

## **CARD No. 27**

### **Peer Review**

#### 27.A.1 BACKGROUND

The Compliance Criteria require DOE to conduct peer review of certain elements of the WIPP so that others working in the field of radioactive waste disposal can confirm the adequacy of various decisions and interpretations made by DOE in its Compliance Certification Application (CCA) (61 FR 5228). EPA imposed specific requirements for the conduct of peer review. These requirements are intended to ensure that EPA can be satisfied that the peer review processes at WIPP are sufficient to assess the scientific premises on which the performance assessments are based; see EPA's Background Information Document for 40 CFR 194, p. 7-2 (EPA 1996). EPA's review of DOE's compliance with the requirements of Section 194.27 principally focuses on process. The Compliance Criteria require that the peer reviews identified by Section 194.27(a) be conducted in a manner compatible with NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (40 CFR 194.27(b)) (NRC 1988). Also, DOE must demonstrate that any peer reviews conducted prior to issuance of the Compliance Criteria were conducted in accordance with a process that is substantially equivalent to NUREG-1297 (40 CFR 194.27(c)).

The requirements in Section 194.27 pertain to all peer reviews described in the CCA except the Engineered Systems, Natural Barriers, and Waste Form and Disposal Room Data Qualifications peer reviews. These three peer reviews were conducted by DOE in accordance with Section 194.22(b) which provides that peer review conducted "in a manner compatible with NUREG-1297. . . may be used to qualify data and information collected prior to the promulgation of the final compliance criteria." This CARD does not address the technical aspects of the various DOE peer reviews, e.g., whether DOE established the appropriate scope for peer reviews, presented correct technical information to peer review panels, or responded to panel findings in an acceptable manner. These issues are addressed in the CARDS for the relevant subject areas. See **CARD 22—Quality Assurance, CARD 23—Models and Computer Codes, CARD 24—Waste Characterization, and CARD 44—Engineered Barriers.**

Also, the criterion at Section 194.23(a)(3)(v) specifies that "conceptual models [must undergo] peer review according to Section 194.27." In practice DOE used the same procedure—i.e., one compatible with NUREG-1297—for all peer reviews conducted after the issuance of 40 CFR 194. Therefore, EPA's assessment of whether DOE's implementation of NUREG-1297 meets the Section 194.27 regulatory requirements may be considered generic for the purpose of evaluating compliance with Sections 194.22(b), 194.23(a)(3)(v), and 194.27.

#### 27.A.2 REQUIREMENT

(a) "Any compliance application shall include documentation of peer review that has been conducted, in a manner required by this section, for: (1) Conceptual models selected and developed by the Department; (2) Waste characterization analyses as required in §194.24(b); and (3) Engineered barrier evaluation as required in §194.44."

### 27.A.3 COMPLIANCE REVIEW CRITERIA

EPA's Compliance Application Guidance (CAG) for the WIPP recommends that DOE document peer reviews in a separate chapter from the chapters addressing conceptual models, waste characterization, and engineered barriers (p. 41). In addition, the peer review of engineered barriers should include all alternatives considered, whether or not they were accepted by DOE.

### 27.A.4 EPA COMPLIANCE REVIEW

DOE completed the required peer reviews and included a description of its peer review process in Chapter 9 and Appendix PEER. For a discussion of the technical aspects and findings of these peer reviews, refer to **CARD 22—Quality Assurance**, **CARD 23—Models and Computer Codes**, **CARD 24—Waste Characterization**, and **CARD 44—Engineered Barriers**. Whether the required peer reviews were conducted “in a manner required by this section” is discussed below under Section 194.27(b).

### 27.B.1 REQUIREMENT

(b) “Peer review processes required in paragraph (a) of this section, and conducted subsequent to the promulgation of this part, shall be conducted in a manner that is compatible with NUREG-1297, “Peer Review for High-Level Nuclear Waste Repositories,” published February 1988. (Incorporation by reference as specified in §194.5.)”

