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Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program

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ABSTRACT

The U.S. Department of Energy (DOE) is conducting a program of site characterization to gather enough information, about the Yucca Mountain (Nevada) site, to be able to evaluate the waste isolation capabilities of a potential geologic repository. Should the site be found suitable, DOE will apply to the U.S. Nuclear Regulatory Commission for permission to construct and then operate a proposed geologic repository for the disposal of spent nuclear fuel and other high-level radioactive waste at Yucca Mountain. In deciding whether to grant or deny DOE's license application for a geologic repository, NRC will closely examine the facts and expert judgment set forth in any potential DOE license application. NRC expects that subjective judgments of individual experts and, in some cases, groups of experts, will be used by DOE to interpret data obtained during site characterization and to address the many technical issues and inherent uncertainties associated with predicting the performance of a repository system for thousands of years. NRC has traditionally accepted, for review, expert judgment to evaluate and interpret the factual bases of license applications and is expected to give appropriate consideration to the judgments of DOE's experts regarding the geologic repository. Such consideration, however, envisions DOE using expert judgments to complement and supplement other sources of scientific and technical information, such as data collection, analyses, and experimentation. In this document, the NRC staff has set forth technical positions that: (1) provide general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation); and (2) describe acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic disposal regulation, currently set forth in 10 CFR Part 60.

In this NUREG, the staff also provides an expanded definition of "peer review" over that provided earlier in NUREG–1297.

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FIGURE

FOREWORD

This Branch Technical Position (BTP) was developed only for application to the high-level waste program, as part of the staff's Iterative Performance Assessment efforts. The technical positions contained here reflect staff experience gained from both monitoring the U.S. Department of Energy's site characterization program at Yucca Mountain, Nevada, and developing the U.S. Nuclear Regulatory Commission's independent regulatory capability.

Although there are several examples of the use of expert elicitation in a nuclear regulatory context, no formal Agency guidance on this subject exists. Thus, in developing this BTP, the Division of Waste Management (DWM) staff has also drawn from previous staff experience of other NRC program offices, in the use of expert elicitation. In this regard, DWM staff has relied on certain Agency resource documents, such as: "Risk Assessment: A Survey of Characteristics, Applications, and Methods Used by Federal Agencies for Engineered Systems"; "A Review of NRC Staff Uses of Probabilistic Risk Assessment"; and "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts," to help formulate its position statements. Consequently, the reader will find that this BTP is largely consistent with these other resource documents, in substance.

Subsequent to the finalization of this BTP, the staff may elect to develop guidance on the use of expert judgment in other areas of nuclear regulatory regulation.

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APPENDICES

1 INTRODUCTION

The U.S. Nuclear Regulatory Commission's regulations for the licensing of a geologic repository for the disposal of spent nuclear fuel and other high-level radioactive waste (HLW) are intentionally non-prescriptive in that 10 CFR Part 60 leaves to the U.S. Department of Energy (DOE) the opportunity and responsibility to determine how best to site and design a potential geologic repository that can meet the performance objectives contained in Subpart E of those regulations. DOE is conducting a program of site characterization, at Yucca Mountain, Nevada. Through this program, DOE is gathering information on the characteristics of the Yucca Mountain site, to evaluate the waste isolation capabilities of the proposed site, as it would perform in concert with DOE's repository design, in order to meet the performance objectives. DOE will need to interpret the geologic record and demonstrate that the repository site and design will comply with explicit numerical performance standards established by the U.S. Environmental Protection Agency (EPA) and adopted by NRC.[1]

For the Commission's part, if it is to reach an affirmative licensing decision, the Commission will need to confirm that the numerical performance standards have been met and must satisfy itself that DOE's analyses of the site and design are sufficiently convincing, that their limitations are well understood, and that DOE has demonstrated that its analyses have made appropriate allowance for the time period, hazards, and uncertainties involved.

Nearly every aspect of site characterization and performance assessment will involve significant uncertainties. The primary method to evaluate, and perhaps reduce, these uncertainties should be collection of sufficient data and information during site characterization. However, factors such as temporal and spatial variations in the data, the possibility for multiple interpretations of the same data, and the absence of validated theories for predicting the performance of a repository for thousands of years, will make it necessary to complement and supplement the data obtained during site characterization with the interpretations and subjective judgments of *technical experts* (i.e., expert judgments—see definition in Section 1.2.1).

Expert judgment is ubiquitous in almost every scientific or technical endeavor. As important as its role may be, however, for the purposes of the HLW program, the subjective judgment of experts should be distinguished from both measured data or technical calculations based on accepted scientific laws and principles. It should be viewed as an alternative, and employed when other means of obtaining requisite data or information have been thoroughly considered and it has been concluded that such means are not practical to implement. Thus, expert judgment, informal as well as formally elicited, may be used by DOE in its demonstrations of compliance with NRC's geologic disposal regulation. Moreover, the NRC staff will continue to accept, for review, those compliance demonstrations and other analyses employing informal expert judgment and expert elicitation.

With this notion in mind, current NRC policy is to encourage the use of probabilistic risk assessment (PRA) state-of-the-art technology and methods as a complement to the deterministic approach in nuclear regulatory activities (NRC, 1995; 60 *FR* 42622)[2] and in keeping with the Commission's paramount responsibility to protect public health and safety. Expert judgment may provide an essential part of the information used in PRAs (or performance assessments, in the case of waste management systems), and may also be used in deterministic analyses. Consistent with the Commission's policy, the NRC staff has developed this Branch Technical Position (BTP) to identify acceptable procedures for the formal elicitation of

[1]The staff recognizes that revised EPA standards, specific to the Yucca Mountain site, required by the Energy Policy Act of 1992 (Public Law 102-486) must be based on and consistent with recent findings and recommendations of the National Academy of Sciences (NAS—see National Research Council, 1995a). Once EPA promulgates regulations establishing its final standards, NRC will modify its requirements at 10 CFR Part 60 to conform to the new standards. Notwithstanding these forthcoming revisions to both EPA's standards and NRC's conforming regulations, the staff presumes that there will continue to be a requirement for some kind of a quantitative performance assessment to estimate the long-term, post-closure performance of the overall repository system.

[2]EPA's 1985 HLW standards (50 *FR* 38066) adopted a probabilistic perspective when making compliance determinations. Because of the uncertainties inherent in the geologic disposal of nuclear waste, it is anticipated that a probabilistic treatment of the performance of the waste disposal system will continue to be the regulatory approach.

such judgments in the area of HLW. The staff believes that PRA methods, such as described in this guidance, can be applied to the HLW program in a manner that would contribute significantly to the necessary confidence that a geologic repository could be licensed without undue risk to the health and safety of the public.

1.1 Background

A geologic repository is a complex system, the future performance of which must be predicted over many thousands of years. Because of the nature of the task and the limitations of scientific understanding in many pertinent technical fields, DOE (and its contractors) will use *expert judgment* throughout site characterization and later, in the preparation of a license application, to construct a potential geologic repository for HLW. DOE and its contractors will also use expert judgment in the identification and screening of events and scenarios; development and selection of models that describe the geology and hydrology of the repository system; assessment of model parameters; collection of data; assessment of volcanic and seismic hazard potential; and for strategic decision-making, about the repository's design, that could affect its long-term performance (e.g., DOE, 1986; Dennis, 1991; Seismic Methods Peer Review Panel, 1991; Test Prioritization Task Force, 1991; DOE, 1991b; Barnard *et al.*, 1992; Andrews *et al.*; 1994, Wilson *et al.*, 1994; and Schenker *et al.*, 1995).

Although acquisition and analysis of physical data should be the primary manner in which licensing information is collected, many considerations may preclude the collection of such information necessary for licensing. As with all complex technical analyses, "professional" judgment, usually informal and implicit, is used routinely by the scientists, engineers, and technical program managers who contribute to the repository program, to supplement and interpret this information, indeed, even to determine how to obtain the data or perform the analyses. The staff believes that its ability to evaluate a potential HLW license application will, in large measure, depend on the transparency with which data are collected, analyzed, and interpreted, and safety-related decisions are made. Therefore, the staff believes that it is important for all program participants to have a common understanding of the general circumstances under which it may be worthwhile to obtain and apply expert judgments in a more formal manner, and of the appropriate methods for doing so.

In reviewing DOE's Site Characterization Plan (SCP—see DOE, 1988), the staff identified concerns related to DOE's proposed use of expert judgment as part of a potential license application. In its Site Characterization Analysis (SCA), the staff noted that DOE's SCP relied too heavily on the elicitation of expert judgment as a substitute for quantitative data and analyses (NRC, 1989; pp. 4-8—4-10). Subsequently, the NRC staff has criticized specific DOE uses of expert elicitation in the Calico Hills Risk/Benefit Analysis (DOE, 1991a) and the Early Site Suitability Study (Science Applications International Corporation, 1992). The NRC staff found fault with both the manner in which these elicitations were conducted and the way in which the elicitation results were used to make site characterization decisions (see Linehan, 1990 and 1991; and Holonich, 1992). As with other types of information, expert judgment can be misinterpreted, misrepresented, and misused. The NRC staff is particularly concerned with the potential for over-reliance on expert judgment as a basis for decision-making, as well as its potential misuse as an inappropriate justification to avoid gathering additional objective data.

Since 1990, the Nuclear Waste Technical Review Board (NWTRB) and the NAS have also addressed DOE's plans to use expert judgment. Both the NWTRB and the NAS, independently, have expressed concerns with these plans and, in particular, with how DOE addresses the potential for "bias" and "conflicts of interest" when conducting expert elicitations (see NWTRB (1990a, p. 21; 1990b, p. 26; 1991, pp. 29-30; 1994, pp. 31-35) and National Research Council (1990, p. 24)).[3] For example, DOE has been criticized for relying almost entirely on its own scientific experts and contractors, with little or no external peer review.

More recently, DOE has announced a series of initiatives that would lead to the restructuring of its geologic repository program, including site characterization activities (see DOE, 1994 (pp. 1-3—1-4) and 1995 (pp. 1-3—1-8)). The exact

[3]DOE's response to some of the Board's recommendations are reprinted in NWTRB (1992 (pp. E-11—E-12) and 1995 (pp. H-20—H-21)).

details of the re-structuring plan have not yet been disclosed, nor have the impacts of recent budget constraints imposed on DOE's repository program been fully evaluated in the context of this plan. That being said, the staff generally understands that DOE will, both by intent and necessity, collect fewer data and, instead, rely extensively on bounding analyses to both form its HLW programmatic decisions and to support a potential license application it would submit pursuant to NRC's geologic disposal regulation (see DOE, 1994; pp. 1-3—1-4).

1.2 What are Expert Judgment, Expert Elicitation, and Peer Review?

1.2.1 Expert Judgment

Expert judgment is information,[4] provided by a technical expert, in his or her subject matter area of expertise, based on opinion, or on a belief based on reasoning. Questions are usually posed to experts because they cannot be answered by other means. Expert judgments can be evaluations of theories, models, or experiments, or they can be recommendations for further research. Expert judgments may also be opinions that can be analyzed and interpreted, and used in subsequent technical assessments. Expert judgments can be either qualitative or quantitative. Expert judgments can also be judgments about uncertain quantities or judgments about value preferences. Expert judgment has also been called *expert opinion, subjective judgment, expert forecast, best estimate, educated guess*, and, most recently *expert knowledge* (see Meyer and Booker, 1990; p. 3). Regardless of how one defines it, expert judgment ultimately reflects the technical expert's evaluation and interpretation of some scientific knowledge base, to the extent that the knowledge base exists. Moreover, expert judgment does not create knowledge, rather it "synthesizes disparate and often conflicting sources of information to produce an integrated picture" (see Hora, 1993).

The distinction between judgmental information (e.g., is there life on other planets ?) and more straightforward, factual information (e.g., what is $\int dx/x$?) is not sharp. The use of expert judgment in technical and scientific work, including that routinely reviewed by the NRC staff, is ubiquitous. This *informal* use of expert judgment is implicit in the choice of mathematical equations to describe a system, the methods used for testing, the interpretation of data, the methods used to obtain numerical results, and other aspects of analysis and testing.

Judicial and administrative proceedings frequently involve "expert witnesses" who, by virtue of their training and/or experience, are judged capable of providing useful opinions or conclusions about certain matters in issue. These experts perform their roles under the rules governing the particular proceeding, whether it be a judicial or an administrative setting. However, in this BTP, the word "expert" will be used more broadly and with reference to the "pre-licensing" and "licensing phases" (Johnson, 1994) of the HLW program. In the context of this BTP, "experts" refer to those knowledgeable individuals, in engineering and science, who, by the nature of their experience and academic achievement, can speak to the understanding of certain scientific laws and principles. This BTP makes no attempt to identify who would be an "expert" for the purposes of a judicial or an administrative proceeding. However, an "expert" used in an elicitation process may also be used as an "expert" in a judicial proceeding.

1.2.2 Expert Elicitation

Expert elicitation is a *formal*, highly structured, and well-documented process whereby expert judgments, usually of multiple experts, are obtained. Although informal expert judgment involves only *subject-matter experts*, formal expert elicitations usually involve *normative experts, generalists*, and *subject-matter experts* (see Appendix A). The *normative expert* has training and experience in statistics, decision analysis, and probability encoding; this expert's main function is to structure the formal elicitation and train the subject-matter experts in probability encoding. The *generalist* understands the context in which the results of the expert elicitation will be used, guides the structure of the elicitation to produce the needed results, provides relevant information and documentation to the subject-matter experts, and helps to train them. Often the generalist's expertise overlaps that of the subject-matter experts or is in a closely-related, allied field. For example, a performance assessment expert could

[4] Expert judgment is sometimes referred to as "data" (e.g., for purposes of aggregating the judgments of multiple experts).

be the generalist in an expert elicitation for climate change. The *subject-matter experts*, of course, provide the subjective judgments that are usually encoded as probabilities (e.g., a probability distribution or a point estimate for an uncertain parameter).

In the context of the HLW program, expert elicitation may play several roles in DOE's decision-making process for a potential geologic repository. Typically an elicitation is conducted to evaluate uncertainty. The uncertainty could be associated with: the value of a parameter to be used in a model; the likelihood and frequency of various future events; or the relative merits of alternative conceptual models. In each of these cases, the information regarding uncertainty would be represented by encoding the subjective probabilities from each subject-matter expert. For example, a few boreholes may yield data necessary to calculate the permeability of a rock type in a particular hydrogeologic unit. Given that these data represent a small sample from a highly variable population and given further that undiscovered structures and features could greatly influence the effective permeability of the unit, each expert might be asked to generate a probability distribution for the effective permeability of the hydrogeologic unit. Similarly, probabilities may be attached to the likelihood of various futures, frequencies of various events, and validity of various models. These probability distributions could be used as direct input to probabilistic performance assessments. Alternatively, discrete distributions describing alternative conceptual models could be used to characterize the outcomes of analyses using each of the alternative concepts. In either event, the outputs of these performance assessments are expected to provide important inputs to DOE's ongoing site characterization and design processes, as well as to indicate the relative importance of various programmatic activities for performance assessment. In addition, these "iterative" assessments are expected to provide important feedback on the nature and importance of improvements to be made in the analytical basis for the performance assessment. Ultimately the performance assessment, supported in part by expert elicitation, is expected to be the central focus of any potential DOE license application, wherein the various lines of evidence (field data, laboratory experiments, natural analogues, theoretical and semi-empirical analyses) are drawn together in an effort to demonstrate compliance. Because the NRC staff has an interest and oversight role[5] in these various aspects of performance assessment and the associated expert elicitation(s), the staff has developed this guidance document.

Finally, it should be noted that NRC evaluation of any potential DOE license application would involve an opportunity for a hearing. If a hearing is requested and if the Commission appoints an Atomic Safety and Licensing Board to preside at the hearing, then that Licensing Board will be responsible for conducting a hearing at which evidence is taken on contested issues. The Licensing Board has considerable liberty in the selection of those values or judgments it would use to reach any potential licensing decision. Although the Board's decision can be based only on evidence in the record, it can exercise wide discretion in the weight it attributes to any particular piece of evidence. Thus, for any particular issue or case, the staff cannot predict what weight, if any, the Licensing Board would attribute to expert opinion derived from an expert elicitation, as opposed to expert opinion obtained by other means.

