26.A.1 BACKGROUND

The requirements of Section 194.26 apply to expert judgment elicitation, which is a process for obtaining data directly from experts in response to a technical problem. EPA prohibits expert judgment from being used in place of experimental data, unless DOE can justify why the necessary experiments cannot be conducted. Expert judgment may be used to support a compliance application, provided that it does not substitute for information that could reasonably be obtained through data collection or experimentation. Expert judgment may substitute for experimental data in those instances in which limitations of time, resources, or physical settings preclude the successful and timely collection of data.

The CCA submitted on October 29, 1997, did not identify any expert elicitation activities. However, during the Agency’s review of performance assessment (PA) parameters, EPA found that adequate information was not provided in the comprehensive parameter database on the derivation of 149 parameters identified in the CCA as resulting from professional judgment (e.g., code control parameters, physical constants, etc.). EPA requested in letters to DOE dated March 19, 1997 (Docket A-93-02, Item II-I-17), April 17, 1997 (Docket A-93-02, Item II-I-25), and April 25, 1997 (Docket A-93-02, Item II-I-27), that DOE provide additional information on the derivation of the 149 parameters. In the absence of data collection or experimentation, EPA expected DOE to derive these input parameters through expert elicitation.

DOE responded to EPA’s requests by adding information to and improving the quality of the records stored in the Sandia National Laboratory (SNL) Records Center to enhance the traceability of parameter values. EPA deemed the documentation provided by DOE adequate to demonstrate proper derivation of all but one of the 149 parameters, i.e., the waste particle size distribution parameter. The other 148 parameters questioned by EPA were found to have adequate documentation to support the values used in the CCA PA calculations. For a comprehensive discussion of the technical review of PA parameters, see Section 194.23(c)(4) in CARD 23—Models and Computer Codes.

EPA required DOE to use the process of expert elicitation to develop the value for the waste particle size distribution parameter (Docket A-93-02, Item II-I-27). The waste particle size distribution parameter is important in performance assessments because the distribution of waste particle diameters affects the quantity of radioactive materials released in spallings from inadvertent human intrusion. Because particle diameters are uncertain and cannot be estimated either directly from available data or from data collection or experimentation, the waste particle size distribution parameter had to be based on an elicitation of expert judgment.

DOE conducted the required expert judgment elicitation on May 5-9, 1997. EPA’s review of DOE’s compliance with the requirements of Section 194.26 focused on the performance of the expert elicitation process.
26.A.2 REQUIREMENT

(a) “Expert judgment, by an individual expert or panel of experts, may be used to support any compliance application, provided that expert judgment does not substitute for information that could reasonably be obtained through data collection or experimentation.

(b) Any compliance application shall:

(1) Identify any expert judgments used to support the application and shall identify experts (by name and employer) involved in any expert judgment elicitation processes used to support the application.

(2) Describe the process of eliciting expert judgment, and document the results of expert judgment elicitation processes and the reasoning behind those results. Documentation of interviews used to elicit judgments from experts, the questions or issues presented for elicitation of expert judgment, background information provided to experts, and deliberations and formal interactions among experts shall be provided. The opinions of all experts involved in each elicitation process shall be provided whether the opinions are used to support compliance applications or not.

(3) Provide documentation that the following restrictions and guidelines have been applied to any selection of individuals used to elicit expert judgments:

(i) Individuals who are members of the team of investigators requesting the judgment or the team of investigators who will use the judgment were not selected; and

(ii) Individuals who maintain, at any organizational level, a supervisory role or who are supervised by those who will utilize the judgment were not selected.

(4) Provide information which demonstrates that:

(i) The expertise of any individual involved in expert judgment elicitation comports with the level of knowledge required by the questions or issues presented to that individual; and

(ii) The expertise of any expert panel, as a whole, involved in expert judgment elicitation comports with the level and variety of knowledge required by the questions or issues presented to that panel.

(5) Explain the relationship among the information and issues presented to experts prior to the elicitation process, the elicited judgment of any expert panel or individual, and the purpose for which the expert judgment is being used in compliance application(s).
(6) Provide documentation that the initial purpose for which expert judgment was intended, as presented to the expert panel, is consistent with the purpose for which this judgment was used in compliance application(s).