### 27.B.2 ABSTRACT

The CCA contains documentation demonstrating that DOE's procedures and plans for the required peer reviews are compatible with NUREG-1297. Peer reviews conducted after promulgation of 40 CFR 194, and intended to demonstrate compliance with Section 194.27, were subject to the requirements of the pertinent procedures and plans. Many of the documents detailing NUREG-1297's implementation are kept as quality assurance (QA) records, and for this reason were not included in the application. To assess the peer review process further, EPA conducted an audit of DOE's QA records for peer review. The audit consisted of an extensive review of DOE's records and interviews of DOE staff and contractors responsible for management of the required peer reviews. The audit raised seven findings,<sup>1</sup> but none of these was sufficient to lead EPA to conclude that any of the required peer reviews had been conducted in a manner incompatible with NUREG-1297.

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<sup>1</sup> A finding is a determination that a specific activity does not meet a Nuclear Quality Assurance requirement or the CAO Quality Assurance Program Document, or fails to implement a procedural requirement properly. In this instance the findings were isolated and of low consequence.

### 27.B.3 COMPLIANCE REVIEW CRITERIA

EPA's CAG called for DOE to provide documentation of peer reviews showing:

- ◆□ The structure of the peer review group, including how relevant technical disciplines are represented.
- ◆□ The technical qualifications of peer reviewers.
- ◆□ The independence of the peer reviewers from the original work, including the rationale why someone with greater independence was not selected, if necessary.
- ◆□ The peer review process, including how issues are presented to peer reviewers.
- ◆□ The conclusions of the peer reviewers, including dissenting views if they exist.
- ◆□ How DOE incorporates these conclusions.

This list incorporates the essential elements of the general guidance provided in NUREG-1297. EPA expected the CCA to describe the procedure developed by DOE to implement NUREG-1297, and to demonstrate that the required peer reviews were conducted through DOE's prescribed procedure.

### 27.B.4 DOE METHODOLOGY AND CONCLUSIONS

Chapter 9 of the CCA discusses DOE's peer review process. It provides: (1) a general overview of the management and documentation of the peer reviews required in Section 194.27(a); (2) brief biographies of the peer review panels; and (3) discussions of specific issues raised by the panels. Also, a plan and final report for each peer review conducted in the spring and summer of 1996 are provided in Appendix PEER.

The guiding documents for the conduct of peer reviews are the Carlsbad Area Office (CAO) Management Plan for Peer Review and the CAO Team Procedure (TP) 10.5 for Peer Review, both of which were issued in March 1996 and are included as references in the CCA. The Management Plan describes DOE's approach to peer review in general terms, identifies the topics for peer review, and establishes a preliminary schedule. TP 10.5 addresses in specific terms how the recommendations of NUREG-1297 are to be implemented in regard to selection of panel members, peer review process, and documentation. TP 10.5 also requires a Peer Review Plan for each peer review and explains the responsibilities of the peer review manager, coordinator, and panel members. Individual Peer Review Plans describe in greater detail the issues (i.e., scope) to be addressed by a peer review. Peer Review Plans are included in the application in Appendix PEER.

To address numerous negative findings by various peer review panels, DOE revised the Peer Review Plans, Management Plan, and TP 10.5 in October-November 1996 to permit peer reviews to be reopened for consideration of additional information from DOE.

The Conceptual Models Peer Review Panel began work in early April 1996. The Panel reviewed 24 conceptual models, of which 13 were deemed adequate for use in the performance assessment. Eleven conceptual models were deemed inadequate for use in the performance assessment. DOE reconvened the Conceptual Models Peer Review in October 1996. DOE presented revised models, specific responses to certain of the Panel's earlier findings, and information that had been subsequently included in the CCA. Based on these factors, the Panel determined that 9 additional conceptual models were adequate for use in the performance assessment. Two conceptual models still were deemed inadequate for use in the performance assessment.