[5]In addition to the review of the site characterization activities specified under 10 CFR 60.18, the Commission noted in its final rule that it contemplated an ongoing review of information on site investigation and site characterization, such as those with long lead-time procurement actions, so as to allow for the early identification and resolution of potential licensing issues. Moreover, NRC's strategic planning assumptions call for the early identification and resolution, to the extent practicable, at the staff level, before the receipt of a potential license application for a geologic repository (see Johnson, 1994). The principal means for achieving this goal is through informal, pre-licensing consultation with DOE, the State of Nevada, Indian Tribes, and affected units of local government. This approach attempts to reduce the number of, and to better define, issues that will be litigated during a potential licensing hearing, by obtaining input and striving for consensus from the technical community, interested parties, or other targeted groups on such issues.

In this regard, the staff has undertaken the development of this BTP as a means for closure on acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic disposal regulations. The staff believes that rigid adherence to the specific steps proposed in the BTP is not sought so much as the use of a consistent process that produces an accurate and properly documented assessment of the state of scientific uncertainty. Moreover, the staff believes that effective implementation of a good elicitation process cannot guarantee acceptance of the technical conclusions; however, use of a flawed process or improper implementation of a good process cannot help but cast serious doubt on the quality of the conclusions.

1.2.3 Peer Review[6]

Much of scientific and engineering development is subjected to the normal review process of critical evaluation by colleagues in various venues. These so-called *peer reviews* are typically documented, critical reviews that evaluate the acceptability and adequacy of some particular form of original research, performed by peers who are independent of the work being reviewed. A peer review can be conducted by obtaining input separately from a number of peers or by convening a panel to conduct the review. Also, discussions among the panel members can generate useful information not available from a set of independent reviews. The most common peer review process (i.e., pre-publication technical review of a scientific article) typically uses informal expert judgment to evaluate scientific methods and results. However, in principle, the nature of peer review is sufficiently flexible that its rigor and formality are commensurate with the study being reviewed. For example, the NAS is frequently called on to review reports or conclusions as a group of technical experts (see National Research Council, 1995b and 1995c). Peer reviews can also be conducted using a formal process to review the solution of problems of high importance. Formal peer review has some of the same basic attributes of the formal expert elicitation process (e.g., disclosure of potential conflicts of panelists, documentation behind decision-making).

The peers are recognized experts in the domain of interest as evidenced by their scientific qualifications. The peers may comment on the validity of the assumptions, the appropriateness and limitations of the methodology and procedures, the accuracy of the calculations, the validity of the conclusions, and the uncertainty of the results and consequences of the work. They may also offer alternative explanations of the results and comment on the adequacy of the information and data used to obtain them.

The peer review process requires the expert judgments of peers. However, it is important to note that peer review as an expert judgment process is different from the formal elicitation of expert judgments in the context of this staff position. The reference to expert judgment herein denotes judgments, opinions, or information provided by subject-matter experts that give rise to or contribute to the generation of a scientific stance or solution to a given problem. Peer review, by contrast, seeks judgments from subject-matter experts regarding the soundness and quality of an existing or proposed scientific stance or solution to a problem. In this context, expert judgments can be the subject of peer review. The admittedly subtle differences between the elicitation of expert judgment and independent peer review notwithstanding, both processes contribute in a positive way to enhancing quality.

[6]This discussion is an expansion of the earlier definition of peer review provided by Altman *et al.* (1988, p. 2).

1.3 Selected Examples of NRC Use of Expert Elicitation

In addition to reviewing DOE's site characterization activities, the NRC staff has drawn on experience obtained in other NRC regulatory programs (see PRA Working Group, 1994) and has been exploring, independently, the ways in which expert elicitation may be applied in the geologic repository program. Some of the staff's program activities are summarized below.

1.3.1 Severe Accident Risk Analysis

The formal use of expert elicitation in NRC PRAs was introduced, during the mid-1980s, with the development of NUREG–1150, an assessment of severe accident risk at five U.S. nuclear power plants (NRC, 1990). Earlier, in 1975, NRC had completed its first study of the probabilities and consequences of severe reactor accidents at two commercial nuclear power reactors. This work, for the first time, used the analytical technique of PRA for the study of core meltdown accidents (see NRC, 1975). After completion of these first PRAs, NRC, industry groups, and the utilities initiated programs to improve PRA technology to measure and enhance nuclear power reactor safety, and NRC gradually introduced PRAs into its regulatory process.

In the late 1980s, the staff updated the 1975 PRA and in doing so, reassessed the 1975 estimates, using improved PRA techniques; the results of this reassessment were documented in NUREG–1150. One of the major accomplishments of the NUREG–1150 study, which continues to be one of the most sophisticated

applications of PRA performed by the staff to date, was the adoption of a formal protocol to elicit expert judgment in areas of the risk studies where little or no operational data existed. Expert judgment was needed to supplement and interpret the available data, and to explicitly address the uncertainties in the analysis itself. The elicitation process relied on a formal set of procedures that are described in detail by Gorham-Bergeron *et al.* (1986).

This approach was subsequently reviewed and modified,[7] based, in large part, on recommendations made by Kouts *et al.* (1987) and Kastenberg *et al.* (1988) after peer reviews of the first draft of NUREG–1150. Based on these recommendations, the elicitation process for the final NUREG–1150 report was made more formal and rigorous by the identification of nine discrete process steps; these process steps are described in Appendix A of the final report.

More recently, expert elicitation was applied to uncertainty assessment for two new probabilistic accident consequence codes. In a joint effort with the Commission of European Communities, the NRC Office of Nuclear Regulatory Research conducted a formal expert elicitation of 16 international experts to develop a library of uncertainty distributions for selected consequence parameters. Distributions of measurable atmospheric dispersion and deposition parameters were successfully elicited from 16 international experts involved in the many phenomenological areas of consequence analysis (see Harper *et al.*, 1995). For the most part, the elicitation protocol used by the NRC/Commission of European Communities followed the same principles that guided the NUREG–1150 process. One noteworthy exception, however, was the expectation in the later study that, should it become necessary (e.g., to support an independent peer review), the subject-matter experts should be willing to be identified with their elicited probabilities and the rationales for those probabilities. In NUREG–1150, experts were permitted complete anonymity if they so desired.

[7]Gorham-Bergeron *et al.* (1986) was available in draft form (as NUREG/CR–4551 in the Public Document Room) as a complementary report to NUREG–1150, when NUREG–1150 was first issued in draft form, for public comment, in 1987. The final version of NUREG/CR–4551 was published as Gorham *et al.* (1993).

1.3.2 Seismic Hazard Analysis

Expert elicitation is also widely recognized as integral to probabilistic seismic hazard analyses (see National Research Council, 1988). In the mid–1980s, NRC sponsored a major study of probabilistic seismic hazard in the eastern United States conducted by Lawrence Livermore National Laboratory (LLNL—see Bernreuter *et al.*, 1980–83, 1985, and 1989). This study of seismic hazard at 69 reactor sites relied heavily on the judgments of experts whose interpretations of geophysical, seismological, and geologic data were individually obtained using a formal elicitation process. In conjunction with funding the LLNL study, NRC recommended that the nuclear power industry perform an independent study to provide a coordinated utility position on seismic hazard estimates. The Electric Power Research Institute (EPRI), with funding from a consortium of nuclear power utilities, developed its own elicitation methodology and applied it to hazard estimates for 56 of the 69 reactor sites examined by LLNL (see Seismicity Owners Group/EPRI, 1986).

In both the LLNL and EPRI methodologies, seismic hazard curves were developed for U.S. commercial nuclear power reactor sites east of the Rocky Mountains, using expert judgment to interpret the available data. Both the LLNL and the EPRI programs were based on the premise that available geologic data were not sufficient to fully predict seismic phenomena, and they adopted the use of expert opinion to characterize the uncertainties in the data. Although both methodologies used essentially the same sets of data, the two methodologies produced significantly different results. The differences in the approaches and results were subsequently reviewed and critically evaluated (see Bernreuter *et al.*, 1987). It was concluded that, in general, the differing results could be attributed to how elicited information was aggregated in the respective elicitation processes (*op cit.*, pp. 254–258). LLNL has subsequently performed a re-elicitation of the seismicity and ground motion experts to improve its earlier estimates of uncertainty in seismicity parameters and ground motion models (see Sobel, 1994).

Most recently, in a separate effort jointly sponsored by NRC, DOE, and EPRI, a "Senior Seismic Hazard Analysis Committee" has developed methodological guidance on how best

to perform a probabilistic seismic hazard analysis, with special emphasis on the formal process for eliciting expert opinion. Results of this project were published in late 1995 (see Senior Seismic Hazard Analysis Committee (SSHAC), 1995) and are currently being reviewed by an NAS committee.

Appendix A ("Geologic Siting and Design Criteria for Nuclear Power Plants") to 10 CFR Part 100 contains existing NRC siting and design policy related to geological and seismological hazards for commercial nuclear power reactors. In conjunction with the Standard Review Plan for nuclear power reactors and other applicable regulatory guides, Appendix A sets forth a regulatory framework that guides the NRC staff in its evaluation of the adequacy of an applicant's investigations of geologic phenomena and proposed design parameters for nuclear power reactors. Also, independent spent fuel storage installations, monitored retrieval storage systems, and mine-tailings dams for uranium processing mills refer to Appendix A for guidance on faulting and seismic criteria. Recently, the Commission proposed revisions to the requirements and application of Appendix A to 10 CFR Part 100 (see NRC, 1994; 59 *FR* 52255). Under review as part of this reassessment are recommendations that NRC's geological and seismological investigations and design criteria be modified to reflect better the current state of the art in these areas. Although probabilistic seismic hazard assessments have been discussed previously in Safety Evaluation Reports for nuclear power reactors, these revised requirements, as proposed, would explicitly recognize the use of probabilistic techniques, as a valid means to assess uncertainty associated with the analysis of and engineering design for seismic phenomena. Specifically, the Commission has proposed the use of either of the probabilistic methodologies independently developed by LLNL or EPRI as acceptable approaches to the evaluation of seismic hazard uncertainty. Because both methodologies rely extensively on the formal elicitation of expert judgment to assess uncertainty in seismic hazard estimates, this proposed rule, if promulgated in final form, would represent the Commission's first explicit regulatory recognition of the value of formal expert elicitation as a technique for assessing uncertainty.

1.3.3 HLW Technical Analyses

The process of formally eliciting the judgments of multiple experts has also been studied and applied in support of the staff's independent performance assessment activities. For example, Bonano *et al.* (1990) discussed the state of the art of formal expert elicitation and its possible application to HLW performance assessments. DeWispelare *et al.* (1993) subsequently applied the formal process of elicitation to the prediction of future climate, with associated parameter distributions, at Yucca Mountain, and to the estimation of corresponding probabilities of occurrence. As part of the NRC staff's independent Iterative Performance Assessment efforts to develop a performance assessment review capability, the staff has relied on informal elicitations to identify and screen scenarios (see Codell *et al.* (1992) and Wescott *et al.* (1995)). A structured elicitation process was used by the staff to evaluate potential quantitative criteria to clarify the ". . . substantially complete containment requirement" (10 CFR 60.113(a)(1)(i)(A)—see Tschoepe and Abramson, 1992). Broader applications of expert judgment were examined by DeWispelare *et al.* (1994) who identified situations where the use of expert judgment might be appropriate in the HLW program. From this review, the staff was able to verify that lessons learned from these direct experiences had relevance for broader applications. In pursuing these reviews of prior Agency experience with expert elicitation, as well as its own elicitation activities, the NRC staff has acquired a better understanding of the critical issues associated with the development and use of expert elicitation (and, more generally, expert judgment).

1.4 Purpose of the BTP

The NRC staff recognizes that expert judgment is implicit in all scientific inquiry and engineering endeavors, and is generally applied in an informal manner. It is the purpose of this BTP to: (1) provide general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation); and (2) describe acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic repository disposal regulations. Included in this BTP is a

recommended procedure for selecting experts, structuring a formal elicitation, and documenting the elicitation process.

The NRC staff believes that formal elicitation procedures, used prudently and appropriately, can help ensure that expert judgments are well-documented and that the technical reasoning used to reach those judgments is openly displayed for review. If conducted optimally, formal elicitation can reveal a wide range of scientific and technical interpretations, thereby exposing (and possibly quantifying) the uncertainties in estimates concerning repository siting, design, and performance attributable to limitations in the state of technical knowledge. Formal procedures may also help groups of experts resolve differences in their estimates by providing a common scale of measurement and a common vocabulary for expressing their judgments.

In preparing this BTP, the NRC staff has drawn on the specific recommendations of DeWispelare and Bonano (1995), as well as earlier, more general recommendations in Winkler *et al.* (1992) and Bonano *et al.* (1990). It should also be noted that this BTP has attempted to incorporate, as appropriate, a number of NWTRB and NAS recommendations with regard to the use of expert elicitation as a formal decision-aiding methodology, including the treatment of "bias." (See Section 4 for a discussion of staff consideration of specific NWTRB and NAS recommendations.) Moreover, this BTP has not attempted to prescribe the specific technical issues for which expert judgment should (or should not) be applied. The staff has viewed such determinations to be the prerogative of DOE. However, with respect to performance assessment, the staff is considering the potential need for future guidance to identify those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate.

The positions and discussions in this BTP are based on the premise that, under appropriate circumstances, it is acceptable to supplement data and analyses with the opinions of experts as part of the support for demonstrating compliance with NRC's geologic disposal regulation, and that, in some cases, these opinions are best obtained using a formal and well-documented process. This BTP gives specific guidance by which DOE may determine if formal expert elicitation would be useful and provides guidelines for an acceptable process for obtaining it. Section 2 summarizes the principal regulatory requirements and considerations that relate to this topic. The staff's technical position statements are listed in Section 3, and Section 4 provides a discussion of the supporting rationale behind each statement of position.

Definitions of key terms used in the BTP are provided as Appendix A. Summarized in Appendix B are lessons learned from a recent expert elicitation exercise performed by the NRC staff and its contractor, the Center for Nuclear Waste Regulatory Analyses (CNWRA). Appendix C contains the final Commission *Policy Statement* with regard to the use of PRA methods in its regulatory activities, including HLW. The staff's response to the public comments received on an earlier draft of the BTP, noticed in the *Federal Register* on February 28, 1996 (61 *FR* 7568), are contained in Appendix D. Appendix E contains the staff's views with regard to a possible course of resolution for NRC SCA Comment 3. Lastly, Appendix F contains the staff's response to comments received from the Advisory Committee on Nuclear Waste on the final draft of the BTP.

The NRC staff recognizes that DOE has the flexibility to determine whether the costs and benefits of performing an expert elicitation are advantageous compared with the costs and benefits of performing theoretical analyses and/or gathering additional field and experimental data. That being said, however, the use of expert elicitation should not be considered as an acceptable substitute for traditional analyses based on adequate field or experimental data, when such data are reasonably available or obtainable, or the analyses are practicable to perform. Nor can the use of a formal elicitation process, even when conducted in a manner consistent with guidance provided in this BTP, guarantee that specific technical conclusions will be accepted and adopted by the staff, a Licensing Board, the Commission itself, or any other party to a potential HLW licensing proceeding. Rigid adherence to a sound elicitation process, in and of itself, in no way guarantees that the resulting judgments will be sufficient to meet the applicant's burden of proof regarding the substantive issues addressed by the elicitation. Nonetheless, expert judgments obtained through

an evidently flawed or poorly documented process will weaken their ability to support demonstrations of compliance.

It should also be noted that nothing in this BTP precludes the use of expert judgment obtained through informal means by DOE, in the preparation of a potential license application. As has been the case in previous regulatory activities, the staff will accept for review the results of formal or informal judgment so long as the rationale associated with the judgment is adequate, transparent, and sufficiently documented.

1.5 BTPs as Technical Guidance

BTPs are issued to describe, and make available to the public, methods acceptable to the NRC staff, for implementing specific parts of the Commission's regulations, and to provide regulatory guidance to regulated entities such as DOE. BTPs are not substitutes for regulations, and compliance with them is not required. Methods and solutions differing from those set out in the BTP will be acceptable if they provide a sufficient basis for the findings requisite to the issuance of a permit or license by the Commission.

This BTP constitutes informal pre-licensing activity between the NRC staff and a prospective applicant under 10 CFR 2.101(a)(1) and is not part of a proceeding under the Atomic Energy Act (Public Law 83–703), as amended. Nothing in this BTP constitutes a commitment to issue any authorization or license, nor in any way affects the authority of the Commission, the Atomic Safety and Licensing Boards, other presiding officers, or the Director, in any such proceeding.

Published BTPs will be revised, as appropriate, to accommodate comments and to reflect new information and experience.

2 REGULATORY FRAMEWORK

The following discussion describes the current regulatory framework and Commission policy that underpin the staff's technical positions presented in this BTP.

