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.

Submitted in accordance with 40 CFR §194.13, Submission of Reference Materials.

	I PROCEDURE Area Office
Title: PEER REVIEW	
Assistant Manager, Office of Regulatory Compliance, Carlsba	ad Area Office
1.0 <u>PURPOSE</u>	
This procedure prescribes the responsibilities, requir performance of peer reviews conducted by the Office o	ements, and methodologies to be incorporated in the frequencies of the frequency compliance (ORC) in support of the Waste

2.0 <u>SCOPE</u>

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.

Isolation Pilot Plant (WIPP) compliance demonstration and applications. This procedure was developed in accordance

3.0 <u>PROCEDURE</u>

3.1 SELECTION OF PEER REVIEW PANEL MEMBERS

with and implements the guidance in NUREG-1297.

- 3.1.1 Education, Experience, and Venfication 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.

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			shall be maintained as a QA Record in a	accordance with Section 6.0 of this
		Justi office need	es of the Peer Review Panel Se fication/Decision Forms are to be transfe er to issue contracts for the services of t led. Contracting documents are to be rdance with Section 6.0.	rred to the appropriate contracting he peer review panel members as
3.2	TRAIN	NING OF PEER	REVIEW PANEL MEMBERS	
	3.2.1		view manager shall ensure that all peer ained prior to performing their assigned w	
	3.2.2	-	take the form of reading assignments, aug emed necessary by the peer review man	· •
	3.2.3	As a minimun	n, assigned reading shall include:	
		a. 40 Cl	FR Part 191, as amended on December 2	20, 1993
		b. 40 Cl	FR Part 194 dated February 9, 1996	
			EG-1297, Peer Review for High-Level Nucl Jary 1988	ear Waste Repositories, published
4		d. CAO revisi	Quality Assurance Program Descriptio on	n (QAPD) (CAO-94-1012), latest
		e. Applio	cable Peer Review Plans	
		f. This p	procedure	
·	3.2.4	Member Trail	er review panel members shall be docur ning Form, Attachment IV, and shall be ith Section 6.0 of this procedure.	
3.3	INTER	FACE REQUIR	EMENTS	
		er protocol shall scribed in Attacl	be maintained during the peer review proc nment V.	ess. Observer protocol guidelines
3.4	PEER	REVIEW PROC	ESS	
	3.4.1	Peer Review F	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.

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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

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				nd frank discu are encourage	•	eviewers and the performers of the
Į		3.4.4	Meetings, Deliberations, and Activities Written Minutes			
				be prepared f	•••	ed materials utilized in the meeting s, and activities of the peer review
				n minutes shall procedure.	be maintained as QA reco	ords in accordance with Section 6.0
		3.4.5	Peer Review I	Daily Caucus		
			sched conce	ule and conductions, questions	ct daily caucuses of the pe	he peer review panel leader shall er review panel to address issues, review panel leader shall resolve etc.
					anel leader shall ensure cords in accordance with	that written caucus minutes are Section 6.0.
		3.4.6	Peer Review F	Report		
-			The Peer Revi	ew Report sha	II as a minimum:	
			b. Descri c. Descri d. Provid dissen e. List th techni	be the work or be the conclus le individual s ting views or a e peer review cal qualificatio	dditional comments, as an panel members and prov	review panel review panel members reflecting
	3.5	QUALI	TY ASSURANC	E ASSESSME	NTS	
		3.5.1	all aspects of th	e peer review c		peer review process to ensure that NUREG 1297, this procedure, and
•		3.5.2		he findings wi	Il include an assessment	resolve any assessment findings. of the impact of the finding(s) on
4.0	<u>REFE</u>	RENCES		<u>ons</u>		
	4.1	REFER	ENCES			

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

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	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	DEFIN	ITIONS
	Refer to	o the CAO QAPD Glossary of Terms (see Reference 4.1.4)
	4.2.1	<u>Peer</u> - 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	<u>Peer Review</u> - 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	<u>Peer Review Panel</u> - 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	<u>Peer Review Observer Protocol</u> - A documented instruction which provides guidance to observer interaction with the Peer Review participants.
	4.2.6	<u>Peer Review Process Observers</u> - Representatives of regulatory entities, CAO, and other CAO participant organizations with the express need to observe the Peer Review process.
	4.2.7	<u>Peer Review Report</u> - A documented in-depth report of the proceedings and findings of a Peer Review.
RESPO	<u>DNSIBIL</u>	ITIES
5.1	<u>CAO A</u>	SSISTANT MANAGER, OFFICE OF REGULATORY COMPLIANCE (ORC) shall:
	•	Request a contract (or contract modification) for conducting peer reviews consistent with this procedure
	RESPO	4.1.4 4.1.5 4.1.6 4.1.7 4.1.8 4.1.9 4.2 DEFINI Refer to 4.2.1 4.2.2 4.2.2 4.2.3 4.2.4 4.2.5 4.2.6 4.2.5 4.2.6 4.2.7 RESPONSIBIL