DOE reconvened the Conceptual Models Peer Review Panel a second time in January 1997. The Conceptual Models Peer Review again concluded that the remaining two conceptual models, Spallings and Chemical Conditions, were inadequate for use in the performance assessment. DOE reconvened the Conceptual Models Peer Review for a fourth time in April 1997. Based on new experimental data related to the use of magnesium oxide (MgO) as backfill, the panel concluded that the Chemical Conditions model was adequate. DOE specifically did not request the Panel to assess the adequacy of the Spallings model. Rather, DOE presented additional information to the Panel, and asked whether, based on this new information, the results predicted by these inadequate conceptual models were "reasonable." The Conceptual Models Peer Review Panel stated that, although it continued to find the Spallings model inadequate to meet the regulatory requirements, the predicted results are reasonable. See Section 194.23(a)(3)(v) in **CARD 23—Models and Computer Codes** for further discussion of the panel's findings.

The initial Waste Characterization Peer Review panel convened in July - August 1996. The Panel identified several deficiencies in DOE's waste characterization analysis. DOE reconvened the Waste Characterization Peer Review in November 1996 to permit DOE to present additional information to the panel in response to their findings in the initial Peer Review Report. The Panel concluded that all identified deficiencies were satisfactorily addressed.

The Engineered Barriers Peer Review convened in April - May 1996. The Panel did not identify any major deficiencies necessitating reconvening of the peer review panel.

The general process for a peer review was as follows:

- ◆□ DOE developed a Peer Review Plan in accordance with TP 10.5.
- ◆□ DOE assigned a subcontractor to coordinate the peer review. Informatics, Inc. coordinated all peer reviews except for the Engineered Alternatives Cost-Benefit Study, which was coordinated by the Waste-Management Education & Research Consortium.

- ◆ □ DOE identified, contacted, and selected potential panel members. The qualifications and independence of the panel members, as well as their potential conflicts of interest, were required to be documented in accordance with the Management Plan and TP 10.5.
- ◆ □ Panel members received orientation, which involved reading background documents and listening to technical presentations. Panel members were trained in DOE's peer review procedures and NUREG-1297 before turning to the specific information under review. Interactions between the panel and others were controlled by the subcontractor's observer protocol. All meetings, except deliberations within the panel, were open to observers.
- ◆ □ The panel issued a report.

#### 27.B.5 EPA COMPLIANCE REVIEW

EPA began its review of DOE's compliance with Section 194.27(b) by examining the documents provided in Chapter 9, Appendix PEER, and the available supplemental reports sent by DOE. On the basis of these materials, EPA reached the following conclusions:

- ◆ The CCA contained documentation confirming that DOE had conducted the required peer reviews.
- ◆ The final reports contained both the issue(s) presented to the panels and the peer reviewers' conclusions.
- ◆ DOE's procedures for conducting peer reviewers (as represented by the Management Plan and TP 10.5) incorporated the essential elements of NUREG-1297, which are identified above in "Compliance Review Criteria."

In regard to the list presented above, EPA's comparison of NUREG-1297 with the information in the CCA raised a number of questions. Some arose due to the absence of documents that would clearly demonstrate DOE's implementation of NUREG-1297. Others pertained to specific aspects of DOE's procedures and the manner in which those procedures were implemented. Some of the questions raised by EPA's initial review of the CCA are listed below:

- ◆ DOE inconsistently provided documentation concerning panel members' organizational independence and freedom from conflicts of interest in the final reports. Many panel members had a current or previous association with DOE or DOE contractors, yet DOE provided no documents to show why someone of equivalent technical qualification and greater independence was not selected.

