

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

**NUCLEAR WASTE TECHNICAL REVIEW BOARD
FULL BOARD MEETING**

**SUBJECT: PRINCIPLES AND GUIDELINES FOR
FORMAL USE OF EXPERT JUDGMENT BY
YUCCA MOUNTAIN SITE
CHARACTERIZATION PROJECT**

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Topics

- **Purpose, goal, and scope of DOE's Expert Judgment Position Statement**
- **DOE's principles**
- **DOE's implementation guidelines**
- **Status of past recommendations on expert judgment**
- **Backup**

Purpose of Expert Judgment Position Statement

- **Provide a set of principles (ingredients) and guidelines (process requirements) for formal elicitations and peer review by the Yucca Mountain Site Characterization Project**
 - **Follow-up to DOE's 1992 Expert Judgment Workshop in Albuquerque, NM**
 - **Resolve NRC's Site Characterization Analysis comment 3 on DOE's SCP, "state criteria for formal use of expert judgment," prior to NRC staff guidance on the subject**
 - **To partially fulfill recommendations from the NWTRB's 10th Report, "establish guidelines for use of expert judgment in both programmatic studies and performance assessment"**

Goal of Expert Judgment Position Statement

- **Preserve DOE's flexibility in applying formal expert judgment**
- **Commit DOE to some basic operating guidelines for the application and documentation of expert judgment**

Scope of Expert Judgment Position Statement

- **Establishes**
 - **thresholds when formal applications of expert judgment (elicitations and peer reviews) might be appropriate**
 - **the principles expected in applications**
 - **general guidelines for conducting applications**
 - **expectations for resulting documentation**

DOE's Principles and Guidelines for Formal Applications of Expert Judgment

- **(Revision 0, May 22, 1995)**

Principles in DOE's Formal Applications

- **Each elicitation or peer review will have a predetermined structure for the collection, processing, and documentation of expert knowledge**
- **Each application must be**
 - **Systematic**
 - **Open to scrutiny**
 - **Easily understood**
 - **Subject to appropriate management and QA controls**
- **The bases for expert judgments, including data, assumptions, and attendant uncertainties, must be explicit**

Principles in DOE's Formal Applications

(Continued)

- **Responsible managers must be involved in planning and monitoring each application to ensure results are useful for management decisions**
- **Documentation will be adequate to provide objective evidence that these guidelines have been implemented and satisfy the controlling management plan**

Implementation Guidelines

- **DOE commits to a set of guidelines for conduct of elicitations and peer reviews**
 - **Planning/procedure**
 - **Selection of experts**
 - **Selection criteria**
 - **Independence**
 - **Qualifications and balance**
 - **Documentation**

Implementation Guidelines

PLANNING DOCUMENT/PROCEDURE:

- **Each elicitation or peer review will require development of a planning document or procedure that defines the application and the appropriate controls, including**
 - **A description of the issue to be evaluated or the work to be reviewed**
 - **The size and spectrum of membership, including minimum qualifications**
 - **The process or methods to be used and a schedule for reporting results**
 - **The considerations or criteria that should be addressed and documented**

Implementation Guidelines

(Continued)

SELECTION OF EXPERTS:

- **The number of experts involved will be commensurate with**
 - **the complexity of the issue to be evaluated**
 - **the importance of the results to program objectives**
 - **the number of technical disciplines involved**
 - **the degree to which uncertainties exist**
 - **the extent to which differing viewpoints are strongly held within the applicable technical community**

Implementation Guidelines

(Continued)

GENERAL SELECTION CRITERIA:

- **Selection of experts for formal elicitations and peer reviews will**
 - **Seek to include diverse technical and institutional points of view**
 - **Seek to include qualified independent experts that are outside DOE**
- **But will not,**
 - **Have anonymous members**
 - **Seek to exclude technically qualified people only on the basis of having been funded by DOE for unrelated work or having reviewed DOE-sponsored work**
 - **Seek to deliberately span the representation of stakeholder groups**

Implementation Guidelines

(Continued)

INDEPENDENCE:

- **A formal elicitation may include qualified experts**
 - **Associated with the Project to capture their site-specific knowledge**
 - **External to the Project to ensure that the range of diverse technical views are adequately represented**

- **A peer review will include qualified experts**
 - **Independent of the work being reviewed, which is consistent with the guidance in NRC NUREG-1297 and requirements in the OCRWM QARD**

Implementation Guidelines

(Continued)

QUALIFICATIONS AND BALANCE:

- **The technical experts involved in formal elicitations or peer reviews will**
 - **Have technical qualifications that are recognized, verifiable, and appropriate to the issues under consideration**
 - **Have technical expertise and qualifications that span the technical issues involved in the evaluation, including divergent technical viewpoints**
- **The potential for technical or organizational partiality will be minimized**

Implementation Guidelines

(Continued)

DOCUMENTATION:

- **Documentation for formal elicitations and peer reviews will**
 - **Be sufficiently thorough and complete enough to enable external parties to reconstruct the process and the rationale for the results**

Status of Expert Judgment Recommendations

- **NRC's 1989 Site Characterization Analysis**
- **DOE's internal recommendations November 1992
Workshop**
- **NWTRB's May 1994 Report (10th)**

Consistent with NRC's Recommendations and Existing Guidance

- **NRC recommendation in Site Characterization Analysis comment 3:**
 - **State criteria for the formal use of expert judgment to ensure that objective, quantitative analyses based on empirical data are used in preference to expert elicitation, wherever possible**
- **DOE's Position prepared specifically to resolve this open item**
- **Inputs to DOE's Position are from**
 - **Background Report on the Use and Elicitation of Expert Judgment (CNWRA 94-019, 1994)**
 - **Elicitation and Use of Expert Judgment in Performance Assessment for High-Level Waste Repositories (NUREG/CR-5411, 1990)**
 - **Peer Review for High-Level Nuclear Waste Repositories (NUREG-1297, 1988)**

Recommendations from November 1992 Expert Judgment Workshop

- **The November 1992 Expert Judgment Workshop was the most extensive exploration of the potential uses of expert judgment YMSCO has staged. It was thorough, well-attended, and provided inputs from wide-ranging viewpoints**
- **There has been follow-up to the six recommendations that take into account**
 - **Shift from programmatic applications in the early 1990s (when new work was held up for permits and QA program) to focused technical applications in recent efforts**
 - **Program management has changed, and OCRWM has entered an era of fiscal limitations with FY 1996 appropriation**

Recommendations from November 1992 Expert Judgment Workshop

(Continued)

- **Evaluating decision-analysis approaches alternate to those DOE has used**
 - **DOE has planned and initiated two EPRI-type geologic hazard evaluations**
- **Developing a flexible plan for future use of expert judgment in the program**
 - **This DOE position is such a plan**
- **Initiating training in quality decision-making and the formal use of expert judgment**
 - **The Probabilistic Volcanic Hazard Assessment (PVHA) included training for the elicitation and treatment of uncertainty**

Recommendations from November 1992 Expert Judgment Workshop

(Continued)

- **Participating in a test case involving the use of expert judgment in a regulatory environment**
 - **DOE did not participate in CNWRA Climate Elicitation because of WBS Manager transition and because YMSCO's climate program was a low priority until very recently**
- **Holding a meeting with stakeholders for insights into alternative views on the use of expert judgment in decision-making**
 - **How stakeholders and the public might be involved in peer review for DOE's 1994 Site Suitability Evaluation methodology was specifically elicited during several 1994 workshops to develop the methodology**

Recommendations from November 1992 Expert Judgment Workshop

(Continued)

- **Investigating the use of expert judgment by other government agencies**
 - **The DOE has investigated other expert judgment studies, such as the ongoing Senior Seismic Hazards Advisory Committee (SSHAC) studies while planning their expert judgment activities**

Consistent with NWTRB Recommendations in 10th Report (May 1994)