2.1 10 CFR Part 60[8]

As noted earlier, the Commission's regulations found at 10 CFR Part 60 address the licensing of a mined geologic repository for the disposal of HLW. Subpart E of those regulations sets forth specific performance objectives, along with a number of general siting and design criteria. Section 60.112 of Subpart E currently establishes compliance with EPA standards for the disposal of HLW. (The previously applicable EPA standards would have limited the release of radioactive material to the accessible environment (weighted by a factor approximately proportional to radiotoxicity, and integrated over a period of time) as the overall system performance objective for the geologic repository after permanent closure.)

With regard to 10 CFR 60.112, Section 60.101(a)(2) states that:

> While these performance objectives and criteria are generally stated in unqualified terms, it is not expected that complete assurance that they will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the objectives and criteria will be met is the general standard that is required. For §60.112, and other portions of this subpart that impose objectives and criteria for repository performance over long times into the future, there will inevitably be greater uncertainties. Proof of the future performance of engineered barrier systems and the geologic setting over time periods of many hundreds or many thousands of years is not to be had in the ordinary sense of the word. For such long-term objectives and criteria, what is required is reasonable assurance, making allowances for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with those objectives and criteria. Demonstration of compliance with such objectives and criteria will involve the use of data from accelerated tests and predictive models that are supported by such measures as field and laboratory data and natural analog studies.

In a subsequent proposal to conform the 10 CFR Part 60 regulations to then extant EPA standards for management and disposal of HLW, the Commission further elaborated on what was necessary for a satisfactory demonstration of compliance (NRC, 1986; 51 *FR* 22288):

> Demonstration of compliance with the performance objectives of §60.112 will also involve predicting the likelihood and consequences of events and processes that may disturb the repository. Such predictions may involve complex computational models, analytical theories and prevalent expert judgment. Substantial uncertainties are likely to be encountered and sole reliance on numerical predictions to determine compliance may not be appropriate. In reaching a determination of reasonable assurance, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity or redundance among multiple barriers of a specific repository.

A primary consideration of a decision to authorize construction of a repository will be whether the site and design comply with the performance objectives and criteria contained in Subpart E. DOE must interpret the geologic record and provide a demonstration that the repository site and design will comply with explicit numerical performance standards. As noted in the regulation, there will be substantial and unavoidable uncertainties[9] in predicting the long-term performance of a geologic repository.

[8]As noted earlier, the need for future revision to 10 CFR Part 60 is under consideration. Should 10 CFR Part 60 be revised, the language of the citations quoted in this section of the BTP would need to be re-examined, and if necessary, be revised accordingly. It is not expected, however, that these revisions would require any change to the staff's technical positions set out here.

[9]Uncertainties may include, but not be limited to the: (a) identification of basic phenomena and their potential effects on repository performance; (b) development and validation of models to describe these phenomena; (c) accuracy of available data; and (d) calculational uncertainties.

Conclusions as to the performance of the geologic repository and of particular barriers over long periods of time, by necessity, will be based largely on inference, as it will not be possible to carry out test programs of sufficient duration or that simulate the full range of potential conditions expected over the period of regulatory concern (see NRC, 1983; 48 *FR* 28204). Given these uncertainties, it will be necessary for DOE to adopt a variety of design features, develop sophisticated models, perform tests, acquire data, and undertake other measures to be able to demonstrate that the performance objectives will be met.

For its part, in reaching a potential construction authorization decision, the Commission has stated that ". . . a reasonable assurance, on the basis of the record before the Commission, that the objectives and criteria will be met is the general standard that is required." (10 CFR 60.101(a)(2)) To reach a "reasonable assurance" finding, the Commission has said it will need to be able to do at least two things (48 *FR* 28201). It must first determine that DOE has demonstrated compliance with the numerical performance standards, and, second, it must satisfy itself that DOE's analysis of the site and design is sufficiently convincing, that its limitations are well-understood, and that DOE has demonstrated that its analyses have made appropriate allowance for the time period, hazards, and uncertainties involved.[10]

Confidence in the adequacy of DOE's data, analyses, and other items and activities associated with the repository program will be enhanced to the extent that they are obtained through a quality assurance (QA) program consistent with Subpart G of 10 CFR Part 60. In this regard, the staff has acknowledged that external peer reviews may be used as part of the QA actions necessary to provide confidence in the work submitted. The NRC staff has provided guidance on how these peer reviews would be conducted in NUREG–1297 (see Altman *et al.*, 1988).

One of the greatest challenges facing the Commission in making the determinations necessary for the licensing of a potential HLW repository will be to assess the validity of DOE's treatment of uncertainty. Various methods may be used (e.g., probability distributions, conservative "bounding" analyses), and the Commission will evaluate quantitative and nonquantitative arguments to assess their application. For purposes of demonstrating compliance with the 10 CFR Part 60 performance objectives, the Commission has acknowledged that the treatment of uncertainty in DOE's compliance demonstrations is expected to ". . . rely heavily on [the use of some form of] expert judgment . . . in the selection of an appropriate [uncertainty reduction] method and for the application of that technique . . . ." (NRC, 1986; 51 *FR* 22292)[11] This is consistent with previous licensing experience where the NRC Licensing Board has admitted expert opinion evidence by one expert or by a panel of experts in the analysis of risks at nuclear power plants where little or no data exist or the available data are unreliable.

As with other NRC licensing actions, a Licensing Board's decision to grant or deny a license for a proposed repository will be based on submitted evidence that is a combination of fact and opinion. The subjective judgments of individual experts and, in some cases, groups of experts, would likely be presented to interpret DOE's data and analyses, and also to address the technical issues presented in the hearing. Such assessments may be not only quantitative but *qualitative* as well. In certain instances, it may not be possible to develop a "correct" estimate of some event or process. Rather, it may only be possible to develop a "range" of estimates. Thus, both DOE and NRC may have no choice but to present the informed judgment of qualified experts.

That being said, however, in its review of DOE's statutory SCP (10 CFR 60.16), the NRC staff noted its concerns with DOE's site characterization programs, specifically calling into question DOE's potential over-reliance on the use of expert judgment to supply the necessary information in any potential license application.[12]

[10]For a more detailed discussion of the Commission's views on the "reasonable assurance" concept, in the context of the geologic repository regulation, see NRC (1983 and 1986).

[11]In the context of the containment requirements (10 CFR 60.112), EPA also noted that ". . . sole reliance on [the] numerical prediction of [geologic repository performance] may not be appropriate . . . [and] the implementing agencies may choose to supplement such predictions with non-quantitative judgments" (EPA, 1985; 50 *FR* 38088).

[12]See the staff's SCA Comment 3 (in NRC, 1989). This open item has not been resolved at this time.

2.2 Commission *Policy Statement* Concerning the Use of PRA Methods in Nuclear Regulatory Activities

NRC has generally regulated the use of nuclear material based on deterministic approaches and used probabilistic approaches only in certain specialized areas. However, after the Three Mile Island incident, NRC has increasingly used PRA techniques to augment the traditional non-probabilistic methods of analyzing nuclear safety. PRA techniques have been applied successfully in several regulatory areas (see DOE *et al.*, 1992) and have proven to be a valuable complement to engineering approaches.

Recently, Commission policies and regulations have been based, in part, on PRA methods and insights (NRC, 1995; 60 *FR* 42623). In light of these developments, the Commission issued an *overall* policy statement on the expanded use of PRA in nuclear regulatory activities, including the area of nuclear waste disposal (60 *FR* 42622). Among other things, the Commission *Policy Statement* (see Appendix C) called for the use of ". . . state-of-the-art . . . [PRA] methods . . . ." in a manner that complements the deterministic approach. (60 *FR* 42628) (According to a recent staff survey, such PRA methods include, among other things, methods to obtain and process expert judgment (see PRA Working Group, 1994).) For the purposes of the regulatory actions in the waste management program, the Commission noted, in the "Statement of Considerations for the final Policy Statement," that it ". . . agrees with [public] comments regarding [the treatment] of uncertainties in projecting repository performance . . . [through] the use of technical expert judgment . . . ." (60 *FR* 42627)

To ensure evenness and consistency in the staff's *future* uses of PRA methods, NRC recently established a PRA Working Group to: (a) evaluate the staff's current uses of PRA; (b) identify areas for improvement in that use; and (c) recommend the tenets of some basic principles and guidance for application in the future. In the area of expert elicitation, the PRA Working Group made a number of general recommendations on *formal* techniques for obtaining, evaluating, and processing expert judgment (PRA Working Group, 1994; pp. C–129—C–148). To ensure the quality and reproducibility of the elicited information, the Working Group recommended that any formal elicitation procedure contain the following process steps (*op cit.*, pp. C–130—C–135):

- Selecting and defining technical issues.
- Selecting experts.
- Organizing assessments.
- Preparing for the elicitation.
- Processing expert judgment.
- Documenting.

The technical positions cited in Section 3 are consistent with these recommended process steps.

3 BRANCH TECHNICAL POSITIONS

In view of the aforementioned policy considerations and statements of regulatory consideration underpinning 10 CFR Part 60, the staff has adopted the following technical positions concerning the use of expert elicitation in demonstrating compliance with the geologic repository disposal regulations. (As a supplement to the technical positions here, Appendix A provides definitions for certain key terms.)

(1) In matters important to the demonstration of compliance, the use of formal expert elicitation should be considered whenever one or more of the following conditions exist:

   (a) Empirical data are not reasonably obtainable, or the analyses are not practical to perform;

   (b) Uncertainties are large and significant to a demonstration of compliance;

   (c) More than one conceptual model can explain, and be consistent with, the available data; or

   (d) Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative.

(2) (a) When formally eliciting expert judgment, the applicant should use a consistent and systematic procedure that will ensure that the results obtained accurately reflect what is known and not known about the topic in question. The components in an acceptable elicitation process are described below and are illustrated in Figure 1. Although written largely for the elicitation of *individual* subject-matter experts, the same approach can be applied to a *panel* (or a team) of subject-matter experts.

Step No. 1—Definition of Objectives

The objectives of the elicitation should be defined explicitly and in a manner that reflects a clear understanding of how the judgments obtained will be used. The explication of these objectives should then guide the choice of experts, the information provided to them, and the form of the judgments that will be required.

Step No. 2—Selection of Experts

Before selection of the subject-matter experts, whose judgments will be elicited, two other types of experts should be recruited— the normative expert and the generalist. Because these types of experts may influence the outcome of the elicitation by the manner in which judgments are elicited, analyzed, or used, care should be taken in their selection to ensure that they can perform in an objective and impartial manner. Working together, the normative experts and generalists generate and apply specific criteria for the selection of the subject-matter experts.

The subject-matter experts selected for elicitation should be individuals who: (a) possess the necessary knowledge and expertise;[13] (b) have demonstrated their ability to apply their knowledge and expertise; (c) represent a broad diversity of independent opinion and approaches for addressing the topic(s) in question; (d) are willing to be identified publicly with their judgments; and (e) are willing to publicly disclose all potential conflicts of interest.

The criteria used to select the various experts of the elicitation team should be documented.

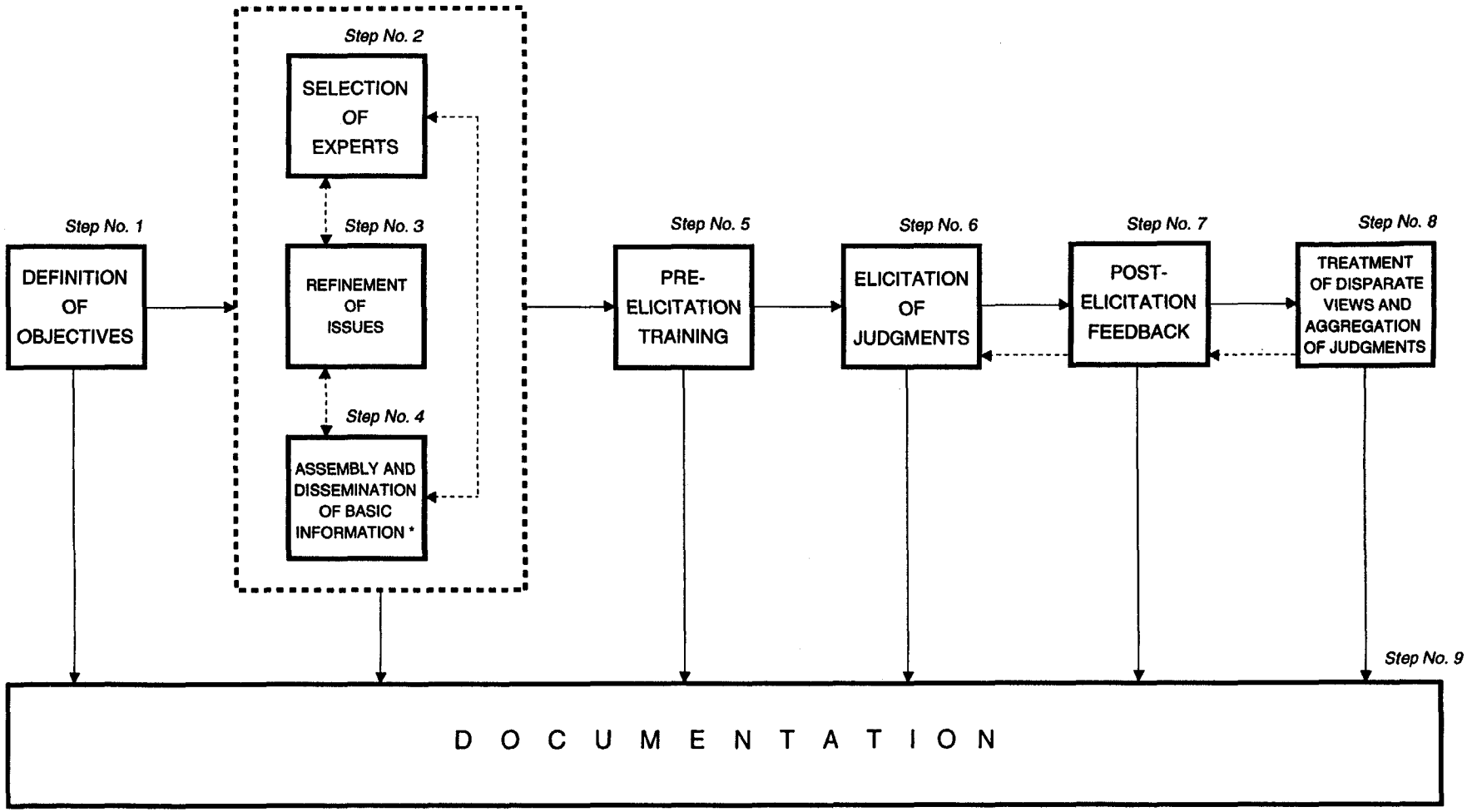
Step No. 3—Refinement of Issues and Problem Decomposition

The generalists and normative experts should work with the subject-matter experts to decompose the broad objectives of the elicitation by clearly and precisely specifying more focused and simpler sub-issues.

Step No. 4—Assembly and Dissemination of Basic Information

Assembly of background information should be initially conducted by the generalists and

[13]With regard to Item (a), it would be useful for members of the expert panel to possess at least some rudimentary knowledge of both decision-making theory and statistics. However, the possession or the lack of this knowledge should not be used as a selection criterion.



* *E.g., the data, evidence, or knowledge base used by the subject-matter experts to arrive at their respective judgments.*

Figure 1 Components in an acceptable expert elicitation process. (Numbers next to the process blocks correspond to the technical position statements described in the text. Dashed lines indicate a feedback loop.)

normative experts. As the elicitation process proceeds, the subject-matter experts may be able to recommend additional sources of information. Bias in the selection of this background material should be avoided such that a full range of views is represented and the necessary data and information are provided in a uniform, balanced, and timely fashion to all subject-matter experts.

Step No. 5—Pre-Elicitation Training

Individual (or teams of) subject-matter experts should be provided training before the elicitations to: (a) familiarize them with the subject matter (including the necessary background information on why the elicitation is being performed and how the results will be used); (b) familiarize them with the elicitation process; (c) educate them in both uncertainty and probability encoding and the expression of their judgments, using subjective probability; (d) provide them practice in formally articulating their judgments as well as explicitly identifying their associated assumptions and rationale; and (e) educate them with regard to possible biases that could be present and influence their judgments.

