attachment I).
- **Peer review chairperson** - One of the peer review panel members designated by the peer review manager as the technical lead to provide technical direction for peer review panel report documentation (service provider as specified in Attachment I).
- **Peer review observer protocol** - A documented instruction that provides guidance for observer interaction with the peer review panel.
- **Peer review observers** - Representatives of regulatory entities, stakeholders, CBFO, and other CBFO participant organizations with the express need to observe the peer review process.
- **Peer review plan** - A documented plan that represents the approach, purpose, and scope the peer review panel will use in conducting a peer review.
- **Peer review procedure** - A procedure that documents how the peer review panel establishes and conducts a peer review. The procedure meets the criteria established in NUREG-1297 and in Attachment I of this procedure.
- **Peer review report** - A documented in-depth report of the proceedings and findings of a peer review.

4.0 RESPONSIBILITIES

4.1 Responsible Assistant Manager (AM) (or designee) shall:

- 4.1.1 Request the Office of Program Support to acquisition services for the conduct of peer review(s) 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 collated in a timely manner.
 - 4.1.4 Ensure that the service provider peer review procedure and the peer review plan are reviewed by the appropriate CBFO staff in accordance with MP 4.2, Document Review.
 - 4.1.5 Provide the required interfaces to ensure an effective and responsive flow of information and logistic support for the adequate, expedient, independent, and timely conduct of 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.
- 4.2 The CBFO Quality Assurance (QA) Manager shall be responsible for the overall assessment of the peer review process

5.0 PROCEDURE

5.1 Initiating the Peer Review Process

- 5.1.1 Upon request for a peer review in accordance with 40 CFR Part 194, the assistant manager (or designee) shall initiate the peer review process by requesting an appropriate service acquisition action from the Office of Program Support that includes:
 - A. The development of a peer review procedure that incorporates the NUREG-1297 peer review protocols established in Attachment I and the use of forms containing the same information as the examples provided in Attachments II through VI. The peer review may be conducted in accordance with Attachment I in lieu of the development of a new procedure and when appropriate service provider documentation (e.g., cover sheet with approvals) is provided to the CBFO.
 - B. The review and concurrence by CBFO prior to use of the peer review procedure and the peer review plan. If Attachment I is used to perform the peer review, further approval of the procedure(s) is not required.
 - 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 (or designee) prior to initiation of the peer review process.
 - D. The specific scope of the peer review(s) to be conducted including a schedule for conducting the peer review(s) and delivery of the final report(s).
 - E. The requirement that the peer review process be conducted in accordance with this procedure.
 - F. Requirement for peer review manager to transfer all QA records to the responsible AM (or designee).
- 5.1.2 If the service provider submits their own procedure for performing peer reviews, the assistant manager (or designee) shall initiate the CBFO document review process in accordance with MP 4.2, Document Review. If the service provider commits to the use of Attachment I of this procedure in total, no further review is required by CBFO.

5.2 Supporting the Peer Review Process

- 5.2.1 The assistant manager (or designee) shall evaluate the qualification documentation of the candidate(s) for the peer review manager submitted by the service provider and communicate with the provider their concurrence or nonconcurrence until an individual is identified as peer review manager.
- 5.2.2 The assistant manager (or designee) shall verify that information and data required to support the peer review is assembled and collated in a timely manner.
- 5.2.3 The assistant manager (or designee) shall provide data (as applicable) to the peer review manager.
- 5.2.4 The assistant manager (or designee) shall process any requests for information, including any additional information required by the peer review panel, in a timely manner.
- 5.2.5 The assistant manager (or designee) shall provide the required interfaces to ensure an effective and responsive flow of information and logistic support for the expedient, independent, and timely conduct of the peer review process.
- 5.2.6 When changes are made to the peer review plan, the assistant manager (or designee) shall initiate the CBFO document review process. The assistant manager shall ensure that all changes to the Peer Review Procedure are reviewed in a timely manner by the appropriate CBFO staff in accordance with MP 4.2.
- 5.2.7 The assistant manager (or designee) will serve as the interface with internal and external observers. The AM (or designee) will coordinate logistics between the peer review manager and the observers.
- 5.2.8 The assistant manager (or designee) will review and approve/disallow applicable requests for information from observers, depending on the nature of the information requested.

5.3 Concluding the Peer Review Process

- 5.3.1 The assistant manager (or designee) shall review the final issued peer review report and any supplemental information for impacts and further actions to be taken.
- 5.3.2 The assistant manager (or designee) shall notify the affected organizations (if applicable) and the appropriate regulatory agency(s) of the conclusions of the peer review.

5.4 Quality Assurance Assessments

- 5.4.1 The QA Manager should conduct assessments of the peer review process to ensure that all aspects of the peer review conforms to this procedure.
- 5.4.2 The QA Manager shall present any assessment findings to the responsible assistant manager and the peer review manager.
- 5.4.3 The QA Manager will review the resolution of any findings to ensure that they include an assessment of the impact of the finding(s) on completed and ongoing peer reviews, as applicable.

5.4.4 The QA Manager will be responsible for assessment/audit coordination with the regulators.

5.4.5 The QA Manager is responsible for determining observer attendance at peer review caucuses. Attendance is limited to individuals performing peer review oversight activities. Attendance requests must be coordinated through the peer review manager or peer review 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 peer review manager, the assistant manager (or designee) shall verify that the QA records to be retained include:

- A. Peer review plan(s)
- B. Service acquisition document(s)
- C. Peer review procedure(s)
- 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 contracting documentation
- H. Observer Inquiry Form(s)
- I. Peer Review Panel Orientation documentation
- J. Written minutes of meetings, deliberations, and activities
- K. Peer review report(s).