(7) Provide documentation that the following restrictions and guidelines have been applied in eliciting expert judgment:

(i) At least five individuals shall be used in any expert elicitation process, unless there is a lack or unavailability of experts and a documented rationale is provided that explains why fewer than five individuals were selected.

(ii) At least two-thirds of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department’s contractors, unless the Department can demonstrate and document that there is a lack or unavailability of qualified independent experts. If so demonstrated, at least one-third of the experts involved in an elicitation shall consist of individuals who are not employed directly by the Department or by the Department’s contractors.

(c) The public shall be afforded a reasonable opportunity to present its scientific and technical views to expert panels as input to any expert elicitation process.”

26.A.3 ABSTRACT

The requirements of Section 194.26 apply to expert judgment elicitation. Expert judgment is typically used to elicit two types of information:

• Numerical values for parameters (variables) that are measurable only by experiments that cannot be conducted due to limitations of time, money, and physical situation; and

• Essentially unknowable information, such as which features incorporated into passive institutional controls will effectively deter human intrusion into the repository.

Quality assurance requirements, specifically those in Section 194.22(a)(2)(v), must be applied to any expert judgment to verify that the procedures for conducting and documenting the expert elicitation have been followed (61 FR 5228). For further information, see the discussion of Section 194.22(a)(2)(v) in CARD 22—Quality Assurance.

The CCA submitted on October 29, 1996, did not identify any expert elicitation activities. Upon review of PA parameters and data record packages supporting these parameters, EPA determined that the waste particle size distribution parameter was not supported by experimental or field data, or the data trail for the parameter was not traceable. Consequently, EPA directed DOE to conduct an expert judgment elicitation for the waste particle size distribution parameter.
EPA observed DOE’s expert judgment elicitation process and conducted an audit of the documentation prepared in support of DOE’s compliance with Section 194.26. The scope of the audit covered all aspects of the expert judgment elicitation process, including: panel meetings, management and team procedures, curricula vitae of panel members, background documents, and presentation materials. EPA also assessed compliance with the quality assurance requirements of Section 194.22(a)(2)(v) during the audit. EPA did not identify any findings, observations, or concerns during the audit of the expert judgment elicitation process; see EPA’s audit report (Docket A-93-02, Item II-A-47).

26.A.4 COMPLIANCE REVIEW CRITERIA

EPA’s Compliance Application Guidance for the Waste Isolation Pilot Plant: A Companion Guide to 40 CFR Part 194 (CAG, pp. 38-40) states that compliance with Section 194.26 can be demonstrated by an analysis that includes:

- Identification of places in the application where the results of any expert judgment elicitation were incorporated.
- An explanation of why data were not obtained, either by experimentation or from the results of previous experiments.
- An estimation of the time and level of effort that would have been required to obtain data experimentally, if applicable.

To describe the process of eliciting expert judgment, the CCA should provide:

- Documentation of all interviews with expert panel members conducted during the formal elicitation process.
- Any written material distributed to expert panel members by a facilitator.
- Copies of written summaries of responses given to the other experts (applies to the Delphi method) in cases where the responses of the experts were elicited individually by a facilitator (the Delphi method is an elicitation method developed by the Rand Corporation to limit the biasing effects of interactions).
- Documentation of any interactive sessions among the experts.
- Documentation of all presentations of technical evidence.
To demonstrate DOE’s application of the Section 194.26 restrictions and guidelines on the selection of panel members, the CAG recommended the CCA include a curriculum vitae for each expert panel member that lists, at a minimum:

- Past and present professional or contractual affiliations.
- Publications and abstracts.
- Work and educational experience.
- A history of research grants and monetary awards from DOE, including documentation of any honoraria received.
- A chart of the expert's employing organization demonstrating the expert's affiliation with any individuals within the organization who perform work relevant to the WIPP.

To document the relationship between the information and issues presented to the expert panel and the intended purpose of the judgment being sought, the CCA should:

- Document the question presented to the experts and provide a copy of any statement of the issue and any similar statement sent to the nominating and selection committees.
- Discuss the relationship of the final result of the expert judgment process to the statement of the issue presented to the experts, as incorporated into the compliance application.