- ◆ □ Documentation concerning the selection of panel members (including representation of relevant technical disciplines) was absent. The composition of the selection committee(s) described in TP 10.5 was unknown.
- ◆ □ Brief biographical sketches of panel members were provided in lieu of curricula vitae.
- ◆ □ The Peer Review Management Plan did not address the peer review related to engineered barriers.
- ◆ □ For each major issue raised by a panel in their final report, Chapter 9 reproduces the issue, rephrases it, responds to it, and then paraphrases the reaction of the panel to DOE's response. DOE provided no documentation to corroborate panels' reactions as paraphrased.

It should be noted that EPA did not require in the compliance criteria that DOE submit specific documents in the CCA to demonstrate compliance. Chapter 9 indicates that documents addressing most of the items listed in Section 27.B.3 of this CARD are retained by DOE as QA records.

EPA conducted an audit of DOE's QA records for peer review in February 1997. The purpose of the audit was to verify that the appropriate records exist to confirm general statements made in the CCA that DOE had: (1) developed procedures to implement NUREG-1297 and (2) followed those procedures in conducting the required peer reviews. QA records for peer review are maintained at a DOE records center in Carlsbad, New Mexico, where the audit was conducted.<sup>2</sup> In cases where DOE had revised documents (e.g., Team Procedure 10.5), EPA considered the revised version in evaluating compliance. Records were examined for Conceptual Models, Waste Characterization, and Engineered Barriers, as well as for three exercises in the qualification of existing data (Engineered Systems, Natural Barriers, and Waste Form/Disposal Room). The reopening of the Conceptual Models Peer Review in April 1997 did not in any way compromise the results of this audit, because the audit was concerned with the overall process of peer review and not with the resolution of substantive technical issues resulting from any individual review.

EPA compared records for the required peer reviews with a 29-item checklist derived from NUREG-1297, 40 CFR 194, and the CAG. Panel members' resumes, panel selection decision forms, orientation and training forms, meeting minutes, attendance lists, and other documents were reviewed. The audit also involved interviews with DOE and contractor personnel responsible for managing the peer review.

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<sup>2</sup> The public may review records kept in DOE records centers. Instructions for access to DOE records centers may be found in EPA's Air Docket A-93-02, Item V-B-1.

EPA's audit confirmed that DOE had developed procedures that adequately implemented NUREG-1297, and that DOE had adequately followed those procedures. The audit resulted in seven findings, nine observations, three concerns, and two recommendations. Procedures, checklist, and results are listed in EPA's audit report (EPA 1997). The seven findings, which were of low consequence, pertained to DOE's implementation of its own procedures. Several findings pointed to inconsistencies or shortcomings in DOE's documentation of panel members' organizational and technical independence. However, the audit team found no evidence of any genuine conflict of interest on the part of a panel member.

Finally, the audit team was told by a CAO staff member that no QA records exist to corroborate statements in Chapter 9 under the subheading "Peer Reviewer Consideration of Response." Because DOE did not produce evidence during the audit that panels actually made the statements attributed to them, EPA disregarded the paraphrased statements in Chapter 9 for purposes of the compliance review. EPA considers final and supplemental reports from peer review panels to be their only official statements of findings.

#### 27.C.1 REQUIREMENT

(c) "Any compliance application shall:

(1) Include information that demonstrates that peer review processes required in paragraph (a) of this section, and conducted prior to the implementation of the promulgation of this part, were conducted in accordance with an alternate process substantially equivalent in effect to NUREG-1297 and approved by the Administrator or the Administrator's authorized representative."

#### 27.C.2 ABSTRACT

DOE did not rely on peer reviews conducted prior to promulgation of the final compliance criteria in order to comply with Section 194.27(a).

#### 27.D.1 REQUIREMENT

(c) "Any compliance application shall:

(2) Document any peer review processes conducted in addition to those required pursuant to paragraph (a) of this section. Such documentation shall include formal requests, from the Department to outside review groups of individuals, to review or comment on any information used to support compliance applications, and the responses from such groups or individuals."