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

7.0 Attachments

Attachment I - 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

ATTACHMENT I

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Typical WIPP Protocol for Implementation of NUREG-1297 Peer Review Process**Note: Refer to Section 3.2 of this procedure for definitions of terms.**

1.0 Establishment of the peer review panel selection committee

1.1 The peer review manager shall document the selection of two individuals to serve on the peer review panel selection committee using the following criteria:

1.1.1 Have knowledge of the peer review process

1.1.2 Have knowledge of the potentially qualified peer review candidates

1.1.3 Are impartial and have no organizational conflict of interest

The peer review manager shall head the peer review panel selection committee.

2.0 Selection of peer review panel members

2.1 Peer Review Panel Size and Composition

2.1.1 The peer review panel size and composition shall be determined by the peer review panel selection committee. The selection committee may utilize technical advisors to assist in the selection process.

2.1.2 The number of peers comprising a peer review panel varies with the complexity of the work to be reviewed, its importance for establishing that safety or waste isolation performance goals are met, 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 selecting peers to provide 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 two requirements: technical qualifications and independence, both of which shall be satisfied.

2.2.2 The requirement for technical qualification shall be satisfied by meeting all of the following:

A. The technical qualifications of the panel member, in the review area, shall be at least equivalent to that needed for the original work under review and shall be the primary consideration in the selection process. The panel member shall have recognized and verifiable technical credentials in the technical area that he or she 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 (example provided as 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 that is to be reviewed.
- B. Because of the Department of Energy's (DOE's) pervasive effort in the waste management area, the lack or unavailability of other technical expertise in certain areas, and the possibility of reducing the technical qualifications of the reviewers in order that total independence is maintained, it may not be possible to exclude all DOE or DOE contractor personnel from participating in a peer review. In those 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 (example provided as 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 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 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 (example provided as 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.
- 2.3.4 If an appointed peer review panel member is unable to continue as a standing member, the member shall submit a resignation stating an inability to maintain an active role on the panel. The peer review manager will then reconvene the peer review selection committee to select an alternate panel 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.

3.0 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 Description (QAPD) (CAO-94-1012)
 - 3.2.5 Department of Energy-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 The applicable peer review plan(s) and procedure(s)
 - 3.2.10 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 Peer review panel member attendance at orientation shall be documented on the peer review panel member orientation form or equivalent (example provided as Attachment V), and shall be maintained as a QA record.

4.0 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. They are welcome to observe the process; however, communication with the peer review panel members during formal panel sessions is disallowed unless requested by the peer panel member(s) or 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 the peer review 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 the peer review chairperson will provide a brief introduction, summary of the objectives of the review, and expectations for observer conduct.
 - 4.4 Observers will be requested to submit their questions in writing to the peer review manager or the peer review chairperson during breaks or other designated times unless otherwise requested by peer review panel member(s) or approved by the peer review manager. The observers should limit their 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 a QA record.
 - 4.5 Observers shall be permitted copies of information distributed to peer review panel members during the peer review process upon request to the peer review manager. Any such requests for information 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 submitting it 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
- 5.0 Schedule/Status
- 5.1 The peer review manager will provide the assistant manager (or designee) and the CBFO QA manager with status updates
 - 5.2 The peer review manager or chairperson will ensure observers are kept informed of daily scheduling and room changes.
 - 5.3 The peer review manager will provide the assistant manager (or designee) with advance information concerning scheduled peer reviews and updates of the peer review schedule with specific dates for each review. This information will be passed on to interested observers as requested.
- 6.0 General Peer Review Process
- 6.1 Peer Review Plan
 - 6.1.1 The peer review manager shall ensure that the peer review plan has been prepared and approved by the CBFO prior to the performance of each peer review.
 - 6.1.2 The peer review plan shall contain, at a minimum:
 - A. The scope of the peer review and description of the work to be reviewed
 - B. The intended use of the work in performance assessment (if applicable)
 - C. The composition of the peer review panel
 - D. Any 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 guidance provided in the peer review plan. Major changes to the peer review procedure(s) or the plan shall be submitted to the responsible assistant manager (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 don't change the intent) to the peer review plan.
- 6.2.2 The peer review process shall consist of an in-depth analysis and evaluation of documented assumptions, calculations, extrapolations, alternate interpretations methodology, acceptance criteria employed, the conclusions drawn in the original work 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.
- 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 (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 responsible assistant manager (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 completed as necessary prior to the start of the peer review process.
- 6.2.11 The peer review manager shall ensure that the peer review implementation 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 peer review chairperson in resolution of the issues discussed in the daily caucus, 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 are believed to 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 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
- 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

6.4.3 The peer review manager shall assist the peer review chairperson in ensuring that the peer review panel findings are documented and the peer review report is developed.

6.5 Supplemental Information and Data

In the event that issues that may affect 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.

7.0 Quality Assurance Assessments

7.1 The CBFO QA Manager shall conduct assessments of the peer review process to ensure that all aspects of the peer review process conform to this procedure.

7.2 The peer review manager shall address and resolve any assessment findings prior to the conclusion of the peer review process. Resolution of the findings will include an assessment of the impact of the finding(s) on completed and ongoing peer reviews, as applicable.

8.0 Retention and Maintenance

8.1 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 assistant manager (or designee).

8.2 QA records to be retained include:

- A. Peer review plan(s)
- B. Peer review procedure(s)
- C. Service acquisition document(s)
- 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 report(s).

ATTACHMENT III

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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 the involvement)

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

If yes, state the reason(s))

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:

For the peer review entitled: _____

Have determined the peer review panel composition to be as follows:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

The justification for this determination is:

Date: _____

Selection committee signatures:

