§ 194.26 Expert judgment.

(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.

§ 194.27 Peer review.

(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