- **Establish guidelines for formal use of expert judgment in programmatic studies and performance assessments**
 - **DOE's Position centers mainly on programmatic studies of technical/management issues**
 - **Formal expert judgment in performance assessment (model uncertainties and scenario analysis) not fully explored because there has been no clear benefit for doing so with the preliminary analyses that have been done in TSPAs**
- **Increase involvement of management in planning and monitoring formal use of expert judgment**
 - **DOE's managers have been involved at all stages of Probabilistic Volcanic Hazard Assessment**

Consistent with NWTRB Recommendations in 10th Report (May 1994)

(Continued)

- **Increase the use of outside experts**
 - **DOE's Probabilistic Volcanic Hazard Assessment has acted fully on this recommendation**
- **Develop an experience base that includes the use of expert judgment in both internal studies and those involving interaction with groups such as the NRC**
 - **DOE's PVHA has provided for outside observation, time for commenting and questions and answers by observers, and the chance for outside parties to present information on the technical issues under consideration**

Conclusion

- **DOE's Principles and Guidelines Document establishes requirements and minimum acceptance criteria for formal elicitations and peer reviews**

BACKUP

General Considerations

- **The issue is not whether formal expert judgment will be used during site characterization, but how and under what circumstances elicitation or peer reviews will be used**
- **Expert judgment**
 - **Is a fundamental component of the scientific method and is inherent in all complex technical analyses**
 - **Is not a substitute for the best data that are reasonably available**
 - **Structures interpretation of data in a consistent framework and in light of judgment-based models**
 - **Can augment the technical basis required for management decisions**

Circumstances Where Formal Use of Expert Judgment is Appropriate

- **The technical issues are important to decision-making**
- **The technical issues are complex**
- **Data are ambiguous, non-reproducible, or not reasonably obtainable**
- **Non-standard practices are employed or data adequacy is questioned**
- **Explicit documentation would help support conclusions**
- **There is opportunity for consensus-building**

Formal Methods for Obtaining Expert Judgment

- **Formal elicitation can be used to help reach conclusions**
 - **Can quantify the range of information and informed technical opinion bearing on technical issues**
 - **Can integrate diverse technical input and document conclusions within the parameters of the evaluation**
 - **Elicitations are not proceduralized under OCRWM QARD**
- **Peer review can be used to evaluate how conclusions were reached**
 - **Used to evaluate the data, analyses, and conclusions developed by other means, including expert elicitation**
 - **Used to critique a technical approach and the resulting conclusions**
 - **Peer reviews are proceduralized under OCRWM QARD**

Limitations on Decision to Use Formal Methods

- **Formalized use of expert judgment is expensive and time-consuming**
 - **Exploratory Studies Facility Alternatives Study, 1990: 13 months duration; \$25 million**
 - **Calico Hills Risk/Benefit Analysis, 1990: 13 months duration; \$5 million**
 - **Test Prioritization Task, 1991: 10 months duration; \$3.5 million**
 - **Early Site Suitability Evaluation (including peer review), 1992: 10 months duration; \$3.5 million**
 - **Probabilistic Volcanic Hazard Assessment, 1994: 14 months duration, \$1.4 million**
 - **Probabilistic Seismic Hazard Assessment: (Projected) 15 months duration; \$4 million**

Limitations on Decision to Use Formal Methods

(Continued)

- **Resource limitations require a balance to be struck between informal uses of expert judgment and the more formalized applications**
- **Formal application of expert judgment does not eliminate the exercise of judgment on the part of the decision-maker (but can be structured for decision makers)**
- **Can data be acquired for the price of applying formalized expert judgment?**

**PRINCIPLES AND GUIDELINES FOR FORMAL USE OF EXPERT JUDGMENT
BY THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT**

REVISION 0

May 22, 1995

**U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office**

PRINCIPLES AND GUIDELINES FOR FORMAL USE OF EXPERT JUDGMENT BY THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT

SUMMARY

The purpose of this document is to present the Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) position on the formal application of expert judgment by the Yucca Mountain Site Characterization Project (the Project). The document sets forth the general principles and guidelines that provide the framework for the formal application of expert judgment by the Project. It is not intended to serve as a management plan or a procedure for such applications. Specific applications of formal methods for obtaining expert judgment will be carried out under procedures or plans appropriate to the application and in accordance with the OCRWM *Quality Assurance Requirements and Description* (QARD).

The use of expert judgment is a fundamental component of the scientific method and is inherent in all complex technical analyses. It also pervades the acquisition and evaluation of the data that support these analyses. The choice is not whether to use expert judgment, but rather how to use it. Expert judgment is not a substitute for the best data that are reasonably available. On the other hand, data must always be interpreted in light of judgment-based models. Interpretation of data in a consistent framework, with adequate treatment of assumptions and uncertainties, creates the technical basis required to aid management decision-making. For most routine technical activities, expert judgment is implicit; other activities may require that expert judgment be explicit. Explicit use of expert judgment can be informal or formal. Formal use of expert judgment is most appropriate in cases where information is not reasonably available, or when uncertainties are significant. Formal use of expert judgment may include an elicitation process. Technical peer review also constitutes a formal means for obtaining expert judgment.

Both peer review and formal elicitation of expert judgment are explicit and documented processes that can enhance the credibility of technical conclusions by bringing a diversity of technical views to bear on a particular issue and by providing independent support for the technical judgments and conclusions that are input to the decision-making process. Formal elicitation of expert judgment is used, where appropriate, to bring out and quantify the range of information and informed technical opinion that bears on the resolution of a technical issue. Such elicitations are used to document conclusions within the parameters of the evaluation. Peer review is used, where appropriate, to evaluate and critique the information, analyses, and conclusions developed by other means, including expert elicitation, to support the resolution of a technical issue. Peer reviews are used to document the critique of a technical approach and the resulting conclusions. In certain cases, expert elicitation and peer review are employed in sequence to complement one another.

It is not practical or reasonable to formalize the use of expert judgment in all technical activities, including the various aspects of repository performance assessment, since the elicitation of expert judgment, or obtaining expert judgment through a peer review process, can clearly be expensive and time consuming. A balance must be struck between the judgments that are obtained from experts through formal methods, and those that are not, so that resources are used effectively without compromising objectives. For this reason, the areas in which formal elicitation or peer reviews are used must be carefully selected. The selection of topics for formal application of expert judgment involves a DOE management decision that is made with input from the appropriate technical experts and managers within the Project and, where appropriate, in consultation with external parties.

The following are indicators of circumstances in which formal use of expert judgment, either through expert elicitation or peer review, or both, is appropriate:

Importance of the Issues.

Complexity of the Issues.

Data that are Ambiguous, Non-reproducible, or Not Reasonably Obtainable.

Non-Standard Practice and Data Adequacy.

Level of Documentation Required.

Extent of the Use of Expert Opinion.

The DOE believes that formal methods for obtaining expert judgment are most useful in dealing with technical issues and uncertainties that are significant in establishing the basis for the technical conclusions that are considered by the DOE in the development of regulatory assessments and by DOE management in making decisions. The process for the formal application of expert judgment needs to be systematic, open to scrutiny, easily understood, and subject to appropriate controls. The bases for expert judgments, including data, assumptions and attendant uncertainties must be articulated and documented. Management involvement in framing each application of formal expert judgment is critical, but may not always insure that all factors ultimately deemed important by the decision-makers have been considered. Since the formal application of expert judgment cannot be expected to address every aspect of a management decision, the results of such applications do not eliminate the exercise of judgment on the part of the decision maker.

PRINCIPLES AND GUIDELINES FOR FORMAL USE OF EXPERT JUDGMENT BY THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT

INTRODUCTION

The use of expert judgment is a fundamental component of the scientific method and is inherent in all complex technical analyses. It also pervades the acquisition and evaluation of the data that support these analyses. The choice is not whether to use expert judgment, but rather how to use it: is the use implicit or explicit; is the application informal or formal; and is the use to be documented and, if so, to what extent. The purpose of this document is to present the Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) position on the explicit and formal application of expert judgment by the Yucca Mountain Site Characterization Project (the Project). The document sets forth the general principles and guidelines that provide the framework for the formal application of expert judgement by the Project. It is not intended to serve as a management plan or a procedure for such applications. Specific applications of formal methods for obtaining expert judgement will be carried out under procedures or plans appropriate to the application and in accordance with the OCRWM *Quality Assurance Requirements Description* (QARD).

