

Waste Isolation Pilot Plant
Compliance Certification Application
Reference 207

DOE (U.S. Department of Energy). 1996.
CAO Team Procedure (TP) 10.5 Rev. 0, Carlsbad Area Office, Carlsbad, NM.



CAO TEAM PROCEDURE
Carlsbad Area Office

TP No. 10.5

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Revision 0

Title: **PEER REVIEW**

[Signature]
Assistant Manager, Office of Regulatory Compliance, Carlsbad Area Office

3/14/96
Date:

1.0 PURPOSE

This procedure prescribes the responsibilities, requirements, and methodologies to be incorporated in the performance of peer reviews conducted by the Office of Regulatory Compliance (ORC) 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.

2.0 SCOPE

This procedure applies to the performance of peer reviews prescribed in 40 Code of Federal Regulations (CFR) Part 194.27 and conducted under the responsibility of the ORC for support of compliance demonstration and compliance applications pursuant to 40 CFR Part 191. This procedure shall be used for the following elements of the compliance application: conceptual models (40 CFR Paragraph 194.27(a)(1)), waste characterization analyses (40 CFR Paragraph 194.27(a)(2)), and engineered barriers (40 CFR Paragraph 194.27(a)(3)). This procedure shall be controlled in accordance with the Carlsbad Area Office (CAO) procedure for document control.

3.0 PROCEDURE

3.1 SELECTION OF PEER REVIEW PANEL MEMBERS

3.1.1 Education, Experience, and Verification Requirements

- a. The acceptability of any peer review panel member is based on two requirements; technical qualifications and independence, both of which shall be satisfied. Peer review panel member independence is addressed in Section 3.1.2. The technical qualifications of the peer reviewer, 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 of the peer reviewer. The peer reviewer shall have recognized and verifiable technical credentials in the technical area he or she has been selected to cover. The technical qualifications of each peer reviewer, 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 education and pertinent experience is verified and documented on a Peer Review Panel Member Verification of Education /Employment Form, Attachment I, prior to the start of the peer review process and that these completed forms are retained as quality assurance (QA) records in accordance with Section 6.0 of this procedure.

form shall be maintained as a QA Record in accordance with Section 6.0 of this procedure.

- e. Copies of the Peer Review Panel Selection, Size and Composition Justification/Decision Forms are to be transferred to the appropriate contracting officer to issue contracts for the services of the peer review panel members as needed. Contracting documents are to be included with the QA Records in accordance with Section 6.0.

3.2 TRAINING OF PEER REVIEW PANEL MEMBERS

- 3.2.1 The peer review manager shall ensure that all peer review panel members have been adequately trained prior to performing their assigned work.
- 3.2.2 Training shall take the form of reading assignments, augmented by briefings and classroom training as deemed necessary by the peer review manager.
- 3.2.3 As a minimum, assigned reading shall include:
 - a. 40 CFR Part 191, as amended on December 20, 1993
 - b. 40 CFR Part 194 dated February 9, 1996
 - c. NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories, published February 1988
 - d. CAO Quality Assurance Program Description (QAPD) (CAO-94-1012), latest revision
 - e. Applicable Peer Review Plans
 - f. This procedure
- 3.2.4 Training of peer review panel members shall be documented on the Peer Review Panel Member Training Form, Attachment IV, and shall be maintained as a QA Record in accordance with Section 6.0 of this procedure.

3.3 INTERFACE REQUIREMENTS

Observer protocol shall be maintained during the peer review process. Observer protocol guidelines are described in Attachment V.

3.4 PEER REVIEW PROCESS

3.4.1 Peer Review Plan

- a. The peer review manager shall ensure that a peer review plan is prepared and approved prior to the performance of each peer review. The peer review plan will be developed to meet the peer review technical requirements documents.

- b. The peer review plan shall contain, as a minimum:
- The scope of the peer review
 - Description of the work to be reviewed
 - Intended use of the work in performance assessment
 - Size and composition of the peer review panel
 - Suggested methods (e.g., the method used to document observations, comments, and conclusions)
 - Schedule to arrive at the peer review report

3.4.2 Peer Review Panel Orientation

- a. All peer review panel members shall receive an orientation prior to the start of the peer review process.
- b. As a minimum, the orientation shall cover the following subjects or documents:
- The peer review process including administrative requirements
 - The applicable peer review plan
 - A brief summary of the peer review technical subject matter which may include a briefing by the cognizant scientist or engineer responsible for the study being reviewed
 - An overview of the requirements of this procedure
 - Any other appropriate topic
- c. After conducting the orientation, the peer review panel leader shall complete a Peer Review Panel Orientation Form (Attachment VI), obtain the signatures of the attendees, and ensure that the form is maintained as a QA record in accordance with the requirements of Section 6.0 of this procedure.