Step No. 6—Elicitation of Judgments

The individual elicitation session with each subject-matter expert (or teams of subject-matter experts) should be held in a private setting conducive to uninterrupted discussion. The generalists and normative experts should be in attendance for the complete session with each subject-matter expert. At the start of the session for each subject-matter expert, the normative expert should summarize the issues to be covered and outline the logistics of the elicitation. All definitions and assumptions agreed to by the group during pre-elicitation meetings should be reviewed. All subject-matter experts should be queried in a uniform manner and asked to provide specific answers to questions about the issues considered and the reasoning behind their responses. Care should be taken to ensure that the required information is obtained and that it is internally consistent. Responses of all subject-matter experts should be documented thoroughly with one or more of the following: written notes, transcription, and audio or video tape.

Step No. 7—Post-Elicitation Feedback

Each subject-matter expert (or teams of subject-matter experts) should be provided feedback from the elicitation team on the results of his or her elicitation as soon as practical after the elicitation sessions are completed. Each expert should be queried as to the need for revision or clarification of his or her respective judgments based on that feedback. As is the case for all the elicited judgments, the rationale for any revisions should be documented scrupulously.

Step No. 8—Aggregation of Judgments (Including Treatment of Disparate Views)

Whatever aggregation method is employed, the individual expert's opinions must be preserved, documented, and provided to the NRC staff. Transparency in the aggregation process will render these judgments, including disparate views or outliers,[14] useful for subsequent analyses. If disparate judgments are aggregated or combined, the applicant should: (a) provide some rationale for the specific aggregation techniques employed and provide documentation sufficient to trace the impact of the individual expert's judgment on the consolidated judgment; and (b) show what effect, if any, the disparate views would have on design and/or performance.

When widely disparate opinions arise, extra effort should be taken to document thoroughly the bases for the differing views. Subject-matter experts with differing views should be asked to comment on opposing views during and/or after their individual elicitations. Should the disparity in views persist, then each of the significantly varying views should be provided as output of the elicitation so that it may be incorporated directly into technical analyses and performance assessments, or used to represent the extremes in a sensitivity analysis.

[14]As used in this guidance, "outliers" refers to those opinions which lie apart from the views or expected (average) views of other experts.

Step No. 9—Documentation

Proper documentation of a formal expert elicitation should indicate what was done, why, and by whom. The resulting judgments should be clearly described along with the reasoning supporting these judgments. The specific issues addressed by the elicitation should be precisely defined. Unambiguous definitions of all specific terms should be provided and any assumptions used in the elicitation should be explicitly stated. The judgments, as they are stated by each subject-matter expert, should be provided, accompanied by the logic and information on which they are based. Any calculations that the experts considered important in determining judgments or models used should be recorded and all literature used, whether public or restricted, should be properly referenced. Proper documentation should clearly distinguish between that information provided directly by each subject-matter expert and any subsequent processing of that information, such as smoothing, interpolation, extrapolation, or aggregation of the judgments of different experts.

(b) The approach described above envisions that all of these process steps would be part of a procedure for an expert elicitation. If preferred, some of these steps can be combined as long as all of the elements of the process are addressed.

If one or more of the process steps are omitted from the recommended procedure, the staff may need additional information for its consideration before accepting the results of an elicitation for its review and evaluation.

(3) If information from an expert elicitation is to be submitted in support of a license application, and if additional data or information becomes available, subsequent to the completion of the elicitation, which could change opinions or judgments obtained in the formal elicitation, the results of the elicitation should be re-examined and updated, as appropriate. In addition to the information requested above, documentation should include a detailed description of the updating process.

4 DISCUSSION

The technical positions outlined in Section 3 are motivated by several primary purposes.

First, as noted in Section 1.1, the NRC staff has traditionally accepted, for review, the appropriate judgments of technical experts regarding the basis of a license application. In this regard, the Commission has already acknowledged that it expects that expert judgment will play an important role in any potential geologic repository licensing proceeding (see NRC, 1986; 51 *FR* 22292). Thus, the staff believes that these technical positions are consistent with both previous Commission practice and Commission expectations on how the geologic repository disposal regulations will be implemented.

In defining its technical positions, the staff has attempted to draw from previous Commission experience with the application of formally elicited expert judgment in a regulatory context. The most prominent examples of the Commission's use of this process can be found in the area of commercial nuclear reactor regulation. As discussed in Section 1.1, the techniques of expert elicitation have been applied heretofore, in NRC's regulatory program, to the assessment of uncertainty associated with seismic hazards and faulting parameters, and to the assessment of risk from severe accidents.

Second, the NRC staff recognizes that, in certain instances, the collection of data is not feasible and that expert judgment must be used to complement existing information, in order to support demonstrations of compliance with the requirements of 10 CFR Part 60. Topics where staff expects that expert judgment will be brought to bear are discussed in more detail in Bonano *et al.* (1990) and DeWispelare *et al.* (1994). Among these are: scenario formulation, development, and probability estimation; development of and confidence building for computational models; parameter estimation; and identification of where additional data and information gathering are necessary and where they may be impractical. As important as its role may be, however, expert judgment should be distinguished from both measured data or technical calculations based on accepted scientific laws and principles. It should be viewed as an alternative, and employed when other means of obtaining requisite data or information have been thoroughly considered and it has been concluded that such means are not practical to implement.

In evaluating the practicality of obtaining the needed information (or data), DOE is expected to consider cost, schedule, resource availability, and other programmatic factors. DOE will need to evaluate the programmatic costs and risks of using expert elicitation as an alternative to more objective data-gathering methods, and the likelihood that the elicitation itself may introduce greater uncertainty into the demonstration of compliance than will the use of objective information.

Lastly, when expert judgments are used to support a demonstration of compliance, whether they are formally elicited or not, sufficient documentation should exist to allow external examination of what the judgments were, how the judgments were arrived at (their basis), how the judgments were used, and why the judgments were used instead of obtaining objective information (e.g., obtaining the needed data). Such documentation supports a broader understanding and acceptance of the expert judgment. For expert judgment to be defensible under external peer review, the basis for the judgment should be well-documented. Peers must be able to trace origins of specific judgments from initial assumptions through integration of results and conclusions. There should be no gaps in the documentation, so that an evaluation can be based on a thorough understanding of the work presented. In addition, the availability of such documentation makes possible technical discussions in terms of underlying principles rather than just the individual outcomes. Documentation should also include the justification for using expert judgment to complement other data and analyses in reducing the residual uncertainty.

All assumptions about the technical issues that were used to develop the expert judgments should be identified. The judgments as they are stated by each individual subject-matter expert should be provided in the documentation. Any calculations that a subject-matter expert considered important in forming judgments, or models used, should be documented. All literature used, whether public or

restricted, should be properly referenced. Any subsequent manipulation of the individual expert's judgments, such as aggregation or combining with other opinions or data, should be documented thoroughly.

In closing, it should be noted that this NUREG discusses the rationale for and the potential benefits derived from the use of expert judgment in a number of places. Without intending to limit those discussions, the following summary is provided. Section 1 describes the ubiquitous nature of expert judgment in scientific and technical activities. Section 1.2.1 provides a description of typical outputs of an expert elicitation and the potential uses of the expert judgments in the evaluation of repository performance assessment. Section 1.3 provides actual examples of the NRC use of expert judgments, including those used in PRA. Section 3 provides the technical position on conditions warranting the consideration of a formal expert elicitation. Later in this section, the staff elaborates on these conditions and discuss the benefits derived from obtaining expert judgments. Finally, Appendix A provides a discussion of expert judgment from a definitional perspective and Appendix B provides results and lessons learned from the NRC-sponsored formal climate expert elicitation.

The following discussion parallels the list of technical positions given in Section 3.

(1) Conditions That May Warrant Consideration of a Formal Process of Expert Elicitation

So-called "professional" or "engineering" judgment is exercised by scientists, engineers, and technical program managers routinely. More often than not, this is done informally and in a non-explicit manner. However, as noted in Section 1, the staff believes that confidence in DOE's HLW program will be enhanced by the transparency of the decision-making process. (This may also enhance public confidence, as well.) Thus, it may be appropriate for DOE to "formalize" the way in which certain decisions on issues or problems are made, as noted below.

One way in which the necessary transparency can be achieved in an expert elicitation process is to use a structured procedure, based on proven decision analysis methods, to gather the necessary judgments from recognized subject-matter experts. The use of such formal methods, as discussed in Technical Position No. 2 and depicted in the figure shown previously, promotes the accurate, consistent, and efficient collection and processing of the expert judgments. Moreover, the use of a formalized process increases the scrutability of the resulting judgments and enhances the communication of the results.

The question thus arises when or under what circumstances might it be appropriate to undertake formal methods of expert elicitation in the HLW program. As discussed in Section 3, the staff believes that formal methods of expert elicitation may be of the greatest value to the program and should be considered in the following situations: (a) empirical data are not reasonably obtainable or the analyses are not practical to perform; (b) uncertainties are large and significant to a demonstration of compliance; (c) more than one conceptual model can explain, and be consistent with, the available data; or (d) technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative, as discussed below.

Precise criteria for determining when an expert elicitation is to be undertaken are not presented here. Programmatic concerns such as timing, cost, and compliance demonstration will have a major impact on determining whether an expert elicitation or some other form of information gathering should be used. For example, expert elicitations may be more costly than a particular type of data-gathering investigation, but they may provide results in a more timely manner. Programmatic concerns dominate the choices of: (a) gathering additional field or laboratory data; (b) undertaking additional theoretical analyses; (c) using expert elicitation; or (d) altering the compliance demonstration strategy, to lessen or eliminate the need to resolve a particular issue. Therefore, the intent of this technical position is to allow DOE the maximum flexibility in choosing an approach, as long as an effective demonstration of compliance with the regulations can be made.

- ***Empirical data are not reasonably obtainable or the analyses are not practical to perform***—In some cases, data directly relevant to a problem, question, or issue may be lacking or incomplete (e.g., do not cover the entire

period of regulatory interest), or are not reasonably obtainable or practical to perform. Under such circumstances, existing data may be supplemented with expert judgments. These judgments may be obtained using a formal elicitation process. Examples of situations where field data are not reasonably or practicably obtainable include: (i) the site characteristics important to waste isolation would be irreversibly compromised by extensive data collection in such a way that could potentially disqualify the site; (ii) it is infeasible or impossible to collect data over the temporal or spatial scales appropriate to adequately address a particular issue; and (iii) the cost of collecting the comprehensive suite of data may be prohibitive.

- ***Uncertainties are large and significant to a demonstration of compliance***—Because of the extremely long period of regulatory concern, a combination of experimental methods, studies of natural analogues, and mathematical models will be used in the technical and performance assessments necessary to support any potential license application. Mathematical models are expected to be the primary tools for estimating the long-term future performance of the repository. Identification of external conditions to which the repository will be subjected during the period of regulatory concern is an essential requirement for applying the mathematical models. These external conditions include evolving tectonism, volcanism, seismicity, climate, hydrology, geochemistry, and other physical processes that may affect repository performance. Because of the complex interactions of these processes, as well as the temporal and spatial scales involved, more than one credible interpretation of existing data is frequently possible.

  As a result of these practical limitations, after every reasonable effort has been made to reduce the uncertainties affecting repository siting, design, and performance, large uncertainties will probably still persist. How the applicant intends to examine and resolve specific residual uncertainties has not yet been identified. However, regardless of the specific approach adopted to accommodate these uncertainties, there is no doubt that expert judgments will be pervasive (Fehringer and Coplan, 1992). Where such judgments have a direct and significant bearing on compliance, formal elicitation methods may be appropriate.

- ***More than one conceptual model can explain, and be consistent with the available data***—Conceptual modeling of a HLW disposal site is based on a combination of the application of fundamental physical and chemical principles and data interpretation. Data interpretation and conceptual model development rely extensively on expert judgments and it is not uncommon for multiple or alternative conceptual models to emerge that are consistent with available data. This is particularly true when the data available are limited and amenable to multiple, equally valid interpretations.

  Because conceptual models provide the underpinning for the development of the mathematical models and computer codes that will be used in the quantitative estimates of performance measures, the selection or rejection of a conceptual model could have a considerable impact on the results of computational analyses. These judgments, when made by DOE to support its calculations in a potential license application, will be subject to considerable scrutiny by the NRC staff (Park *et al.*, 1994), and therefore are appropriately derived from a formal elicitation process.

- ***Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative***—Bounding assumptions or calculations are used as a technical approach to providing scientifically based estimates when the level of uncertainty is very high, when the subject matter is complex, and when approximations are sufficient to resolve the issue at hand. If such assumptions and calculations are used as a basis to terminate or curtail further data collection or analyses, judgments must be made, and justified, that such estimates are sufficiently conservative for their intended application. For issues critical to compliance

demonstration, formal elicitation of these judgments and justifications may be of value.

(2) A Consistent and Systematic Process for Elicitation Should Be Applied

If expert elicitations are to render accurate representations of the legitimate range of scientifically supportable interpretations among the informed technical community, they should be conducted using a structured procedure, based on proven decision analysis methods. A structured, *thoroughly documented procedure* allows reviewers to reconstruct the logic and events involved in the elicitation and use of expert judgment. Use of such a protocol establishes and maintains the quality of the process in much the same way as use of a QA program for field data collection. Adherence to such a protocol is also critical in supporting internal and external reviews of the resulting judgments and to foster confidence in the integrity of the process. That being said, however, scrupulous adherence to a sound elicitation process, in and of itself, in no way guarantees that the resulting judgments will be sufficient to meet the applicant's burden of proof regarding the substantive issues addressed by the elicitation. Nonetheless, expert judgments obtained through an evidently flawed or poorly documented elicitation process might ultimately undermine the credibility of any demonstrations of compliance supported by those judgments.

The procedure set forth in Section 3 in summary form, and repeated below, has elements of several other protocols—see, for example, NRC—NUREG/CR-5411 (Bonano *et al.*, 1990) and NUREG-1150 (NRC, 1990); EPRI (Coppersmith *et al.*, 1993); the Sandia National Laboratories (Trauth *et al.*, 1994); and the CNWRA (DeWispelare *et al.*, 1993 and 1994). It is provided here, but not with the intent that it be rigidly applied in every instance where judgments are elicited. Instead, it should be viewed as a general framework for a formal elicitation acceptable to the NRC staff. The applicability of any of the proposed process steps and thus the degree to which the overall process is implemented should be evaluated in each separate elicitation, and the process may be customized or revised, as needed, for the elicitation of interest.

In addition, although the process steps are listed in numerical order, it is not necessary that the individual steps be performed in the exact sequence presented. In fact, it is expected that several of these process steps will proceed or can be initiated concurrently, subject to repeated iterations and opportunities for feedback from the subject-matter experts. This may be especially true for Step Nos. 2, 3, and 4, which are depicted as parallel process steps with feed-backs, as shown in the preceding figure. What this figure shows, for example, is that once the subject-matter experts are identified (in Step No. 2), they can help to better define the objective of the elicitation (Step No. 1) and thus aid in the decomposition of the elicitation issue into its constituent parts (Step No. 3). Moreover, the subject-matter experts can also aid in the identification of additional information that could facilitate the elicitation (Step No. 4).[15]

Step No. 1—Definition of Objectives

Perhaps the most important step in any elicitation process is the precise definition of its ultimate objective(s). Proper definition of the objective(s) calls for an understanding of how the judgments will be used in subsequent analyses. This understanding should direct the overall content of the elicitation by defining the nature of the expertise that should be brought to bear (Step No. 2); the assumptions and information that will be provided to the appropriate subject-matter experts (Step Nos. 3 and 4); and the form of the judgments that should result (Step No. 6). This is a critical step that should include input from generalists who are familiar with the overall project and the specific information needs and intended uses.

Step No. 2—Selection of Experts

Types of Experts: Three types of experts are ordinarily recruited to participate in a formal elicitation: *generalists, normative experts*, and *subject-matter experts* (the last of whom are usually referred to as "the experts"). Generalists and normative experts are recruited first and together comprise the *elicitation team*, which is responsible for

[15]Alternatively, before deciding on the final panel of subject-matter experts (Step No. 1), in contacting candidate experts, it might be useful to solicit their input on refining the general problem (Step No. 3) that was previously formulated by the generalists and the normative experts. In this way, a much larger knowledge base is available to fine-tune the issues that will ultimately be addressed by the final group of subject-matter experts. Further, final refinement of the sub-issues (and questions—Step No. 3) should be performed ultimately by the selected panel of subject-matter experts.

organizing, conducting, and documenting the elicitation process.

Generalists are individuals knowledgeable about various overall, and one or more specific aspects related to site characterization, repository design, and performance assessment. Typically, generalists have substantive knowledge in one discipline (e.g., hydrology, geology, material science, transport phenomena, etc.) and a solid general understanding of the technical aspects of the problem.