- 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

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	Appoint a	and delegate (in writing) the ORC pee	er review coordinator
	Appoint tl	he peer review manager (if contractua	ally appropriate)
	• Ensure th		a timely and effective manner and that the
5.2	ORC PEER REVI	EW COORDINATOR shall:	
	• Ensure th	nat the scope of work associated with	each peer review is adequately defined
		nat information and data required to s n a timely manner	support the peer review is assembled and
	 Ensure th manner 	nat the peer review plan is develope	d, documented, and approved in a timely
	 Ensure that schedules 		documented in accordance with prescribed
		•	tive and responsive flow of information and I timely conduct of the peer review process
5.3	PEER REVIEW M	ANAGER shall:	
		at the required peer review plans are de ents in a timely manner	eveloped to meet the peer review technical
•	select pee ability to	er review panel members based on the review the technical requirements ants documents, and their independe	iew panel. The peer review Manager shall heir documented technical expertise, their as defined in the peer review technical ence as described in Section 3.1.2 of this
	Ensure that	at all forms are completed prior to the	start of the peer review process
	Appoint the	e peer review panel leader	
		sible for training and for the administra w panel members	ative orientation and documentation of the
			n is accomplished and documented in equirements and in an effective and timely
		t adequate resources are provided in nely manner	compliance with contractual requirements
	coordinato		er review panels and the ORC peer review Id responsive flow of information and
		e ORC peer review coordinator with v progress against prescribed schedu	periodic progress reports on the status of ules

 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 <u>PEER REVIEW PANEL LEADER shall:</u>

- 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 <u>CAO QA MANAGER shall</u> at a minimum, be responsible for the overall assessment of the peer review process.

6.0 <u>RECORDS</u>

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.

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	6.2 QA re	cords to be retained, as a minimum, are:
	• • • • •	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	ATTACHMEN	<u>TS</u>
	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

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Example of Peer Review	Panel Member Verification of Education	ion/Employment Form
My signature verifies that the information information.	on contained in this resume is correct. Yo	u are hereby authorized to verify this
Printed Name:	Social Security #:	
Signature:	Date:	
EDUCATION (Please list Educational Ir number):	nstitution, degree[s], discipline[s]/subject[s],	year[s], and contact person and phone
Contact/Title:	Phone#:	
EMPLOYMENT HISTORY (Please list a c (10) years):	contact person and phone number for each pl	ace of employment for the previous ten
Employer:		
Contact/Title:	Phone# :	
Responsibilities (in general terms):		Years:
Comments:		
Verified by:	Date	e:
Employer:		
Contact/Title:		ne#:
Responsibilities (in general terms):		Years:
Comments:		
Verified by:	Date	e:

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Example of Determ	ination of Peer Review Panel Memb	er Independence Form
Are you currently employed by DOE	E or DOE Contractor?	Yes/No
Were you employed by DOE or a D	OE Contractor previously?	Yes/No
If yes, give dates, location, company	y, position, and type of work performed	i.
	• •	
Do you or have you had any direct in in the work under review?	nvolvement or financial interest	Yes/No
If yes, describe the involvement.		
•		
as a participant, supervisor, technica		t of my knowledge. I was not involved g reviewed, and to the extent practical, impartially reviewed.
Signature:	· · · · · · · · · · · · · · · · · · ·	
Print Name:		
Date:		

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Example of Peer Review Pa	nel Selection, Size, and Composition Ju	stification/Decision Form
Selection Committee members:		
for the Peer Review entitled:		
have determined the Peer Review P	anel size and composition to be as follows	:
1. 2 3. 4. 5. 6. 7. 8. 9. 10. The justification for this determination	n is:	
Date:		
Selection Committee signatures:		

			Nie Marzen gewannen werden in der Bergen werden einen vorden einen einen einen einen einen einen einen einen ein
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Example	of Peer Review Panel Me	ember Training	ATTACHMENT IV Page 1 of 1 Form
1,	have read and under	stand the followi	ng documents:
b 40 CFR Part 194 date c. NUREG-1297, Peer F 1988; d. DOE CAO Quality As	Review for High-Level Nuc surance Program Descrip cedure TP 10.5. Peer Revi	lear Waste Rep ion (QAPD) (CA	ositories, published February O-94-1012), latest revision:
Signature:			
Print Name:			
Date:			
Peer Review Manager:			
Print Name:			
Date:			
•			

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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.
- 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.

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	Example of Peer Review Panel Orientation	
Date: Peer R	Review Panel Leader:	<u> </u>
Peer Review Subject or Title:		
Attendees:	• • • • • •	
NAME	SIGNATURE	DATE
		·
	<u> </u>	
	<u> </u>	
	· <u> </u>	