3.4.3 Peer Review Process

- a. Peer reviews shall be conducted in accordance with the guidance provided in the peer review management plan and subject matter peer review plans. Major changes to any of these peer review plans require the same review and approval process as the original. The peer review manager can approve minor changes to the subject matter peer review plans.
- b. The peer review process shall consist of an in-depth analysis and evaluation of documented assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work in accordance with all requirements.
- c. The peer review panel shall evaluate and report on:
- Adequacy of requirements and criteria
 - Validity of assumptions
 - Alternate interpretations
 - Uncertainty of results and consequences if wrong
 - Appropriateness and limitations of methodology and procedures
 - Adequacy of application
 - Accuracy of calculations
 - Validity of conclusions

- d. Full and frank discussions between the peer reviewers and the performers of the work are encouraged.

3.4.4 Meetings, Deliberations, and Activities Written Minutes

- a. Written minutes including graphic or calculated materials utilized in the meeting shall be prepared for meetings, deliberations, and activities of the peer review panel.
- b. Written minutes shall be maintained as QA records in accordance with Section 6.0 of this procedure.

3.4.5 Peer Review Daily Caucus

- a. When peer review activities are conducted, the peer review panel leader shall schedule and conduct daily caucuses of the peer review panel to address issues, concerns, questions, conflicts, etc. The peer review panel leader shall resolve caucus issues, concerns, questions, conflicts, etc.
- b. The peer review panel leader shall ensure that written caucus minutes are maintained as QA records in accordance with Section 6.0.

3.4.6 Peer Review Report

The Peer Review Report shall as a minimum:

- a. Be signed by each peer review panel member individually
- 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 potential technical and/or organizational partiality

3.5 QUALITY ASSURANCE ASSESSMENTS

- 3.5.1 The CAO QA Manager shall conduct assessments of the peer review process to ensure that all aspects of the peer review conform to the guidance of NUREG 1297, this procedure, and the latest version of CAO QAPD (CAO-94-1012).
- 3.5.2 The peer review manager shall promptly address and resolve any assessment findings. Resolution of the findings will include an assessment of the impact of the finding(s) on completed and ongoing peer reviews.

4.0 REFERENCES AND DEFINITIONS

4.1 REFERENCES

- 4.1.1 40 CFR Part 191, as amended on December 20, 1993
- 4.1.2 40 CFR Part 194, dated February 9, 1996

- 4.1.3 NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories, published February 1988
- 4.1.4 CAO QAPD (CAO-94-1012)
- 4.1.5 CAO Management Procedure (MP) 4.1, Preparation and Maintenance of CAO Procedures
- 4.1.6 CAO MP 4.2, Document Review
- 4.1.7 CAO MP 10.2, Surveillances
- 4.1.8 CAO MP 10.3, Audits
- 4.1.9 CAO MP 4.4, Document Preparation and Control

4.2 DEFINITIONS

Refer to the CAO QAPD Glossary of Terms (see Reference 4.1.4)

- 4.2.1 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.
- 4.2.2 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 work.
- 4.2.3 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.
- 4.2.4 Peer Review Manager - The administrative manager of the Peer Review process.
- 4.2.5 Peer Review Observer Protocol - A documented instruction which provides guidance to observer interaction with the Peer Review participants.
- 4.2.6 Peer Review Process Observers - Representatives of regulatory entities, CAO, and other CAO participant organizations with the express need to observe the Peer Review process.
- 4.2.7 Peer Review Report - A documented in-depth report of the proceedings and findings of a Peer Review.

5.0 RESPONSIBILITIES

5.1 CAO ASSISTANT MANAGER, OFFICE OF REGULATORY COMPLIANCE (ORC) shall:

- Request a contract (or contract modification) for conducting peer reviews consistent with this procedure
- Ensure the timely development of the peer review plans and other documents that govern the conduct of peer reviews
- Approve all relevant peer review planning and controlling documents

- Appoint and delegate (in writing) the ORC peer review coordinator
- Appoint the peer review manager (if contractually appropriate)
- Ensure that peer reviews are conducted in a timely and effective manner and that the process and results have been duly influenced by the interfaces.