Although formal methods for obtaining expert judgment are applied wherever appropriate, the most significant application of formal expert judgment methods by the Project is expected to be in dealing with the technical issues and inherent uncertainties associated with characterizing and predicting the performance of a geologic disposal system for thousands of years into the future. Formal and informal judgment by technical experts, based on reasonably available information, is a primary ingredient in conducting performance assessments for a geologic disposal system. Complex calculations based on sophisticated mathematical models, including quantitative estimates of uncertainty in the calculations, may be performed to evaluate system performance. The validity of the model outputs, however, is no better than the validity of the technical judgments used in developing the conceptual models that provide the foundation for the mathematical models.

The Project intends to make formal use of expert judgment one mechanism for quantifying uncertainty and ensuring that diverse viewpoints and interpretations are considered in developing or evaluating the technical basis for management decision-making. The informal application of expert judgment, which is inherent in all Project technical activities, is documented in the products that result from these technical activities. These technical products explain the conditions and circumstances of data collection and analysis, document key assumptions and uncertainties, and provide input for consideration in formal applications of expert judgment when such applications are warranted.

The Project has no plans to make use of formal methods for dealing with the value judgments made by the DOE managers in the decision-making process. Value judgments and management decisions related to regulatory compliance or programmatic issues need to

consider the results of technical analyses, but are not, in themselves, purely technical in nature; other factors, such as programmatic risk, cost, and schedule, may need to be considered. For this reason, it is beneficial to clearly differentiate between the technical analysis and any regulatory analysis or management decision that follows. This facilitates a purely technical approach to the formal application of expert judgment and provides a clear distinction between these judgments and the value judgments made in regulatory compliance evaluations and DOE management decisions.

BACKGROUND

A Project-sponsored workshop was held in Albuquerque, New Mexico, in November 1992, to discuss the use of expert judgment by the Project. The objective of the workshop was to develop specific recommendations for improving the DOE's use of expert judgment in future performance assessment iterations. One recommendation developed by the workshop steering committee was that the Project should prepare guidelines regarding the appropriate role of expert judgment in its decision-making process. They suggested that the guidelines be flexible enough to tailor the application of expert judgment on a case-by-case basis and recommended that the guidelines address:

- the appropriate degree of formalism in elicitation and analysis,
- the appropriate level of modeling and quantitative analysis,
- the need for outside experts and public involvement.

The principles and guidelines presented in this document are responsive to these recommendations and to specific recommendations made by the NWTRB in their tenth report, *Report to the U.S. Congress and the Secretary of Energy* (1994). In that report, the NWTRB recommended that the DOE prepare and implement a plan to increase the quality and effectiveness of its use of expert judgment. In particular, the NWTRB recommended that the DOE establish guidelines for the formal use of expert judgment in both programmatic studies and performance assessments. They also recommended increased involvement of management in planning and monitoring the formal use of expert judgment, and the increased use of experts outside the DOE and its contractor organizations.

The principles and guidelines set forth in this document are consistent with the DOE's response to a recommendation made by the Nuclear Regulatory Commission (NRC) staff in their Site Characterization Analysis (NUREG-1347, 1989, comment 3) of the DOE's Site Characterization Plan for the Yucca Mountain site. The NRC recommended that the DOE:

State criteria for the formal use of expert judgment to assure that objective, quantitative analyses based on empirical data are used in preference to expert elicitation wherever possible.

In its response, the DOE stated that:

The [DOE] does not plan to rely on expert judgment as a substitute for objective, quantitative analyses based on empirical data. However, where appropriate mechanistic models are not available or the collected data are consistent with differing interpretations, DOE plans to rely on expert judgment, as appropriate.

DOE intends to preserve the flexibility to define the level of judgment or review to be applied in each specific case when use of subjective methods becomes necessary. DOE also intends to control the use of subjective methods and the documentation of the results of any reviews or decision-making in accordance with established quality assurance (QA) procedures

The DOE position presented in this document is consistent with the general approach to the formal use of expert judgment presented in the NRC contractor report, *Elicitation and Use of Expert Judgment in Performance Assessment for High-Level Waste Repositories* (NUREG/CR-5411, 1990) and with the NRC's generic technical position, *Peer Review for High-Level Nuclear Waste Repositories* (NUREG-1297, 1988).