Normative experts have training in probability theory, psychology, and decision analysis. They assist the generalists and subject-matter experts in articulating their professional judgments and thought processes in a form suitable for input into a particular technical assessment.

Subject-matter experts are the experts from whom judgments are elicited. These are individuals who are at the forefront of a specialty relevant to geologic waste disposal, and are recognized by their peers as authorities because of their sustained and significant research on the topic.

In selecting each of the three types of experts, especially the subject matter experts, it may be useful to seek qualified nominations from outside sources, or recognized peers in the field. This would include, for example: the National Academies of Sciences and Engineering; academia; recognized professional societies (e.g., *Sigma Xi*, The Geological Society of America, The American Society of Civil Engineers); National laboratories; knowledgeable Federal Agencies and International Organizations; private industry; State development and regulating bodies; representative public interest groups; and interested stakeholders. (Examination of the frequency of citations in the scientific literature may also be of help in this regard.) The elicitation team members, and their respective assignments, would then be selected from the list of nominees (for example, see Appendix A in DeWispelare *et al.*, 1993).

Selection Criteria: Among its many tasks, the elicitation team generates and applies criteria for the selection of the subject-matter experts. For this reason, and because the elicitation team members may influence the outcome of the elicitation by the manner in which judgments are elicited, analyzed, or used, special care should be taken in the selection of generalists and normative experts to ensure that they can perform in an objective and impartial manner. Although the selection criteria discussed below focus primarily on those attributes necessary to establish the suitability and substantive knowledge of prospective subject-matter experts, *the same criteria should be applied to the selection of generalists and normative experts insofar as they relate to their expertise, experience, and ability to carry out their respective roles. This is particularly true as it relates to the criterion concerning the appearance of bias or conflict of interest owing to the influence the generalist and normative expert can have on the outcome of any potential elicitation,* as discussed below.

As stated in the technical position, the panel of experts selected for elicitation should comprise individuals who: (a) possess the necessary knowledge and expertise; (b) have demonstrated their ability to apply their knowledge and expertise; (c) represent a broad diversity of independent opinion and approaches for addressing the topic(s) in question; (d) are willing to be identified publicly with their judgments; and (e) are willing to identify, for the record, any potential conflicts of interest.

Technical knowledge, expertise, and the ability to address the topic of the elicitation by a subject-matter candidate can be established through examination of his or her educational background, professional experience (including research and consulting activities in related problems or studies), publication record, previous experience as a peer reviewer for the work of others, membership and leadership positions in professional societies, and awards and other indications of peer recognition.

A subject-matter expert's ability to apply his or her substantive knowledge to the task at hand can be determined by examining the expert's record of published research and

participation in consulting activities on related problems or studies, prior participation in other expert elicitations, as well as experience as peer reviewer of the work of others. Although difficult to quantify, an expert's flexibility of thought and ability to objectively consider evidence that challenges his or her own conventional wisdom, as well as an ability to explain complex topics in clear and straightforward terms, is also of value for a successful elicitation.

In selecting subject-matter experts, it is important to identify candidates who have the requisite credentials, including a variety of backgrounds and experiences, to ensure that the full range of legitimate opinions on a particular scientific topic is represented and is incorporated into the study. Particular care should be taken to avoid selecting experts with similar educational backgrounds and experiences, because this increases the likelihood that they will invoke similar assumptions and approaches to arrive at their respective judgments. Dependence among subject-matter experts (so-called "expert dependence"—see Clemen and Winkler (1985); and Chhibber and Apostolakis (1993)) can significantly diminish the diversity of opinion. In this regard, care should be taken to select experts who have had training at different academic institutions and, to the extent possible, represent a diversity of scholarly approaches.

Conflict of Interest: The credibility of the judgments from any formal elicitation will be increased when the subject-matter experts have fewer conflicts of interest in the areas of institutional influences, financial or professional gain, or promotion of a social or political agenda, to the extent practicable. If some subject-matter experts are encumbered by such conflicts of interest, an attempt should be made to balance the influences by other panelists. The NWTRB has commented frequently on this point and has recommended using balanced panels of experts, incorporating experts from outside DOE and its contractors, who have independent and varying perspectives on an issue. This is important to building credibility into the judgments of the experts (NWTRB, 1990a, 1990b, 1991, 1993, and 1995).

Perhaps the most frequent conflict-of-interest concern is that of "set bias" by virtue of who employs the experts. The issue here, for example, is whether the subject-matter experts derive employment or income from organizations charged with conducting the overall performance assessment or with the construction and licensing of the repository. Other potential conflicts of interest may involve subject-matter experts' close-working relationships with individuals involved in repository characterization or development. Subject-matter experts should be asked to provide written statements of any potential or potentially perceived conflicts of interest, each of which should be made a part of the record of the elicitation.

The staff position does not assume, however, that any individual with a perceived or real conflict of interest will permit this conflict to influence his or her professional judgments. Furthermore, the staff does not wish to exclude crucial information from an expert elicitation simply because a knowledgeable individual has a potential conflict of interest. The HLW program is a small technical program in many respects and in certain key subject disciplines, there are relatively few experts. The population of known experts has probably been involved with one or more of the interested/affected parties, and therefore some conflicts of interest may be unavoidable.

Consequently, an elicitation should be designed such that the knowledge and reasoning of experts with potential conflicts, along with the fact and nature of those potential conflicts, should be made available to all subject-matter experts. Convening balanced elicitation panels and disclosures of possible conflicts are appropriate measures to counter the appearance of a potential conflict of interest.

Also, credibility of the elicitation can be enhanced when nominations for candidate subject-matter experts can come from organizations such as professional and academic societies, peers in the field, or reviews of the scientific literature. The subject-matter experts should be selected from the list of nominees, using explicit criteria, and the entire selection process

should be systematic and thoroughly documented.

Finally, this staff position is not intended to preclude the ability of DOE to use its own staff or its contractor's staff in any elicitation panel. NRC has traditionally considered, for review, the technical analyses prepared by the licensee (and its contractors) and will continue to do so.

Step No. 3—Refinement of Issues and Problem Decomposition

After definition of the objective of the elicitation (Step No. 1), perhaps the next most important process step in an elicitation would be decomposition of the problem into concise and distinct questions. (As noted earlier, this step may be initiated concurrently with the selection of the subject-matter experts.) Generalists and normative experts comprising the elicitation team may make a preliminary attempt to identify key sub-issues and to decompose the problem. Problem decomposition in elicitation refers to breaking down issues to provide for easier and less complex assessments that can be recombined into a probability distribution or utility function for the quantity of interest. The recombination is usually accomplished using one or more mathematical models that express the value of interest as a mathematical function of component quantities.

Definition of the issues should be precise; clarity of the issues is important for the elicitation design. The issues can range from general to specific and from simple to complex. Conventionally, complex problems are broken up into smaller and simpler components to facilitate the solution of the problem. The basic tenet of problem decomposition is that the solution of the smaller components is more tractable than that of the entire problem. Problem decomposition related to the elicitation of expert judgments is advocated by many (see Chhibber *et al.* (1992); and Hora and Iman (1989), among others) as the vehicle to increase the likelihood that the judgments are focused on issues with which the subject-matter experts are thoroughly familiar. If possible, issue definition and problem decomposition should first place emphasis on making explicit the subject-matter expert's direct knowledge, based on experience and evidence, and second on his or her ability to process or encode this knowledge into probability estimates (as in the approach advocated by Kaplan (1992). The normative expert, drawing on his or her expertise, may assist the subject-matter experts in the framing of key questions or sub-issues in such a way as to minimize the introduction of certain types of bias. For example, it is known that soliciting input on the extremes of a probability distribution can help reduce the tendency for experts to "anchor" on a central value and, thereby, reduce bias from over-confidence (a form of cognitive bias).

A preliminary statement of the issues and assumptions may be prepared by the elicitation team, presented to the subject-matter experts, and then, later, refined, based on their feedback. Alternatively, the elicitation team can work with the subject-matter experts in structured interactions to develop the entire list of issues and assumptions. In either case, it is important that the subject-matter experts have ample opportunity to provide input to the formulation of technical questions and the decomposition of the problem into more tractable sub-issues. Structured interactions among the subject-matter experts to discuss and decompose the problem enhance the likelihood that all share a common understanding of the problem, relevant sub-issues, and appropriate boundary conditions that are used to define the problem.

By having the subject-matter experts agree on a common decomposition of a particular problem, the views of the various experts on the sub-issues can be compared in a consistent fashion. Ad hoc or arbitrary decomposition of a problem, by each expert, may not permit such comparisons.

Step No. 4—Assembly and Dissemination of Basic Information

When subject-matter experts are asked to provide judgments, they are being asked to

analyze information provided to them about a given question, issue, or problem. The fact that expert judgments are being sought is an indication that there is either a lack of directly relevant information or major gaps in the available information about the question or problem being addressed, and more importantly, that obtaining such information or closing critical gaps, using experimental or other traditional approaches, is not feasible. The goal of the elicitation, therefore, is to identify the true state of uncertainty within the scientific community—be it aleatory (stochastic) or epistemic (state-of-knowledge) uncertainties (see SSHAC, 1995; pp. 13–14).

Accordingly, it is reasonable that, *as a starting point*, the sponsors of the elicitation should assist the elicitation team by assembling a preliminary body of basic information,[16] which, in the view of the sponsors, is necessary to allow the subject-matter experts to arrive at their judgments. It is important to recognize, however, that the judgments of the subject-matter experts may be influenced by the type of information they receive, and the manner in which that information is presented. Information that covers the full range of views (i.e., information that is all-inclusive) on the subject of the elicitation should be provided. Biasing may be introduced at this very influential point, and credibility of the elicitation could be reduced, if a suitably broad range of available information on a particular issue or sub-issue is not made available.

As the subject–matter experts interact to identify issues and decompose the problem (Step No. 3), they may identify additional data and information they will need to assess the relevant sub-issues. Therefore, feedback from the subject-matter experts and suggestions of additional sources of information should be solicited before the elicitations. It is important that data and information identified as necessary by the subject-matter experts are provided in a uniform, balanced, and timely fashion to all members of the expert panel as they prepare for the elicitations.

Step No. 5—Pre-Elicitation Training

Because many subject-matter experts are unfamiliar with the purpose and mechanics of formal expert elicitation, it is important that sufficient training be provided by the elicitation team to adequately prepare them for the elicitation of their technical judgments. This training should: (a) familiarize them with the elicitation process; (b) educate them in uncertainty encoding and the expression of their judgments using subjective probability; (c) provide them practice in formally articulating their judgments as well as explicitly identifying their associated assumptions and rationale; and (d) educate them with regard to possible biases that could be present and influence their judgments.

Before conducting an elicitation, the subject-matter experts should have a clear understanding of the objective of the elicitation, the reason for obtaining their judgments through a formal process, and the manner in which their judgments will be used. In most expert elicitations, the subject-matter experts are specialists with extensive knowledge and experience in a highly refined, but perhaps very narrow field of study. If, for example, the purpose of the elicitation is to obtain probability judgments that are to serve as input to a performance assessment, it is important that the subject-matter experts receive some basic overview training in performance assessment to provide a context for how their specific expert judgments and any associated mathematical functions or distributions will be used.

As a designated member (or members) of the elicitation team explains the purpose and process of the elicitation, it should be emphasized that the goal is not consensus, but rather a realistic description of the true state of scientific knowledge and uncertainty about the subject area in question. Training should consist of familiarizing the subject-matter experts with the elicitation process; motivating them to provide

[16]e.g., knowledge base—can be in the form of data, evidence, models, analyses, parameters, or statistics.

judgments; giving them practice in formally expressing their judgments as well as the assumptions and rationale for the judgments (especially uncertainty encoding); and educating them about possible biases that could be present and influence the judgments.

One important aspect of training is the conduct of rehearsal sessions to assist the subject-matter experts in becoming familiar and comfortable with offering judgments and the corresponding underlying reasoning and assumptions. Training helps ensure that the judgments represent the subject-matter experts actual state of knowledge about the problem of interest.

The most common method of encoding uncertainty associated with an expert's judgment is through elicitation of a subjective probability distribution. When subject-matter experts are asked to express degrees of belief in terms of subjective probabilities, they must become familiar with the techniques that will allow them to perform this task. Rehearsal sessions provide the means for the subject-matter experts to practice the application of these techniques.

Familiarizing the subject-matter experts with possible biases that may be present and influence their opinions is another reason for conducting elicitation training. There are two general classes of bias: *motivational* and *cognitive*. *Motivational biases* occur because a subject-matter expert has a vested interest in an issue and consciously or unconsciously distorts his or her judgment. Examples of circumstances that might contribute to motivational bias were noted under Step No. 2 (above). *Cognitive biases* occur because of a failure to process, aggregate, or integrate the available data and information. Motivational biases can generally be reduced, or at least mitigated, by careful selection of the subject-matter experts and by sensitizing the subject-matter experts to the motivational bias' potential for influence. Cognitive biases are more difficult to address, and to date, the best approach to deal with them is to become familiar with and practice the application of debiasing techniques during elicitation training sessions.

In addition to their expertise, it should also be noted that subject-matter experts, themselves, are likely to bring preconceived notions (e.g., cognitive biases) to the questions or problems they are addressing. These are most often the result of many years of involvement in research in the specific area in which their judgments are sought—one of the main reasons why specific individuals are recruited in the first place. It is inevitable that these notions or biases will significantly influence the expert's judgments. Because of their extensive experience, subject-matter experts may tend to focus quickly on solutions for problems of a similar nature without closely examining the manner in which the current problem may differ from past experiences and the impact those differences should have on their judgments of the problem at hand. Slovic (1991) concluded that most individuals have great difficulty in accepting information that does not confirm prior experience, and generally tend to discard information that does not fit within their reasoning paradigms. Morgan and Henrion (1990) suggest that subject-matter experts need to be presented with, and *required* to consider, information that challenges their conventional wisdom. These investigators state that subject-matter experts are most likely to exhibit over-confidence and bias when they fail to examine information that supports a point of view different from their own. If, instead, subject-matter experts explicitly consider and address information that contradicts their prior judgments, Morgan and Henrion argue that over-confidence biases are reduced and overall judgments tend to improve. For these reasons, normative experts should challenge the subject-matter experts to consider afresh conflicting information, especially when new information becomes available that could result in a re-evaluation of earlier judgments.

Step No. 6—Elicitation of Judgments

The actual elicitation of the judgments is the climax of the process for the individual subject-matter experts (or teams of subject-matter experts—i.e., all activities preceding the elicitation were aimed at preparing for it). The elicitation must be tailored to the specific question or issue at hand, the type of judgments required (e.g.,

identification of events and phenomena, subjective probabilities, probability distributions, etc.); the resources available for the elicitation; the availability of the subject-matter experts; and the individual professional preferences (e.g., the scheduling and length of elicitation sessions, format for conducting the elicitations, etc.). These factors may influence the methods and techniques employed in the elicitation. Regardless of the manner in which the elicitation is carried out, reviewers should be able to discern not only the judgments themselves, but also the reasons, assumptions, approaches, and information that each of the subject-matter experts used. A dry run or rehearsal of the elicitation is very beneficial to familiarize the elicitation team with the procedure. This rehearsal should occur in advance of the individual elicitation sessions.

Step No. 7—Post-Elicitation Feedback

The subject-matter expert (or teams of subject-matter experts) should be given individual feedback from the elicitation team on the results of the elicitation as soon as practical after the elicitation sessions are completed. In particular, they should be provided with numerical, graphical, and/or other useful representations of their judgments. The subject-matter experts should be allowed to revise their judgments based on the feedback. However, the rationale for any revisions should be carefully documented.

The elicitation team should seek confirmation of the conclusions from each subject-matter expert, but guard against attempting to force consensus or influence their outcome, during the individual feedback session, if disparate opinions exist. Finally, this step also allows the elicitation team members the opportunity to verify data codification and check for encoding errors.

Step No. 8—Aggregation of Judgments (Including Treatment of Disparate Views)

The preceding steps make no assumptions with respect to whether individual expert judgments (or teams of judgments) rather than combined or aggregated results are ultimately needed. The advantages of focusing on the individual judgments, up to this point, include traceability of specific judgments to an individual and the voicing of diverse views and perspectives that increase the likelihood that the actual state of knowledge on a given problem or issue has been captured. The use of multiple subject-matter experts as a means to capture the existing diversity of opinion about the answer to a given question or the solution of a problem of interest gives rise to multiple judgments—typically at least one different judgment for each subject-matter expert. In those cases where a similar or the same conclusion is arrived at from different paths, the confidence in this conclusion is obviously enhanced.