5.2 ORC PEER REVIEW COORDINATOR shall:

- Ensure that the scope of work associated with each peer review is adequately defined
- Ensure that information and data required to support the peer review is assembled and collated in a timely manner
- Ensure that the peer review plan is developed, documented, and approved in a timely manner
- Ensure that the peer review is implemented and documented in accordance with prescribed schedules
- Provide the required interfaces to ensure an effective and responsive flow of information and logistic support for the effective, independent, and timely conduct of the peer review process

5.3 PEER REVIEW MANAGER shall:

- Ensure that the required peer review plans are developed to meet the peer review technical requirements in a timely manner
- Establish the make-up and size of the peer review panel. The peer review Manager shall select peer review panel members based on their documented technical expertise, their ability to review the technical requirements as defined in the peer review technical requirements documents, and their independence as described in Section 3.1.2 of this procedure
- Ensure that all forms are completed prior to the start of the peer review process
- Appoint the peer review panel leader
- Be responsible for training and for the administrative orientation and documentation of the peer review panel members
- Ensure that the peer review implementation is accomplished and documented in accordance with approved technical and QA requirements and in an effective and timely manner
- Ensure that adequate resources are provided in compliance with contractual requirements and in a timely manner
- Provide the required coordination between the peer review panels and the ORC peer review coordinator to ensure that an effective and responsive flow of information and logistic/technical support are provided
- Provide the ORC peer review coordinator with periodic progress reports on the status of peer review progress against prescribed schedules

- Retain QA records until completion of the peer review process in accordance with the requirements of NQA-1-1989. Upon completion of the peer review process, the QA records shall be delivered to Project Records Services (PRS) for retention.

5.4 PEER REVIEW PANEL LEADER shall:

- Conduct the peer review panel technical orientation and ensure that all necessary training has been completed prior to the start of the peer review process in accordance with the requirements of Sections 3.2 and 3.4 of this procedure
- Assign peer review panel members to specific review tasks and activities
- Manage peer review panel activities in accordance with applicable procedures and peer review plan(s) to ensure adequate review of all aspects of the work to be reviewed
- Ensure that written minutes are prepared for meetings, deliberations, and activities during the peer review process
- Manage the documentation to the peer review panel findings and the development of draft and final peer review report(s)
- Assist the peer review manager in resolution of any CAO assessment findings of peer review activities
- Identify and assemble QA records, ensure completeness of the records, and deliver the QA records to the peer review manager

5.5 EACH PEER REVIEW PANEL MEMBER shall:

- Complete and document the necessary training prior to the start of the peer review process
- Perform an in-depth critique of documented assumptions, calculations, extrapolations, alternate interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work in accordance with approved technical and quality assurance requirements, and the applicable peer review plan(s)
- Interact with other peer review panel members to ensure that sufficient consideration is given to interdisciplinary and coupled data and information
- Prepare peer review report(s) on those specific areas reviewed
- Sign the peer review final report to show concurrence

5.6 CAO QA MANAGER shall at a minimum, be responsible for the overall assessment of the peer review process.

6.0 RECORDS

- 6.1 QA records shall be retained by the peer review manager until completion of the peer review process. Duplicate records shall be generated and maintained at separate facilities. Upon completion of the peer review process, the QA records shall be delivered to PRS for retention.

6.2 QA records to be retained, as a minimum, are:

- Peer Review Plans (Management and Subject Matter)
- Peer Review Panel Member Verification of Education/Employment Form
- Determination of Peer Review Panel Member Independence Form
- Peer Review Panel Size and Composition Justification/Decision Form
- Peer Review Panel Member contracting documentation
- Peer Review Panel Member Training Form
- Peer Review Panel Orientation Form
- Written minutes of meetings, deliberations, and activities
- Peer Review Report(s).

7.0 **ATTACHMENTS**

- Attachment I Example of Peer Review Panel Member Verification of Education / Employment Form
- Attachment II Example of Determination of Peer Review Panel Member Independence Form
- Attachment III Example of Peer Review Panel Size and Composition Justification/Decision Form
- Attachment IV Example of Peer Review Panel Member Training Form
- Attachment V Example of Peer Review Observer Protocol
- Attachment VI Example of Peer Review Panel Orientation Form

Example of Peer Review Panel Member Verification of Education/Employment Form

My signature verifies that the information contained in this resume is correct. You are hereby authorized to verify this information.