#### 27.D.2 ABSTRACT

Section 194.27(c)(2) requires DOE to document all peer reviews other than those specified in Sections 194.27(a) and 194.22(b), including reviews that took place prior to promulgation of the final compliance criteria. EPA recognizes that past examinations of DOE's WIPP activities may be equivalent, if not identical, to peer review. DOE must document such

activities as part of the CCA. DOE's documentation should be sufficient to identify the purpose, scope, membership, and findings of a given peer review. DOE developed a list of criteria, based principally on guidance in NUREG-1297, to determine whether a past review activity constituted a peer review. Nineteen activities were identified as peer reviews and included in the CCA. EPA reviewed the materials provided and found that sixteen past review activities were appropriate for inclusion in the CCA to show compliance with Section 194.27(c)(2). The CCA contained sufficient documentation to allow EPA to discern the genesis and outcome of the sixteen historical peer review activities. However, formal requests from DOE to reviewers in the form of correspondence were not found in most instances.

### 27.D.3 COMPLIANCE REVIEW CRITERIA

In order to comply with this criterion, DOE was required to submit information in the CCA that accounts for any of the peer reviews it instigated other than those for conceptual models, waste characterization, and engineered barriers. (Note that Section 194.27(c)(2) is not applicable to peer reviews conducted in order to qualify existing data. Those peer reviews are associated with Section 194.22(b). See Section 27.A.1 of this CARD.) Section 194.27(c)(2) does not distinguish between peer reviews conducted before or after promulgation of the final compliance criteria. Review activities conducted prior to promulgation of 40 CFR 194 are referred to here as “past reviews” for the purpose of clarity.

Whether conducted before or after promulgation of 40 CFR 194, additional peer reviews would ideally be documented in a detailed manner similar to the peer reviews identified in Section 194.27(a). EPA recognizes that such detailed documentation may not be possible for peer reviews held before promulgation of the final compliance criteria, and so does not hold DOE strictly to that standard. Documentation of the past reviews and other peer reviews, however, should be sufficient to identify the purpose, scope, membership, and findings of a given review. In addition, the requirement specifies that DOE include in the CCA formal requests for review and the responses (i.e., findings) of reviewers.

### 27.D.4 DOE METHODOLOGY AND CONCLUSIONS

Documentation of sixteen past reviews, which were conducted before the promulgation of 40 CFR 194 in 1996, is provided in Chapter 9.4 of the CCA and in Appendix PEER. Another peer review related to passive institutional controls, which was conducted after the promulgation of the final compliance criteria, is described in Chapter 9.3.7 and Appendix PEER. Finally, two international peer reviews are discussed in Chapter 9.5.

Chapter 9.4 of the CCA provides criteria, in the form of questions, for determining whether or not a given past review activity constitutes a peer review and whether it should be included in the CCA. DOE derived the following criteria from 40 CFR 194 and NUREG-1297:

- ◆□ Was the peer review relevant to this application?
- ◆□ Was there a formal report by the reviewer?



- ◆□ Was the review a peer review rather than a technical review?
- ◆□ Was the review a peer review rather than an expert judgement?
- ◆□ Was the technical expertise of the reviewer at least that needed to perform the original work?
- ◆□ Were the reviewers independent?
- ◆□ If the answer to any of the above questions is no, is there an overriding consideration that would still serve to qualify the review as an appropriate and acceptable peer review for incorporation into the historical review section of the application?

In cases where an organization (e.g., the National Academy of Sciences or the Environmental Evaluation Group) conducted multiple reviews of DOE's work, DOE considered the reviews as a whole in answering the questions. DOE concluded that nineteen reviews or groups of reviews constitute peer reviews and merit inclusion in the CCA, because they involved issues or technical areas circumscribed by the compliance criteria.

#### 27.D.5 EPA COMPLIANCE REVIEW

Whether or not a past review activity constitutes a peer review depends principally on how the review was conducted. A peer review is a formalized process involving individuals who are not responsible for producing the material under review and who are independent of the source organization. Such individuals are therefore presumed to be free to comment objectively on its quality. The objectivity of peer reviewers, in both an institutional and technical sense, is very important.