To render differing judgments from multiple subject-matter experts useful for certain practical analyses and assessments, or for discrete input to a performance assessment calculation, it may be necessary to aggregate, or combine, in some fashion, the individual judgments. Two general approaches to combining expert judgments are commonly identified as *behavioral* and *mechanical aggregation. Behavioral aggregation* usually entails the bringing together of the subject-matter experts to discuss and combine their judgments. Such interactions allow the thinking, logic, and experience base of the different experts to be exchanged. This may bring about some reconciliation of differences and result in a single consensus representation of the state of knowledge, or it may minimize the differences among experts. At a minimum such interactions should reduce the potential for unintentional disagreement. The behavioral approach is most beneficial when subject–matter experts have basic differences in fundamental assumptions, on which their judgments are based, which have not been made explicit. Interactions among the differing experts can thereby illuminate these assumptions and may lead to a more thorough understanding and documentation of conflicting approaches.

Mechanical aggregation techniques (also known as *analytical aggregation*) consist of logic, and formulas consistent with that logic, that have been developed by normative experts for combining individual judgments.

Individual judgments are combined mathematically such that the sum of the weighted individual judgments is normalized (e.g., equal to one). Among the obvious advantages of mechanical combination are ease of use, amenability to extensive sensitivity analyses, and the fact that individual experts need have no influence on the judgments of other experts, after elicitation. The most common and straightforward mechanical aggregation is a simple average that assigns equal weights (parity) to the judgment of each expert. However, differential weighting techniques have also been used to account for relative expertise or experience of individual experts (see PRA Working Group, 1994; pp. C–139—C–142).

A third approach to aggregation is one recently discussed by SSHAC (1995), whereby both the behavioral (judgmental) and mechanistic schemes are "blended" or combined. In this approach, the mathematical models used to produce preliminary elicitation results are shown to the experts, along with an explanation of the assumptions used to construct the models. The experts are subsequently asked if they wish to revise their judgments, given the knowledge about the consequences of the results, and they thus develop a "consensus" representation or aggregate distribution behaviorally based on their revised judgments.

In the stepwise approach to elicitation, the value of structured, iterative, interactions among the subject-matter experts is recognized. The staff believes that interactions, among the experts, properly structured to permit exchange of reasoning, data, and assumptions, may outweigh the potential disadvantage previously ascribed to a behavioral approach, namely that some experts may be dominated or "forced" to suppress their ideas and contribute to an artificial consensus. Should interaction among the experts, after the individual elicitations, result in any changes of judgments by the individual experts (as in the manner cited by SSHAC (1995), above (e.g., repeating Step Nos. 6–8 after some initial integration has been achieved)), the descriptions and implications of the changes should be included in updated representations of the individual experts' states of knowledge. If such interactions lead to a commonly held representation of the state of knowledge, then the representation of each individual should also reflect the representation for the group. More commonly, however, residual differences between the individual experts will persist, and these can then be combined using mechanical techniques.

It is not the intent of the NRC staff to prescribe any particular algorithm or aggregation technique, or require aggregation itself. Choice of an appropriate method or methods of aggregation may be highly issue-specific. That being said, however, the staff believes that adherence to a step-wise elicitation process similar to that identified in this technical position will tend to foster conditions where equal weighting of individual judgments may be most appropriate. *Regardless of which aggregation techniques are ultimately selected, however, sufficient documentation must be provided to trace the impact of each individual subject-matter expert's judgment on the consolidated position.* It cannot be emphasized enough that, because of the reviewer's potential need to examine an individual expert's judgments and reasoning bases, the professional judgment of each subject-matter expert must be explicitly documented as opposed to that of a person who is a panel spokesman or facilitator. A unanimous, consensus, or summary opinion without such documentation, will generally not be suitable to support a compliance demonstration, for purposes of licensing.

Step No. 9—Documentation

An essential element of a formal elicitation process is thorough documentation of all aspects of the process, the judgments acquired, and the rationale and basis for the judgments. The reasons for documenting the use of expert judgment for technical problems are derived from the following objectives: (a) to improve decision-making associated with public policy; (b) to enhance communication; (c) to facilitate peer review, appraisal, and acceptance; (d) to recognize

and minimize biases in expert judgment; (e) to indicate the current state of knowledge about important technical and scientific matters; and (f) to provide a basis for updating that knowledge.

Since credibility and acceptability are objectives of any expert elicitation associated with controversial issues in the licensing and public acceptance of a repository, as suggested by the NWTRB (1990a), an organized, thoroughly documented procedure allows reviewers to reconstruct the logic and events involved in the elicitation and use of expert judgment. The availability of such documentation supports a broader understanding and acceptance of what was undertaken. In addition, it makes possible technical discussions in terms of underlying principles rather than just the individual outcomes. Comprehension of the elicitation results and the utility of their use will be greatly enhanced by the use of a uniform and consistent reporting format for documenting the elicitation of each subject-matter expert.

Documentation is a continuous task that begins as soon as an issue is identified as a candidate for expert judgment elicitation. Precise and complete documentation is pivotal to the success of the elicitation (and ultimately, acceptance of the results). For example, the documentation should include a discussion of all steps in the elicitation procedure. Each step should be described and the results presented. Moreover, the documentation should also reflect what specific information was used or relied on by the experts (e.g., rationale) to reach a particular judgment (reached in Step No. 4). As emphasized above, the results should be provided for each subject-matter expert as well as for any aggregated judgments.

(3) Elicited Judgments Should Be Updated as Warranted

When new data or information becomes available before license application submittal, it could potentially change a DOE position with regard to the design and perhaps the performance of the geologic repository. To the extent practicable, any potential license application should address the significance and impact that any new information might have on the validity of all previously existing data and elicited judgments used. If the impacts are determined to be significant, then the data and expert judgments should be updated to incorporate the new data or information, as the information becomes available. Of course, the new information may resolve the issue by providing the objective data needed and thus obviate the need for a new elicitation.

The methods of updating the expert judgments range from the use of Bayes' Theorem, for statistical updating, to conducting another set of individual elicitations for the same or a different set of experts. Whichever method is used for incorporating the new data or information into the existing expert opinions, it should be thoroughly documented to provide a transparent view of the updating process and resulting judgments.

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APPENDIX A
GLOSSARY

As used in this guidance:

"Aggregation of judgments" refers to the combining of the individual elicited judgments of more than one subject-matter expert to produce a single judgment, point estimate, range, or uncertainty distribution.

"Behavioral aggregation methods" use personal interactions among the subject-matter experts employing consensus techniques to combine multiple individual judgments.

"Cognitive bias" occurs when a subject-matter expert fails to process, include, or integrate the available data or information available.

"Debiasing techniques" refers to training the subject-matter experts in dealing with and reducing the effects of cognitive biases on the elicitation results. Examples of these techniques are: (i) familiarity and practice with the elicitation task; and (ii) awareness of the biases through personal experiences, making use of feedback.

"Elicitation team" refers to the group of generalists and normative experts conducting and facilitating the elicitation. This group may also be referred to as the project team or panel.

"Expert judgment" refers to the data or information provided by a subject-matter expert. It is the subject-matter experts opinion or belief based on reasoning. Expert judgments can be evaluations of theories, models, experiments, or recommendations for further research. Expert judgments may also be opinion that can be analyzed and interpreted and can be used in performance assessment and other technical models. Expert judgments can be either qualitative or quantitative. Expert judgments can also be judgments about uncertain quantities or judgments about value preferences. A subject- matter expert may provide a probability distribution or a point estimate for an uncertain parameter.

"Expert elicitation" is a formal, highly structured, and well-documented process for obtaining the judgments of multiple experts.

"Generalist" is an individual with substantial technical background in one or more of the disciplines needed to solve the problem of interest—but whose understanding of the problem typically spans beyond the particular discipline—and is well-versed on how the judgments will be used in the solution of the problem. Generalists may be selected from the project staff and they work with the normative experts in the conduct of the elicitation. They serve several roles: (i) propose the problem decomposition; (ii) prepare the issue definition; (iii) provide assistance to the subject-matter experts by explaining how their judgments will be used; and (iv) together with the normative experts and with input of the subject-matter experts, orchestrate the final presentation and, where appropriate, aggregation of the elicited judgments.

"Mechanical aggregation methods" rely on analytic formulae (such as weighted averaging) to combine multiple individual judgments.

"Motivational bias" occurs when a subject-matter expert has a vested interest in an issue, institution, political agenda, or personal relationship, and when that vested interest consciously or unconsciously acts to distort his or her judgment.

"Normative expert" refers to individuals with a sound theoretical and conceptual knowledge of probability and practical experience in the elicitation of judgments from individuals. Normative experts are well-versed in the psychological and cognitive processes that subject-matter experts follow in the analysis of information to produce the desired judgments.

"Peer review" is frequently described as a form of expert judgment; however, in the context of this BTP, peer review does not fall within the aforementioned definition of expert judgment. The staff recognizes a subtle, yet fundamental, difference between *peer review* and *expert judgment* as used here. The former refers to judgments provided regarding the soundness and quality of an existing solution to a given problem, whereas the latter refers to judgments which, themselves, give rise to or contribute to a scientific stance or solution. In this context, the staff expects expert judgments to be elicited and used in a manner that would allow

the elicitation and the judgments to be the subject of peer review.

"Subject-matter expert" is the individual from whom the expert judgment will be elicited. The subject-matter expert is an individual recognized by his or her peers as an authority in a specific subject matter or topic. Subject-matter experts typically gain recognition as such because of significant and sustained research in the subject matter or topic, and their knowledge is believed by others to represent the current state of the art in that subject or topic.

APPENDIX B
AN ELICITATION ON FUTURE CLIMATE: LESSONS LEARNED

B-1 Introduction

In 1992–93, the Center for Nuclear Waste Regulatory Analyses (CNWRA) conducted an elicitation, to familiarize the U.S. Nuclear Regulatory Commission staff with a state-of-the-art formal expert judgment elicitation. This work was performed as part of the staff's Iterative Performance Assessment efforts to develop an independent license application review capability (see Appendix D in Johnson, 1994). The subject of the elicitation was the future climate in the Yucca Mountain vicinity. The details of this formal elicitation itself, as well as the results, are described in DeWispelare *et al.* (1993).

B-2 Rationale

A formal elicitation was selected for this subject, for the following reasons:

(1) The state of climate science and modeling does not support accurate sub-regional long-term projections based on historic or current meteorologic data. Expert judgment is a way to integrate and supplement the output of general circulation models.

(2) There are great uncertainties associated with predictions of future climate at Yucca Mountain. This is especially evident when one considers that climate varied during the Quaternary Period (ranging from pluvial to arid conditions), and that the influences of such variations on infiltration can potentially dominate the predicted performance of a geologic repository for high-level waste.

(3) Because of the state of science in long-term climate prediction, there exist a number of conceptual approaches. These range from general circulation models conditioned with combinations of past and present meteorologic data, to energy-balance models based on current physical data, to empirical historic data used to establish past conditions.

(4) The published record contains a variety of data and opinion that establishes various bounding limits, some of which have been interpreted to be conservative.

Several lessons were garnered, from the climate elicitation, that have relevance for the process of expert elicitation, generally:

- The ability to understand and compare the judgments of each participant in an expert elicitation is far easier when uniform procedures are used to elicit judgments and document results. The generalists all commented that the clarity and logic that the subject-matter experts provided in the judgments and supporting rationale were attributable to their overall expertise.

- It is possible to have a defensible process for selection of subject-matter experts. To address concerns regarding the lack of bias or independence in the selection of the subject-matter experts, a documented process of peer nomination and selection can be conducted even within a relatively short time schedule.

- Debiasing training of the subject-matter experts is essential to a smooth elicitation. Most subject-matter experts have had only limited or no experience at producing consistent subjective probability distributions. All the subject-matter experts agreed with the normative experts and generalists that this training was essential to the process.

- The elicitation team had considerable difficulty in constructing a behaviorally-based aggregation because of the variation in the individual judgments and the subject-matter experts conviction regarding their judgments. After an attempt at behavioral aggregation, a mechanical aggregation of the subject-matter experts judgments was attempted. This approach was faster and easier to implement than a behavioral aggregation. When it is necessary to aggregate the individual judgments of the subject-matter experts after they have been elicited, it is efficient to use a

mechanical aggregation scheme. This scheme can be easily documented to provide traceability.

- It is valuable to have the subject-matter experts visit the site. The subject-matter experts indicated that experience gained through the site visit was important to their preparing for the elicitation, and facilitating the post-elicitation validation process. The subject-matter experts noted that by visiting the site, they were able to place the data and research assembled for the elicitation into the context of the physical setting at Yucca Mountain, thus leading to what the subject-matter experts regarded as a more realistic interpretation of this information.

- Individual documentation is critical to a successful elicitation. The documentation consisted of two parts. First, a short paper, which formed the scientific basis for a particular judgment, served as the reference for understanding the technical reasoning expressed in the elicitation. The second part consisted of the elicitation team's documentation of the elicited judgments (e.g., probability distributions associated with the climate variables) and accompanying specific reasoning resulting from each expert's elicitation session, to ensure that the rationale used by each subject-matter expert was well-understood and expressed consistently. Video taping of each elicitation session helped the team to check session notes and served as a permanent record of each session.

B–3 References

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Johnson, R.L., "Appendix D: NRC Post-Closure Performance Assessment Strategy for a High-Level Nuclear Waste Repository" in "Overall Review Strategy for the Nuclear Regulatory Commission's High-Level Waste Repository Program," U.S. Nuclear Regulatory Commission, NUREG–1495, November 1994.

APPENDIX C
FINAL COMMISSION *POLICY STATEMENT* ON THE USE OF PRA METHODS IN NUCLEAR REGULATORY ACTIVITIES

C–1 Introduction

The following statement presents the policy that the U.S. Nuclear Regulatory Commission will adopt in the use of probabilistic risk assessment (PRA) methods in nuclear regulatory matters. This policy was developed because the Commission believed that the potential applications of PRA methodology could improve public health and safety decision-making while promoting stability and efficiency in the regulatory process and reducing unnecessary burdens on licensees. After a public workshop, the *Policy Statement* was published in draft form in the *Federal Register* (NRC, 1994; 59 *FR* 63389). On receipt and consideration of public comments, it was published in final form (see NRC, 1995; 60 *FR* 42622).

C–2 The Commission Policy (at 60 *FR* 42628)

1. The use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data and in a manner that complements NRC's deterministic approach and supports NRC's traditional defense-in-depth philosophy.

2. PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state of the art, to reduce the unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109 ("Backfit Rule"). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

3. PRA evaluations in support of regulatory decisions should be as realistic as practicable, and appropriate supporting data should be publicly available for review.