To document DOE’s efforts to solicit experts who are not employed by DOE or its contractors, the CCA should:

- List all non-DOE employees and non-DOE contractors who were sent letters of nomination or otherwise solicited to participate on the panel.
- Document all responses to letters of solicitation by those potential participants.

To document DOE’s efforts to provide the public with a reasonable opportunity to incorporate its views into the process, the CCA should provide:

- Documentation and descriptions of the methods used to solicit participation of the public, including outside groups and individuals.
- Copies of any publicly available notices that solicited presentations from the public.
DOE did not identify any expert judgment elicitations in the CCA submitted to EPA on October 29, 1996. However, EPA reviewed the PA parameters and determined that value of the waste particle diameter in the Cuttings Model for direct brine release (waste particle size distribution parameter)—i.e., parameter ID No. 3246, Material BLOWOUT, Parameter PARTDIA—was not adequately supported by data. Because EPA identified this parameter as “sensitive” (i.e., having potential impact on the PA), EPA directed DOE in an April 25, 1997 letter to commission a panel of experts to elicit a distribution for the waste particle size parameter (Docket A-93-02, Item II-I-27).

DOE conducted the required expert judgment elicitation on May 5-9, 1997. Two documents were used for the conduct of the expert judgment elicitation: the Carlsbad Area Office (CAO) Team Plan, Expert Panel Elicitation Plan, Rev. 2 (DOE 1997a) and the CAO Team Procedure (TP) 10.6, Expert Judgment, Revision 0 (DOE 1997b).

The Expert Panel Elicitation Plan describes, in general terms, the process DOE used to elicit expert judgment. The Plan includes scope, definitions, planning and implementation, definition of technical issues, public notification, selection and contracting of experts, intended use of the particle diameter distribution, schedule, etc. The CAO Team Procedure prescribes the responsibilities of individuals involved in the process, documentation requirements, and methodologies incorporated in the expert judgment elicitation for the waste particle size distribution parameter.

The expert judgment elicitation involved a third-party elicitor guiding a six-person panel of experts through the resolution of technical issues. The process included opportunities for public involvement and consisted of the following steps:

- Definition of technical issue.
- Public notification (the public and other interested parties were notified in a variety of ways at least 10 days before the elicitation began).
- Selection of experts.
- General orientation and elicitation training.
- Presentation and review of issue(s).
- Preparation of expert analysis by elicitor.
- Discussion of analysis by panel members.
- Elicitation.
- Recomposition.
Review and approval or dissenting opinions provided by the experts.

Documentation of the process and results.

DOE submitted a draft report on May 12, 1997, for public review and comment. The Environmental Evaluation Group (EEG) submitted comments, which were reviewed by the expert panel and incorporated in the final report.

The results of the expert judgment elicitation consisted of a model for predicting waste particle size distribution as a function of the processes occurring within the repository, as predicted by the PA. For a discussion of how the results of the elicitation were used, see Section 194.23(c)(4) in CARD 23—Models and Computer Codes. DOE’s final report, entitled “Expert Elicitation on WIPP Waste Particle Size Distributions(s) During the 10,000-Year Regulatory Post-closure Period” was completed on June 3, 1997 (DOE 1997c).

26.A.6 EPA COMPLIANCE REVIEW

In Chapter 5.1.5 of the CCA, DOE reported that no expert judgment activities were identified at SNL, Westinghouse Waste Isolation Division, and waste generator sites. DOE submitted no further information on expert judgment elicitation.

For the reasons discussed in Section 26.A.1 above, EPA sent a letter dated April 25, 1997, that directed DOE to conduct an expert judgment elicitation for the waste particle size distribution parameter (Docket A-93-02, Item II-I-27). DOE conducted the elicitation from May 5-9, 1997. EPA’s review of DOE’s compliance with the requirements of Section 194.26 focused on the performance of the expert elicitation process.

EPA observed DOE’s elicitation process and subsequently conducted an audit of DOE’s documentation of the expert judgment elicitation. The scope of the audit covered all aspects of the expert judgment elicitation process, including: panel meetings, management and team procedures, curricula vitae of panel members, background documents, and presentation materials. The audit team developed a checklist to verify compliance with Section 194.26. A copy of the checklist is included in EPA’s Audit of Expert Judgment Elicitation (Docket A-93-02, Item II-A-47).