By requiring DOE to follow NUREG-1297 guidance in conducting certain peer reviews, EPA prescribed in broad terms the process that must be followed. The specific process developed by DOE in 1996 in response to the compliance criteria was novel in its implementation of the general guidance in NUREG-1297. Thus, EPA does not expect past review activities to meet these strict guidelines.

DOE was faced with a number of external reviews related to its WIPP activities, in particular the performance assessment. DOE's criteria for determining whether a peer review activity warranted inclusion in the CCA are rooted in the definitions and procedures described in NUREG-1297. Given that NUREG-1297 constitutes the best available guidance for conducting peer reviews related to radioactive waste disposal systems, it was appropriate for DOE to apply NUREG-1297 in considering the extent to which previous external reviews constitute peer reviews.

DOE identifies passive institutional controls (PICs) peer review, sixteen past review activities, and two international peer reviews in Chapter 9. Because the PICs peer review was conducted in 1996 according to an elaborate, NUREG-based procedure, DOE did not treat it as a

past review activity. Nevertheless, a peer review for PICs was not specifically required by the compliance criteria and so falls into the category of Section 194.27(c)(2) for the purpose of EPA's evaluation.

DOE identifies the regulatory process associated with the National Environmental Policy Act (NEPA) as a past review activity. Documentation of the NEPA process, represented in large part by a Final Environmental Impact Statement for the WIPP, was not included in either Chapter 9 or Appendix PEER. EPA considers the NEPA regulatory process to be separate and distinct from the certification rulemaking, and so did not consider NEPA as appropriate for inclusion as a peer review in support of the CCA.

Of the two international peer reviews cited in Chapter 9.5, EPA considered only one—a joint review by the Nuclear Energy Agency and the International Atomic Energy Agency—to be appropriate for inclusion in the CCA. This peer review was begun in 1996 and concluded in April 1997 (the report is filed as Docket A-93-02, Item II-I-32). The other international peer review, GEOTRAP, was not considered by EPA in determining compliance with the requirement, since no information was provided beyond a very brief description in Chapter 9 and the peer review is ongoing.

Documentation of the sixteen past review activities in Appendix PEER consists almost solely of peer review findings, which are discussed in letters, reports, and testimony before Congress. Documentation regarding the qualifications and degree of independence of panel members, procedures governing conduct of the reviews, and DOE's treatment of findings generally is not provided. In addition, DOE did not include any letters or other documents that would constitute formal requests for peer reviews. In most cases, a final report (or reports) is provided, but in the case of the Performance Assessment Peer Review Panel there is only a summary memo from an employee of Sandia National Laboratory.

EPA cross-checked the descriptions of peer reviews in Chapter 9 with information in Appendix PEER and found that Chapter 9 accurately summarizes who the peer reviewers were, what they were asked to review, and the substance of their findings. Because the aim of EPA's review related to Section 194.27(c)(2) was to determine that DOE had documented additional peer reviews, not to determine if those peer reviews were conducted in accordance with NUREG-1297, EPA finds that the absence of the documentation identified above is not sufficient to compromise DOE's compliance with the requirement.

## 27.E REFERENCES

EPA 1996. U.S. Environmental Protection Agency. Background Information Document for 40 CFR Part 194. EPA 402-R-96-002. January 1996. (Docket A-92-56, Item V-B-1)

EPA 1997. Audit of the Peer Review Process Conducted by the Department of Energy, Carlsbad Area Office, Revision 0. 1997. (Docket A-93-02, Item II-A-46)

NRC 1988. Peer Review for High-Level Nuclear Waste Repositories: Generic Technical Position. NUREG-1297. U.S. Nuclear Regulatory Commission. Washington, DC. 1988. (CCA Reference #484)