4. The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

C–3 References

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APPENDIX D
DISPOSITION OF PUBLIC COMMENTS[1] ON FEBRUARY 28, 1996, DRAFT BRANCH TECHNICAL POSITION (61 *FR* 7568)

State of Nevada

The following comments were submitted by the State of Nevada (see Loux, 1996):

> The Agency for Nuclear Projects/Nuclear Waste Project Office has reviewed the subject Draft Branch Technical Position (BTP) and finds that it is, in general, favorably responsive to concerns transmitted in our letter of July 25, 1995 (see Loux, 1995), regarding the U.S. Department of Energy's (DOE's) June 5, 1995, *Principles and Guidelines for Formal Use of Expert Judgment by the Yucca Mountain Site Characterization Project Office* (see Brocoum, 1995).
>
> The BTP properly emphasizes the need to formalize and thoroughly document the process of preparing for and eliciting expert opinion, aggregating judgments, and performing follow-up, when appropriate. However, missing from the discussion is explicit guidance that it is equally important that DOE's decision, and its basis, to employ the expert elicitation process, be thoroughly documented and transparent to future reviewers. Also, the documentation of the decision should be maintained as part of the record of the expert elicitation process.
>
> It will be particularly important to know at the time of license application review whether cost was a primary consideration in the decision to employ expert judgment rather than performing theoretical analyses and/or gathering additional field and experimental data, as the BTP suggests it might be (pages 11 and 24). This is important because the Yucca Mountain Project has a continuing history of changing priorities on field and lab data collection and analysis that often is driven from year to year by available funds. What may seem to DOE to be practical and necessary one year can be deemed impractical the next year, with the issue then set aside as if it were closed and unnecessary to pursue. An example of this which may persist into a license application is the question of additional field study to understand the high hydrologic gradient north of Yucca Mountain. At present, it appears that some informal expert judgment has determined that it is not important to understand why this condition exists, whereas in the past it has been considered important by DOE when more money was available to the project for surface-based testing.
>
> The BTP states the four conditions under which the use of expert elicitation should be considered (page 17 and elaborated on pages 24–25):
>
> (a) Empirical data are not reasonably obtainable, or the analyses are not practical to perform;
>
> (b) Uncertainties are large and significant to a demonstration of compliance;
>
> (c) More than one conceptual model can explain, and be consistent with, the available data; or
>
> (d) Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative.
>
> Throughout the text of the BTP, the use of expert judgment is described in various manners that are only in some cases obviously consistent with the above list, e.g., an alternative when other means of obtaining data and information are not practical to implement; a means of reducing uncertainty; an assessment of the state of scientific uncertainty; a means of exploring the state of knowledge on a particular topic complementing and supplementing other sources of scientific and technical information; etc. It would be helpful for the BTP to collect and discuss all of the various descriptions of the beneficial use of expert judgment in one place in order for the reader to better

[1]The indented portions of this appendix quote the public comments.

interpret the Staff's apparently broader view on when the use of expert elicitation might be appropriate, and to what purpose. This further discussion possibly could be added to [Section] 4(1) as a supplement. It also appears that the final three items in the above list of conditions are often simply a subset of the first condition. Each of the final three conditions can be the result of a DOE decision that further data collection and analysis is not practical, but, in some cases such as the above example, the condition likely could be mitigated by additional data collection and analysis. The BTP repeatedly admonishes against substituting expert judgment for traditional analyses, but in each case makes cost and practicality a prominent consideration. As the regulator, the NRC should be most concerned with safety considerations, which can only be derived from a high-quality license application firmly grounded on data and analyses. As in every regulatory arena, it is the applicant's responsibility to weigh cost against quality in the preparation of its license application, and it is the regulator's responsibility to judge whether the product is adequate. The BTP gives helpful guidance regarding how the regulator might view the quality of DOE's application, but, [we] believe, errs in emphasizing cost and practicality on the part of the applicant as a potential measure of compromise in determining the "reasonable assurance" that the applicant's safety case is adequately proven. The text of this BTP should be revised to reflect that the NRC's primary regulatory role, and highest priority, is to promote safety. As it stands, the unfortunate implication in this BTP is that cost and practicality for the applicant are acceptable measures against which to weigh safety in the regulatory proceeding.

And finally, despite DOE's view[2] that much of [Sections] 1 and 2 of the BTP is an unnecessary review of past experience with the use of formal expert judgment exercises, [The State] believes that it is a useful description that adds basis to the staff's positions as set out in [Section] 3 and further discussed in [Section] 4. The use of expert judgment in a licensing proceeding in this unique case will remain a prominent issue throughout, and it will be important to understand as thoroughly as possible the current staff's basis for the guidance which it provided to the applicant and other parties prior to preparation of the license application. It must be remembered that, in the licensing proceeding the product of this guidance may or may not be found acceptable, and the original basis for the guidance could be integral to that decision.

Response

With respect to the State of Nevada's first general comment, that missing from the guidance is some discussion that it is important for DOE to document its decisions, and their bases, when it employs an expert elicitation process, the staff is fully aware of this issue and generally shares a somewhat related concern. In fact, DOE's use of expert judgment, during site characterization, was first identified as an issue by the NRC staff in the course of its review of DOE's Site Characterization Plan (SCP—see DOE, 1988). In its Site Characterization Analysis (SCA) Comment 3, the staff expressed the concern that DOE might ". . . rely [too] heavily on the use of expert judgments (e.g., expert elicitations) to supply the licensing information or to substitute for quantitative analyses" (NRC, 1989; pp. 4–8—4–40). Because of NRC's regulatory interest and oversight role in the repository program, the staff has consistently expressed the view that DOE needs to document its decision-making record so as to allow for the identification and resolution, at the staff level, of any potential licensing issues. The staff repeated its concerns later, during the conduct of DOE's site characterization program.

That being said, it is generally recognized that DOE's repository program has evolved significantly beyond that described in the 1988 SCP. As DOE prepares its future program plans for site characterization and the repository Viability Assessment, the staff believes that DOE understands NRC's overall intent to ensure that there is transparency in its (DOE's) decision-making process and fully expects DOE to provide sufficient documentation to support its decisions, including those that relate to the use of formal expert judgment. Consistent with DOE's own

[2]Expressed during a joint NRC/DOE/State of Nevada telephone conference call on April 23, 1996.

Principles and Guidelines for Formal Use of Expert Judgment by the Yucca Mountain Site Characterization Project Office (hereafter referred to as the *Principles and Guidelines*), the staff also expects that DOE would prepare the necessary documentation, as recommended by the State in its comment. The staff believes that this point is apparent throughout Section 1 of the BTP and acknowledged specifically elsewhere in the BTP (e.g., in Section 4, refer to the following locations in the discussion: paragraph 2 (in the introduction); Technical Position 1, paragraph 1; and Technical Position 2, Step No. 9, paragraph 1). Therefore, the staff does not agree with the State that it is necessary to provide further guidance or to include additional information in the BTP.

With respect to the State of Nevada's second general comment, ". . . to collect and discuss all of the various descriptions of the beneficial use of expert judgment in one place. . . ," the staff has no objection to including additional information. The staff has added the following paragraph to the introduction of Section 4 of the BTP to address the State's request:

> In closing, it should be noted that this NUREG discusses the rationale for and the potential benefits derived from the use of expert judgment in a number of places. Without intending to limit those discussions, the following summary is provided. Section 1 describes the ubiquitous nature of expert judgment in scientific and technical activities. Section 1.2.1 provides a description of typical outputs of an expert elicitation and the potential uses of the expert judgments in the evaluation of repository performance assessment. Section 1.3 provides actual examples of the NRC use of expert judgments, including those used in PRA. Section 3 provides the technical position on conditions warranting the consideration of a formal expert elicitation. Later in this section, the staff elaborates on these conditions and discuss the benefits derived from obtaining expert judgments. Finally, Appendix A provides a discussion of expert judgment from a definitional perspective and Appendix B provides results and lessons learned from the NRC-sponsored formal climate expert elicitation.

In its third general comment, the State of Nevada observed that the ". . . implication in this BTP is that cost and practicality for the applicant (DOE) are acceptable measures against which to weigh safety in the regulatory proceeding. . . ." The staff does not share this view of the implications of the BTP. For example, paragraph 2 of Section 1.4 of the BTP states that:

> ". . . under appropriate circumstances, it is acceptable to supplement data and analyses with the opinions of experts as part of the support for demonstrating compliance with NRC's geologic disposal regulation, and that, under certain circumstances, these opinions can be obtained using a formal and well-documented process. . . ."

In making this statement, in recognition that compliance with NRC regulations is the measure for judging safety in an NRC licensing proceeding, the staff also provided additional caveats (highlighted) to the BTP (see Section 1.4, paragraph 5):

> *The NRC staff recognizes that DOE has the flexibility to determine whether the costs and benefits of performing an expert elicitation are advantageous when compared with the costs and benefits of performing theoretical analyses and/or gathering additional field and experimental data.* That being said, however, the use of expert elicitation should not be considered as an acceptable substitute for traditional analyses based on adequate field or experimental data, when such data are reasonably available or obtainable, or the analyses are practicable to perform. *Nor can the use of a formal elicitation process, even when conducted in a manner consistent with guidance provided in this BTP, guarantee that specific technical conclusions will be accepted and adopted by the staff, a Licensing Board, the Commission itself, or any other party to a potential HLW licensing proceeding.* Rigid adherence to a sound elicitation process, in and of itself, in no way guarantees that the resulting judgments will be sufficient to meet the applicant's burden of proof regarding the substantive issues addressed by the elicitation. Nonetheless, expert judgments obtained through an evidently flawed or poorly documented process will weaken their

poorly documented process will weaken their ability to support demonstrations of compliance.

It should also be noted that nothing in this BTP precludes the use of expert judgment obtained through informal means by DOE, in the preparation of a potential license application. As has been the case in previous regulatory activities, the staff will accept for review the results of formal or informal judgment so long as the rationale associated with the judgment is adequate, transparent, and sufficiently documented.

However, in order to avoid any ambiguity on this subject, the staff has revised the first sentence of the fifth paragraph of the "Introduction" to Section 1 of the BTP to emphasize that NRC's primary regulatory role and highest priority is to ensure public health and safety; the revision will read as follows:

"With this notion in mind, current NRC policy is to encourage the use of probabilistic risk assessment (PRA) state-of-the-art technology and methods as a complement to the deterministic approach in nuclear regulatory activities (NRC, 1995; 60 *FR* 42622)[2] and in keeping with the Commission's paramount responsibility to protect public health and safety. . . ."

[2]EPA's 1985 HLW standards (50 *FR* 38066) adopted a probabilistic perspective when making compliance determinations. Because of the uncertainties inherent in the geologic disposal of nuclear waste, it is anticipated that a probabilistic treatment of the performance of the waste disposal system will continue to be the regulatory approach.

In providing this clarification, the staff wishes to finally note that it is DOE's ultimate prerogative and responsibility to adopt a strategy for demonstrating compliance with NRC's regulations. The intent of this NUREG, therefore, is to allow DOE the maximum flexibility in choosing an approach, as long as an effective demonstration of compliance with the regulations can be made.

In its final comment, the State of Nevada disputes DOE's views regarding the value of or the need for the background information contained in Sections 1 ("Introduction") and 2 ("Regulatory Framework") of the BTP. The staff believes that this information provides a helpful context for the technical positions themselves insofar as it summarizes the history and considerations that relate to guidance on this particular subject. The information may be of value, for example, to a member of the public and thereby furthers NRC's interest in conducting its regulatory activities in such a way that those activities are understandable to *all* interested parties. (See NRC (1996) for a discussion of the Commission's "openness policy" with respect to how the Commission conducts its regulatory activities.)

U.S. Department of Energy

The following comments were submitted by DOE (see Brocoum, 1996):

The NRC's "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program" provides guidance to develop a structured process to conduct formal expert elicitations. DOE and NRC seem to have consistent positions on the general steps that are appropriate for these structured exercises. DOE has identified no substantive disagreements with respect to the process the NRC has outlined for elicitation and its associated documentation. DOE followed each of the nine steps specified in the NRC's process while conducting its recently completed "Probabilistic Volcanic Hazard Analysis for Yucca Mountain, Nevada" (Geomatrix Consultants/TRW Environmental Safety Systems, Inc., 1996).

DOE's only major comment on the BTP centers on the possibility that the NRC may offer additional guidance on the use of expert elicitation in the area of performance assessment. The Department believes that additional guidance is unnecessary.

As stated in DOE's June 1, 1995, letter to NRC (Brocoum, 1995), DOE's elicitation process will identify and document the basis for any judgment, and this basis could include both site-specific information developed during site characterization (including qualitative, descriptive, and quantitative analytical information) as well

as information from other relevant or similar settings.

Response

With regard to DOE's first overall comment, that ". . . DOE and NRC seem to have consistent positions on the general steps [for the formal elicitation of expert judgments]. . ." and that DOE has ". . . identified no substantive disagreements with respect to the process the NRC has outlined for elicitation and its associated documentation. . . ," the staff welcomes DOE's view. The staff also believes that it may be possible to resolve, at the staff level, the staff's earlier concerns expressed in SCA Comment 3 (e.g., criteria for the use of expert elicitations are needed in light of the requirement for a license application to be as complete as possible given reasonably available information). (See the discussion in Appendix E for more on the staff's reasoning in this area.)

The staff is mindful, however, that despite this apparent convergence in thinking, the instruction contained in DOE's *Principles and Guidelines* is not identical to the guidance contained in this BTP. DOE should view this BTP as the primary guidance, in this area, although as with other NRC staff guidance, it may choose to pursue alternative approaches, at its own risk. In addition, consistent with the BTP, the staff has identified a number of specific concerns with DOE's *Principles and Guidelines* documentation itself, which appear, along with a possible path to their resolution, in Section E–2 of this document.

With regard to DOE's second overall comment, that additional guidance is not necessary in the area of performance assessment, the staff will take this comment into account in due course but has made no decision as yet on this option. In view of the potential that new performance measures may be established for a potential repository at Yucca Mountain, pursuant to the Energy Policy Act of 1992, and consistent with the findings and recommendations of the recent National Academy of Sciences (NAS) report (see National Research Council, 1995),[3] the staff wishes to provide for the possibility that site-specific standards may necessitate the development of additional implementing guidance. The staff, therefore, continues to leave open this option, as noted in Section 1.4, paragraph 3 of the BTP (e.g., that it ". . . is considering the potential need for future guidance to identify those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate. . ."). Currently, the staff has no plans for, or resources devoted to, preparing any additional guidance in this area. If the staff decides that additional guidance should be considered, it will explain its reasons and offer the opportunity for comment by DOE (and others).

General Comments (Prescribed Use of Elicitations in the Area of Performance Assessment)

In Section 1.4 of the BTP, NRC is appropriately silent about the specific technical issues for which expert elicitation should or should not be applied, except in the area of performance assessment. DOE would like clarification of why the staff believes they should consider additional guidance (page 11), ". . . to identify those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate." DOE believes that once the NRC staff have set out the process, as described in the BTP, it is the applicant's prerogative to decide if and how its use is advantageous to support arguments for licensing.

DOE believes that the BTP may suggest generic circumstances when use of expert elicitation is appropriate, but that it is not appropriate to prescribe categories or topical requirements for these exercises. DOE will have to balance many factors in selecting the topic and scope for expert elicitations. DOE is currently evaluating the advisability of conducting expert elicitations in several areas supporting development of its Total System Performance Assessment (TSPA) for the Viability Assessment, including: scenario analysis and associated estimates of probability, parameter uncertainty and bounding case identification, and certain aspects of process model abstraction and conceptual model evaluation. DOE's plans currently do not include an elicitation on the totality of the TSPA submittal forming the basis of a license application. DOE

[3]In addition to the recent NAS recommendations, the staff notes that there are pending legislative proposals that could affect the regulation of HLW at Yucca Mountain. See summary in the *1994 Findings and Recommendations* of the Nuclear Waste Technical Review Board (NWTRB—see NWTRB, 1995; pp. 46–48).

expects to discuss our future plans in this area with the NRC when our planning has matured.

DOE notes that development of prescriptive guidance for performance assessment is in conflict with the BTP description (page 11) which states ". . . under appropriate circumstances, it is acceptable to supplement data and analyses with opinions of experts as part of the support for demonstrating compliance. . . ." Decisions as to when or whether to conduct an elicitation exercise, the identification of specific issues or topics, or other "appropriate circumstances" are management prerogatives of the DOE. DOE is concerned with the potential for prescriptive definitions or circumstances that might limit management's alternatives or options to use expert elicitations as part of the technical basis for our compliance argument(s). DOE intends that any use of expert elicitations in the area of performance assessment be consistent with its *Principles and Guidelines*.

Response

In this general comment, DOE has requested clarification regarding why the staff believes it might consider additional guidance ". . . to identify those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate. . . ." As noted above, in response to DOE's second overall comment, it is premature to decide whether and, if so, what additional guidance is appropriate or to attempt to predict those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate. If the staff decides that additional guidance should be considered, it will explain its reasons and offer the opportunity for comment by DOE (and others).

Specific Comments

The specific comments below (Nos. 1–5) refer to format and content issues or subject headings that may be prescribed for BTPs. DOE's theme in these comments is that, early on and for some length, they tend to focus the document on a look back instead of forward. DOE's general concern is that together Sections 1 and 2 tend to cloud the points of agreement between the two agencies in Sections 3 and 4 by including and discussing tangential or marginal issues. Section 2.2 of the BTP is a good example.

1. Section 1 ("Introduction"): The "Introduction" section is somewhat confusing because it is not clear whether the NRC's intent is to provide guidance on the generic use of expert elicitation (i.e., in any repository program) or restrict the guidance to the Yucca Mountain Project. It is also not clear to which part of the NRC this BTP applies.

   DOE suggestions: Include a statement of "scope" to describe the NRC's intentions in developing the BTP generic or project-specific guidance. A suitable description of scope appears to be available (with minor modifications) in Section 4, Discussion, on pages 22 and 23.

   Also, include a reference to the Division of Waste Management, or the Branch(es) within it that are responsible for preparation of the BTP. This information is not obvious and only now occurs in the "Foreword."

Response

The staff believes that the clarification requested by this comment already exists within the body of the BTP, as discussed below.

With regard to DOE's first comment, regarding the applicability of the BTP to NRC's regulatory programs, it should be noted that this BTP applies to the HLW program. There are a number of references to that effect, both explicitly as well as implicitly throughout the BTP. For example, see the "Foreword," "Abstract," and "Introduction" (5th paragraph). Because this guidance was developed for application to the HLW program, it is the staff's view that it would apply, generically, to any potential repository licensed by NRC.