Section 194.22(a)(2)(v) requires that a quality assurance program be established and executed for the implementation of expert judgment elicitation. EPA determined that DOE met this requirement by establishing and implementing the CAO Team Procedure 10.6 (DOE 1997b), the CAO Expert Judgment Elicitation Plan (DOE 1997a), and the CAO Technical Assistance Contractor (CTAC) Experimental Programs Desktop Instruction (DOE 1997d).

The expert panel was composed of six experts, including four from consulting firms and two associated with universities. Two of the six panel members were DOE contractors, therefore, two-thirds of the panel were not employed by DOE or DOE contractors, as required by Sections 194.26(b)(7)(i) and (ii). In accordance with Sections 194.26(b)(3)(i) and (ii), the panel did not include individuals who will use the judgments or individuals who maintain, at any organizational level.
level, a supervisory role or who are supervised by those who will utilize the judgment. EPA reviewed documentation that demonstrated compliance with this requirement (Docket A-93-02, Item II-A-47).

EPA determined that the experts on the panel demonstrated the required level and variety of knowledge required by the questions or issues presented, as required by Sections 194.26(b)(4)(i) and (ii). The panel’s personnel files, maintained by CTAC, contained curricula vitae and organizational conflict of interest forms. Each panel member received notebooks containing background and training information. On May 5, 1997, panel members and observers received training in concepts necessary to complete the elicitation. Training included reading the Expert Panel Elicitation Plan (DOE 1997a), which identified the purpose and intended use of the judgment, as required in Section 194.26(b)(5). Presentations were made by SNL and EEG. The audit team found that the background and orientation materials adequately addressed the relationship between the issues at hand and the information presented to the experts, as well as the purpose and intent of the judgment. EPA also found adequate documentation of questions and issues presented to experts in transcripts produced by a court reporter and on request disposition forms. The transcripts documented all interviews used to elicit judgments from the experts, deliberations, formal interactions, and opinions (DOE 1997e).

EPA found that DOE afforded the public sufficient opportunity to present scientific and technical views to the expert panel, in accordance with Section 194.26(c). The notice period was held April 18 to May 5, 1997. Approximately 2,900 announcements were distributed to Federal, State, and local agencies, newspapers and radio stations, and public interest groups. DOE also posted the announcement on the Internet via the DOE WIPP web page (http://www.wipp.carlsbad.nm.us). The public comment period was held from May 5-27, 1997. The elicitation schedule included afternoon and evening time slots for public comments. The public submitted views and questions via disposition forms. DOE made the draft elicitation report available for public comment on May 12-27, 1997. The panel incorporated comments from EEG in the final report, but determined that the remaining public comments were outside the scope of the elicitation and did not need to be addressed.

In accordance with Section 194.26(b)(6), EPA found documentation showing that the initial purpose for which expert judgment was intended, as presented to the expert panel, was consistent with the purpose for which the judgment was used in the Performance Assessment Verification Test (PAVT). The waste particle diameter size distribution parameter was used in the PAVT calculations to derive the shear strength of the waste (TAUFAIL) used in the CUTTING_S computer code to calculate the cavings release (WPO 46646, filed at Docket A-93-02, Item II-G-34). The CAO Expert Panel Elicitation Plan, Attachment D—Supplemental Intended Use Statement, provided information and clarification to the expert panel on EPA’s direction regarding the anticipated use of the expert judgment results (DOE 1997a).
EPA’s audit team did not identify any findings during the audit of the expert judgment elicitation process. The audit team did have one recommendation, specifically, that DOE acknowledge all public comments with a postcard of receipt. For more information, see EPA’s audit report (Docket A-93-02, Item II-A-47).

26.B REFERENCES


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1 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 that this activity fails to properly implement a procedural requirement. A finding requires a satisfactory response from DOE. A recommendation is an endorsement of a proposed action that will further support the implementation of a quality assurance management program. A recommendation is based on an auditor’s judgment and does not require a response.