GENERAL PRINCIPLES FOR THE FORMAL APPLICATION OF EXPERT JUDGMENT

Expert judgment is not a substitute for the best data that are reasonably available. On the other hand, data must always be interpreted in light of judgment-based models. The formal application of expert judgment provides a means to address significant uncertainties in data interpretation and modeling. Interpretation of data in a consistent framework, with adequate treatment of assumptions and uncertainties, creates the technical basis required to aid management decision-making.

The Project may use expert judgment to support:

assessments of system and subsystem performance, including evaluation of available input data and uncertainties;

definition of scenarios and related probabilities to be included in performance assessments;

test planning and design studies, including sensitivity studies to establish priorities for testing, and sensitivity studies and analyses to evaluate design options;

technical input for programmatic and regulatory decisions, including sensitivity and performance evaluations related to compliance and cost-benefit analyses;

legal proceedings where expert testimony is required (e.g., licensing hearings).

Formal Methods for Obtaining Expert Judgment

For most routine technical activities, the application of expert judgment is implicit; other activities may require that expert judgment be explicit. Explicit use of technical expert judgment can be informal (unstructured) or formal (structured). Formal use of expert judgment is most appropriate in cases where information is not reasonably available, or when multiple working hypotheses and conceptual models consistent with available information,

event probabilities,

assumptions and inputs for numerical performance models.

The use of bounding or appropriately conservative calculations relies implicitly, if not explicitly, on expert judgment. Formal application of expert judgment can provide the basis for selection or evaluation of data, models, and assumptions, and should help to build confidence that the models are adequate and the results appropriately conservative.

Formal use of expert judgment may include a formal elicitation process. Technical peer review also constitutes a formal means for obtaining expert judgment. Both peer review and formal elicitation of expert judgment are explicit and documented processes that can enhance the credibility of technical conclusions by bringing a diversity of technical views to bear on a particular issue and providing independent support for the technical judgments and conclusions that are input to the management decision-making process. Formal elicitation of expert judgment can be used, where appropriate, to bring out and quantify the range of information and informed technical opinion that bears on the resolution of a technical issue. Such elicitations are useful in integrating diverse data sets and modeling activities, and lead to documented conclusions within the parameters of the evaluation. Peer review can be used to evaluate and critique the information, analyses, and conclusions developed by other means to support the resolution of a technical issue. Peer reviews can be used to document the critique of a technical approach and the resulting conclusions. The results from the formal elicitation of expert judgment can, and often should, be subject to peer review. In certain cases, expert elicitation and peer review may be employed in sequence to complement one another.

The process for formally obtaining expert judgment, either through elicitation or peer review, should be systematic, open to scrutiny, easily understood, well documented, and subject to appropriate quality assurance controls. It is important for the responsible managers to be involved early in the planning phase of each formal application of expert judgement methods so that the focus, objectives, and factors for consideration in an elicitation or peer review are clearly defined and the results are useful to managers in the decision-making process. Strong leadership is needed to keep the expert judgment process focused on the objectives established by management and to provide useful results in a timely and cost-effective manner. The selection and makeup of expert panels is crucial: multiple experts in each discipline area are

preferred, and the technical credibility and breadth of technical opinion represented by the panel members are important considerations, as is their independence from both the Project and the work performed. The bases for expert judgments, including data, assumptions and attendant uncertainties must be articulated and documented.