Printed Name: _____ Social Security #: _____ - _____ - _____

Signature: _____ Date: _____

EDUCATION (Please list Educational Institution, degree[s], discipline[s]/subject[s], year[s], and contact person and phone number):

Contact/Title: _____ Phone#: _____

EMPLOYMENT HISTORY (Please list a contact person and phone number for each place of employment for the previous ten (10) years):

Employer: _____

Contact/Title: _____ Phone# : _____

Responsibilities (in general terms): _____ Years: _____

Comments: _____

Verified by: _____ Date: _____

Employer: _____

Contact/Title: _____ Phone#: _____

Responsibilities (in general terms): _____ Years: _____

Comments: _____

Verified by: _____ Date: _____

Example of Determination of Peer Review Panel Member Independence Form

Are you currently employed by DOE or DOE Contractor? Yes/No

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

If yes, give dates, location, company, position, and type of work performed.

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

If yes, describe the involvement.

I hereby certify that the above information is complete and correct to the best of my knowledge. I was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, I have sufficient freedom from funding considerations to ensure the work is impartially reviewed.

Signature: _____

Print Name: _____

Date: _____

ATTACHMENT III

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Example of Peer Review Panel Selection, Size, and Composition Justification/Decision Form

Selection Committee members:

for the Peer Review entitled:

have determined the Peer Review Panel size and 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:

Example of Peer Review Panel Member Training Form

I, _____ have read and understand the following documents:

- a. 40 CFR Part 191, as amended on December 20, 1993;
- b.. 40 CFR Part 194 dated February 9, 1996;
- c. NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories, published February 1988;
- d. DOE CAO Quality Assurance Program Description (QAPD) (CAO-94-1012), latest revision:
- e. DOE-CAO Team Procedure TP 10.5, Peer Review; and
- f. Applicable Peer Review Plan.

Signature:

Print Name:

Date:

Peer Review Manager:

Print Name:

Date:

ATTACHMENT V

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Peer Review Observer Protocol**GENERAL**

1. The purpose for observers in the Peer Review process is to allow the observers to understand and personally observe how the process is implemented. Additionally, Peer Review observers are encouraged to provide suggestions in writing to the Peer Review Manager which may improve the Peer Review process.
2. Observers are not active participants in the Peer Review process. They are welcome to observe the process, however communication with Peer Review Panel members is disallowed. The Peer Review Panel Leader is responsible for the conduct of the Peer Review and will maintain control of the Peer Review process. Observer questions, feedback, and recommendations are welcome and should be directed to the Peer Review Manager or the Peer Review Panel Leader during breaks and other designated times.
3. Internal observers are Waste Isolation Pilot Plant (WIPP) project participants, e.g., Carlsbad Area Office (CAO), Westinghouse Waste Isolation Division (WID), Sandia National Laboratories (SNL), and CAO employees. External observers, such as employees of the U.S. Environmental Protection Agency (EPA), State of New Mexico, etc. are considered guests of the CAO.
4. All observers will be treated professionally in accordance with this protocol.

PLANNING

1. The Peer Review Manager will provide the Peer Review Coordinator with updates of the Peer Review schedule with specific dates for each review.
2. The Peer Review Manager will provide the CAO Assistant Manager with advanced information concerning scheduled peer reviews and updates of the Peer Review schedule with specific dates for each review. The CAO will pass this information on to interested observers, as requested.
3. CAO will make every effort to notify the Peer Review Manager in advance of observers. CAO will provide names, organization affiliation, and any required security information.
4. The CAO will serve as the interface with internal and external observers. CAO will coordinate logistics with the Peer Review Manager and the observers.

CONDUCT

1. The Peer Review Manager or the Peer Review Panel Leader will ensure that all internal and external observers are introduced in the pre-review meeting and dealt with professionally.
2. The Peer Review Manager or the Peer Review Panel Leader will provide observers with a brief introduction, summary of the objectives of the review, and expectations for observer conduct.
3. Observers will be requested to hold their questions until breaks and then address them to the Peer Review Manager or the Peer Review Panel Leader. The observers should limit their questions to issues directly related to the information/data being reviewed. The Peer Review Panel Leader will document observer questions and Peer Review Panel responses as written minutes and retain same as a QA Record.