Management Involvement and Decision-Making

Management involvement in framing the elicitation and analysis process, or the objectives of a peer review, is critical, but may not always insure that all factors ultimately deemed important by the decision-makers have been considered. Since formal methods for obtaining expert judgment cannot be expected to address the non-technical aspects of a management decision, the results from the application of such methods do not eliminate the exercise of judgment on the part of the decision maker. Managers and decision-makers must be free to consider other information in reaching a decision (e.g., management risk, cost, schedule). Managers also need to be able to understand and explain the basis for decisions to external parties, including the public. Experience suggests that even if the formal use of expert technical judgment is clearly presented as a decision-aiding tool, its use can generate the expectation that the decision must directly follow the results of the analysis. Perceptions regarding the relationship between the results of a decision-aiding process and the decision itself can be viewed by decision-makers as inappropriately limiting their discretion to consider other information or values in reaching a decision. These latter considerations make the use of relatively complex, formal methods of decision analysis for elicitation of subjective value judgments less attractive from a management perspective.

Value judgments and management decisions related to regulatory compliance or programmatic issues need to consider the results of technical analyses, but decisions are not made solely on the basis of technical input; other non-technical factors may need to be considered. For this reason, it is beneficial from the standpoint of formally obtaining expert judgment, either through elicitation or peer review, to clearly differentiate between the technical analysis and any regulatory analysis or management decision that follows. This facilitates a purely technical approach to expert elicitation or peer review of the technical information and provides a clear differentiation between this information, which is an input to decision-making, and the value judgments made in regulatory compliance evaluations and DOE management decisions. This is consistent with an observation made by the DOE in the background information for its siting guidelines (10 CFR Part 960, 49 FR 47727):

The DOE has not found support in the technical community [for a numerical method or equivalent for "computing" compliance and for the resulting DOE decisions] . . . nor has the DOE been able to determine the framework for a predetermined method that would be sufficiently complete to eliminate the exercise of judgment on the part of the Federal officials who will make these decisions

GENERAL GUIDELINES FOR THE FORMAL APPLICATION OF EXPERT JUDGMENT

Circumstances Appropriate to the Use of Formal Expert Judgment Methods

It is not practical or reasonable to formalize the use of expert judgment in all Project technical activities, including the various aspects of repository performance assessment, since the elicitation of expert judgment, or obtaining expert judgment through a peer review process, can clearly be expensive and time consuming. A balance must be struck between the judgments that are obtained from experts through formal methods, and those that are not, so that Project resources are used effectively without compromising Project objectives. For this reason, the areas in which formal elicitation or peer reviews are used must be carefully selected. The selection of topics for formal application of expert judgment involves a DOE management decision that is made with input from the appropriate technical experts and managers within the Project and, where appropriate, in consultation with external parties.

The following are indicators of circumstances in which formal use of expert judgment, either through expert elicitation or peer review, or both, is appropriate. They are based on the indicators identified by the NRC in NUREG-1297 (1988) on the use of peer review and in the NRC contractor report, NUREG/CR-5411 (1990), on the use of expert elicitation in performance assessment. These indicators are also consistent with the OCRWM *Quality Assurance Requirements and Description* (QARD) as it applies to peer review.

Importance of the Issues. Formal methods are most appropriate when expert judgments on technical issues are likely to have a major impact on the management decision-making process (e.g., cases where critical interpretations or decisions will be made in the face of significant uncertainty, or that will have a significant impact on performance assessment conclusions).

Complexity of the Issues. When a problem is complex, or when several experts are employed, formal methods are likely to be appropriate. Formal methods can provide a structure so that all participants understand the methods used and apply procedures consistently.

Data that are Ambiguous, Non-reproducible, or Not Reasonably Obtainable. When the data or interpretations are ambiguous (e.g., the data permit multiple alternative conceptual models), or the results from tests are highly variable or non-reproducible, or data directly relevant to a problem are lacking and unobtainable by reasonable means, it may be worthwhile to supplement the existing information and interpretations by means of formal use of expert judgment.

Non-Standard Practice and Data Adequacy. When novel or beyond the state-of-the-art data acquisition or analysis methods are used, formal expert judgment methods may prove useful. Formal application of expert judgment may also be useful when

data adequacy or documentation is questionable (e.g., data not collected under approved quality assurance procedures).

Level of Documentation Required. Formal methods for obtaining expert judgment are a means to obtain documentation of the methods and findings. Informal methods are more likely to generate documentation that is less complete with regard to the assumptions and procedures used. The end uses of the information obtained from the application of expert judgment may also suggest whether a formal process should be employed.

Extent of the Use of Expert Opinion. When expert judgments are used extensively in a study, such as may be the case for some of the more critical inputs used in performance assessments, formalization of the collection and processing of the information from the application of expert judgment may be done most accurately, consistently, and efficiently using formal methods.

Guidelines for Implementing Formal Expert Elicitation and Peer Review

Both a formal elicitation of expert judgment and the conduct of a peer review will have a predetermined structure for the collection, processing, and documentation of expert knowledge. In the case of expert elicitation, a planning document or procedure will be developed consistent with these guidelines, but with details specific to the intended application. The experts will be trained for the elicitation of their judgments and the actual elicitation will involve the expert(s) and a person trained to assist the expert(s) in expressing their judgments. Peer reviews will be conducted in accordance with the OCRWM QARD and appropriate quality assurance procedures.

Formal elicitation of expert judgment will be used, where appropriate, to bring out and quantify the range of information and informed technical opinion that bears on the resolution of a technical issue. Such elicitations will be used to document conclusions within the parameters of the evaluation. Peer review will be used, where appropriate, to evaluate and critique the information, analyses, and conclusions developed by other means, including expert elicitation, to support the resolution of a technical issue. Peer reviews will be used to document the critique of a technical approach and the resulting conclusions. In certain cases, expert elicitation and peer review will be employed in sequence to complement one another.

The following general guidelines apply to either a formal elicitation or a peer review used to obtain expert judgment:

In conducting an elicitation or peer review, the DOE will ensure that:

The form of documentation is adequate to provide objective evidence that these guidelines have been addressed and that the record is complete enough to permit an independent assessment of the results by external parties. The documentation and the controls applied will satisfy the appropriate quality assurance requirements.

The number of experts involved is commensurate with:

- the complexity of the issue and the spectrum of work to be evaluated,
- the importance of the results to program objectives,
- the number of technical disciplines involved,
- the degree to which uncertainties in the data or technical approach exist,
- the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under consideration.

The collective technical expertise and qualifications of the experts span the technical issues and areas involved in the evaluation, including divergent technical viewpoints.

The potential for technical or organizational partiality is minimized.

The technical experts involved in formal elicitation or peer reviews will:

Have technical qualifications that are recognized and verifiable, and appropriate to the issues under consideration.

A formal elicitation may include:

Experts associated with the Project in order to capture their site-specific knowledge as part of the elicitation process.

Experts external to the Project to ensure that the range of diverse technical views is adequately represented and captured in the elicitation.

A peer review will involve experts independent of the work being reviewed, consistent with the requirements in NRC NUREG-1297 and the OCRWM QARD.

Due to the DOE's substantial involvement in supporting work carried out by experts in the technical community external to the OCRWM program, it is not practical for membership on a peer review panel, or selection as an external expert for an elicitation, to be predicated on an absolute standard of no prior involvement in, or review of, DOE-sponsored work. It is more important to ensure that well qualified experts are selected who reflect the appropriate diversity of technical disciplines and views necessary to support the intended application of expert judgement.

Planning Document or Procedure Required

Peer reviews will be conducted in accordance with the requirements of the OCRWM QARD and its implementing procedures, which are consistent with the guidance provided by the NRC in NUREG-1297.

The initiation of an expert elicitation or peer review will require development of a planning document or procedure that defines the intended application of expert judgment to the issue under consideration and the controls appropriate to this application, including:

A description of the issue to be evaluated or the work to be reviewed.

The size and spectrum, including minimum qualifications, of the technical experts that will be involved in the elicitation or peer review.

The process or methods to be used in the application of expert judgment and the schedule for reporting of results.

The considerations or criteria that should be addressed by the elicitation or review and documented in the resulting report, including, as appropriate, assessment of:

- the appropriateness and limitations of the methods employed in collecting, analyzing, and interpreting the data;
- the validity of the assumptions and the adequacy of the treatment of uncertainties;
- the validity of the conclusions and the basis for the conclusions given the associated uncertainties;
- the possibility of credible alternate interpretations consistent with the available data that would significantly alter the conclusions.

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