As regards DOE's second comment, as indicated on both the cover page and in the "Foreword" of the guidance, the BTP was prepared by Division of Waste Management (DWM) staff (Kotra, Lee, and Eisenberg) with assistance from its technical assistance contractor, the Center for Nuclear Waste Regulatory Analyses—CNWRA (DeWispelare). As indicated, these authors incorporated the many useful comments and suggestions of other DWM and CNWRA staff members, representatives of the Office of the

General Counsel, and members of the staff from the Office of Nuclear Reactor Regulation, the Office of Nuclear Regulatory Research, and the Office for Analysis and Evaluation of Operational Data. (These individuals are identified in the "Acknowledgments" section of the BTP.) Lastly, the final technical positions reflect discussions with and recommendations from NRC's Advisory Committee for Nuclear Waste (ACNW), which are documented in Appendix F. As noted in the "Foreword," separately and at a later time, the staff may expand and refine this guidance for application in other areas of NRC regulation.

2. Section 1.1: The "Background" section is distracting. To revisit and critique DOE's past uses of expert judgment or prior elicitations recapitulates a comment record already made by the NRC on the DOE's past efforts and documentation. It distracts from the BTP's purpose in establishing expectations on how these exercises are performed in the future.

   DOE suggestion: Delete this section or condense significantly.

Response

The staff does not share DOE's view that the "Background" section (Section 1) of the BTP distracts from the technical position statements. Although the information is historical in nature, the staff believes this information provides a useful context for the technical positions themselves insofar as it summarizes the history, reasoning, and staff considerations that go into a decision to issue guidance on a particular subject. As noted in its response to the State of Nevada (above), the staff believes that this information could provide a helpful context for the technical positions themselves insofar as it summarizes the history and considerations that relate to guidance on this particular subject. The information may be of value, for example, to a member of the public and to this extent, furthers NRC's interest in conducting its regulatory activities in such a way that those activities are understandable to *all* interested parties.

3. Section 1.5: The "Branch Technical Positions as Technical Guidance" section provides little value toward the purpose of the guidance, to establish process expectations for future elicitation applications.

   DOE suggestion: Condense significantly or move the material in Section 1.5 either to front material such as a "Foreword," or an Appendix.

Response

In conformance with a standard format for all DWM staff guidance documents, the information in question, in Section 1.5, is typically contained in staff technical positions, and is intended to communicate the staff's overall goals in issuing regulatory guidance.

4. Section 2.1 ("Regulatory Framework—10 CFR Part 60"): The last paragraph in the section is a good example of raising issues that are not relevant to the purpose of the BTP, i.e., establishing process expectations for expert elicitations. It refers to a past comment and response dialog on the DOE's SCP.

   DOE suggestion: Delete the paragraph.

Response

The staff does not share DOE's view concerning the relevance of the paragraph in question to the BTP. As a result of the staff's review of DOE's statutory SCP, several subsequent reviews of DOE site characterization activities, and recommendations of certain advisory bodies—the ACNW and the NWTRB (all of which are summarized in Section 1.1), the staff decided to develop guidance in this area.

5. Section 2.2 ("Commission *Policy Statement* Concerning the Use of PRA Methods in Nuclear Regulatory Activities"): This section has little apparent relevance to the development of guidance for the use of expert elicitation, and only the last sentence in the entire section states the essence of the section that could bear the purpose of the BTP. The "Regulatory Framework" section, in general, is distracting and does not appear to be relevant to the purpose of the BTP as process guidance.

   DOE suggestion: Delete Section 2.2; move the last sentence [with edits], "The technical

positions cited in Section 3 are consistent with the recommended process steps [from the NRC's staff's Probabilistic Risk Assessment Working Group."] to an appropriate place in Section 3. Consider condensing Section 2, and especially Section 1 significantly.

Response

The staff does not agree with DOE's comment to delete the material contained in Section 2.2 of the BTP. In the staff's view, a brief discussion of the Commission's *Policy Statement*, concerning the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities (see NRC, 1995; 60 *FR* 42623), contributes useful information to the BTP that places it in a broader regulatory context. The staff believes that the Commission's decision regarding "emerging" PRA technologies in the *Policy Statement* is supportive of the BTP.

6. Section 3 ("Branch Technical Positions")—page 17, Technical Position 2(a), line 2: The inclusion of the word "defensible" in the description of the procedure includes a criterion whose definition is arbitrary until it can be determined whether the procedure was in fact successfully or unsuccessfully defended. Furthermore, "defensibility" or the "need to defend" are management considerations which are inappropriate topics for the guidance.

   There are similar references to "defensible" in Section 4 ("Discussion"), p. 25, Item (2) and p. 29, 3rd paragraph.

   DOE suggestion: Revise these references to "defensible" to describe thoroughly documented processes.

Response

The staff's intent behind the use of the word "defensible" in Technical Position 2(a) (and elsewhere) was to reference the obligation of the potential applicant (i.e., DOE) to demonstrate the acceptability of both the elicitation process and the outcome of that process. With that understanding in mind, the staff has no objection to making the requested change.

7. Technical Position No. 3 in Sections 3 and 4—pages 21 and 36, respectively: The time frame implied in the description on page 21 is not clear. One interpretation would indicate that expert judgment, expert elicitation, and peer review are intended to be snap-shots in time of the experts' views of the issue in question based on the information available at the time the exercise was conducted. An alternative interpretation would imply that the guidance envisions an elicitation process that is iterative and might never be completed if additional data were continuously available.

   On page 36, the expectation for re-examining and updating the results of past elicitations to new, relevant data needs clarification. It is the DOE's prerogative and responsibility to ensure that the materials submitted to the NRC for a licensing action are current. When new information becomes available, DOE will evaluate and document its relationship to the assumptions and range variation established in prior elicitations. It is not necessary, however, for the BTP to establish expectations for how an elicitation is re-evaluated in light of new information, beyond the means of being well documented.

   DOE suggestion: Use wording that does not imply a process-specific means of re-examining the results of a prior elicitation in light of new data.

Response

NRC expects that a potential license application for a geologic repository to be complete as possible in light of the information that is reasonably available at the time of docketing (10 CFR 60.24(a)). As a potential applicant, the intent of this technical position was to remind DOE of the staff's expectation on this matter. However, to avoid any additional confusion in this area, the staff has revised Technical Position No. 3 to read as follows:

> If information from an expert elicitation is to be submitted in support of a license application, and if additional data or information becomes available, subsequent to the completion of the elicitation, which could change opinions or judgments

obtained in the formal elicitation, the results of the elicitation should be re-examined and updated, as appropriate. In addition to the information requested above, documentation should include a detailed description of the updating process.

Consistent with these changes, the staff has also revised the second paragraph of the rationale for this technical position (in Section 4) to read as follows:

> The methods of updating the expert judgments range from the use of Bayes' Theorem, for statistical updating, to conducting another set of individual elicitations for the same or a different set of experts. Whichever method is used for incorporating the new data or information into the existing expert opinions, it should be thoroughly documented to provide a transparent view of the updating process and resulting judgments.

8. Section 4 ("Discussion" behind Technical Position No. 2)—page 26, 2nd full paragraph, lines 6–9: The staff's expectations with regard to the use of subject-matter experts, to better define the objective of the elicitation, are not clear. Using subject-matter experts to define the objectives of the elicitation on which they have been asked to participate, represents a potential to create conflicts of interest—especially financial and professional conflicts of interest. Discussion of the same consideration on page 30 is clear and does not contain the apparent ambiguities found in the discussion on page 26.

   DOE suggestion: Delete the sentence "What this figure shows, into its constituent parts (Step No. 3)" to remove this ambiguity and potential inconsistency that could create a conflict of interest.

Response

The staff does not agree with DOE's characterization of this issue. It is the staff's view that there is no ambiguity regarding the sentence in question (introductory discussion in Section 4 behind Technical Position No. 2—page 26). The staff is expressing the view in this section of the BTP that subject-matter experts, working with the generalist, can help to better define the overall objectives of any particular elicitation. Although not expressed in the BTP itself, it is the staff's view that the normative expert and generalist, working with the elicitation sponsor (i.e., DOE), reserve the right to limit the scope and extent of any proposed elicitation given, of course, contrary (documented) advice from the subject-matter experts themselves.

9. Appendix C: This Appendix is relevant only to Section 2.2 of the draft Branch Technical Position.

   DOE suggestion: Delete Appendix C if Section 2.2 is deleted, as suggested.

Response

The staff's response to this comment is addressed under DOE specific comment no. 5.

U.S. Nuclear Waste Technical Review Board

The following comments were submitted by the NWTRB (see Cantlon, 1996):

> The Board has had a long-standing interest in the use of formal expert judgment by DOE as it characterizes the potential repository site at Yucca Mountain and moves toward a possible application to construct a permanent underground repository there. The Board has addressed the need for DOE to develop sound elicitation methodologies, to involve outside experts in any formal elicitation conducted, and to resolve possible conflicts with the NRC well before the submission of any license application.
>
> The BTP lays out in a thoughtful and well-argued manner the key issues involved in carrying out a successful and reliable formal elicitation. For the most part, the BTP has incorporated the best current thinking of decision analysts who have examined this area as well as appropriate lessons from previous NRC experience. The BTP correctly recognizes that DOE ultimately bears the burden of convincing a Licensing Board, and probably others as well, that its use of expert judgment on a particular issue has properly

characterized the relevant uncertainties and that their magnitude is, in fact, acceptable.

There are, however, some areas and issues where the Board feels greater specificity in the BTP might be helpful.

- Based on its own analyses, does the NRC [staff] believe that there are technical issues that are so critical to demonstrating the safety of a repository system that their resolution should be based almost exclusively on primary data, minimizing the reliance on expert judgment? If so, what are they?

- Has the NRC staff developed views or guidance as to when "it is infeasible or impossible to collect data" and what types of management challenges would support a determination that "data collection [has] become "prohibitively expensive" (p. 24)?

- Are there any circumstances where the NRC staff might not accept the results of a DOE elicitation that was conducted in accordance with the process outlined in the BTP? If so, what are they?

- Can some guidance be offered to DOE on the conditions and circumstances that justify departure from equal weighting of experts' judgments?

NRC might wish at some point to explore, with DOE, the related question of how biases of experts might be minimized when their judgment is rendered informally, although such an effort could be outside of the scope of the BTP.

Response

With respect to the NWTRB's first comment, it should be noted that it is DOE's responsibility, in the first instance, to formulate a strategy for demonstrating compliance; the staff is, therefore, reluctant to constrain DOE by identifying technical issues that must be resolved almost exclusively by the use of primary data, rather than expert elicitation. For issues DOE elevates to critical importance, DOE should make an adequate, but decisive, case. The responsibility will then fall to the staff to evaluate the acceptability of DOE's analysis, in the context of a complete license application. DOE will have to decide how much reliance to place on various features and components of the repository system in order to demonstrate compliance with the total-system performance objective. The staff should not attempt to predict, in the BTP, whether DOE may choose to take credit at all for certain potentially helpful components or features (e.g., cladding of spent fuel as an additional barrier isolating the waste). The repository system is highly complex and nonlinear; modeling the repository system is based on limited data. Determination of critical issues is difficult and might be subject to change under these conditions, even presupposing that DOE has a firm strategy for demonstrating compliance. Some important issues of repository performance (e.g., the validity of long-term predictions), must necessarily be based on scant primary data. For all these reasons, the staff is not inclined to specify issues, in this BTP, requiring resolution almost exclusively using primary data. These points are either made already in the responses to public comments or may be found in Section 1 of the BTP.

With respect to the NWTRB's second comment, concerning possible guidance on when it might be ". . . infeasible or impossible to collect data . . ." or when the cost of data collection might be "prohibitive," the staff tends to think that this matter, like the first NWTRB comment, is better left for later consideration, in the context of a topical report or a completed license application, for example. However, the staff believes that it is impossible to collect some data, such as direct confirmation of long-term predictions of radionuclide migration at the site. Nevertheless, the staff has not developed guidance on these issues. Furthermore, DOE, the party responsible for collecting the necessary site characterization data, as the potential applicant, has not requested further guidance at this time. Moreover, as the party responsible for preparing a potential license application, it might be more appropriate to defer this question to DOE. In this regard, the staff notes in Section 1.4 ("Purpose of the BTP"—see paragraph 6) of the BTP that:

> "DOE has the flexibility to determine whether the costs and benefits of performing an expert elicitation are advantageous

compared to the costs and benefits of performing theoretical analyses and/or gathering additional field and experimental data."[4]

In response to the NWTRB's third comment, concerning ". . . circumstances where the NRC staff might not accept the results of a DOE elicitation that was conducted in accordance with the process outlined in the BTP. . . ," the staff's preference is to be cautious on what adherence to the BTP can provide and not to predict where it can fail. Hypothetically, though, circumstances could arise in which the staff might not accept the results of an elicitation. For example, one circumstance might be the existence of subsequent analyses or opinions that contradict the conclusions reached by an elicitation. In anticipation that such situations cannot be completely discounted in the future, the staff acknowledged this possibility (see Section 1.4 of the BTP). However, the staff believes that following the guidance set forth in the BTP enhances the chances of the acceptance of the elicitation and its results.

In response to the NWTRB's final comment regarding conditions or circumstances that might justify departure from equal weighting of experts' judgments, although there may be some circumstances in which unequal weighting might be appropriate, the staff prefers not to speculate on what those conditions or circumstances might be. The staff believes that the response to the NWTRB's question is more appropriately addressed by DOE, again, as the practitioner. Whatever weighting factors are used, DOE should document its rationale for selecting them. However, the reader is referred to DeWispelare *et al.* (1994) and the Senior Seismic Hazard Analysis Committee (1995) for discussion and examples of how this issue has been dealt with in specific applications.

Lastly, with respect to the NWTRB's recommendation, that NRC and DOE explore the related question of how biases of experts might be minimized when their judgment is rendered informally, the staff agrees with the NWTRB that this issue is beyond the scope of the BTP and should be addressed separately.

[4]As noted in the staff's response to the State of Nevada's third general comment, this BTP is consistent with current NRC policy which encourages the use of PRA state-of-the-art technology and methods as a *complement* to the deterministic approach in nuclear regulatory activities and is also in keeping with the Commission's paramount responsibility to protect public health and safety.

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APPENDIX E
STAFF VIEWS ON DOE'S 1995 *PRINCIPLES AND GUIDELINES* AND THE POSSIBLE DISPOSITION OF SCA COMMENT 3

E–1 Introduction

The staff's original intent, as indicated in correspondence to both the U.S. Department of Energy (DOE) and the State of Nevada (see respectively, Austin (1995) and Holonich (1995)), was to comment on both DOE's *Principles and Guidelines for Formal Use of Expert Judgment by the Yucca Mountain Site Characterization Project Office* (Brocoum, 1995) (hereafter referred to as the *Principles and Guidelines*) and, in that comment, to reflect its consideration of the State's review (Loux, 1995), thereof, after a Fall 1995 U.S. Nuclear Regulatory Commission/DOE technical exchange. However, the proposed technical exchange was cancelled, at DOE's request. In light of the cancellation, the staff decided to defer comment until after public comments had been received on the draft Branch Technical Position (BTP).

In its comments on the draft BTP, DOE indicated that it is now in "substantial agreement" with the NRC staff's technical positions on the formal use of expert elicitation in the high-level waste program (see Brocoum, 1996). For its part, the State commented that the draft BTP was "favorably responsive" to its earlier concerns (see Loux, 1995). Therefore, the staff is inclined to believe that with publication of the BTP, the staff's original intention, to comment on the DOE *Principles and Guidelines*, has been overtaken by events (i.e., issuance and acceptance of the NRC guidance).

With these thoughts in mind, the NRC staff offers the following comments and describes a possible path to resolution, at the staff level, of the particular Site Characterization Analysis (SCA) open item, SCA Comment 3, to which this issue applies.

E–2 DOE's *Principles and Guidelines*

To address the concerns raised by the staff in its SCA Comment 3, the staff made two recommendations to DOE (NRC, 1989; p. 4–10):

"• State the 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.

• Modify the Site Characterization Plan, in an early update, to assure that the requisite data will be available."

Consistent with the staff's first recommendation, ". . . to state criteria for the formal use of expert judgment. . . ," DOE issued its 1995 *Principles and Guidelines* and in doing so, has argued that the information contained in it provides the necessary criteria. Along with the information and direction contained in the *Quality Assurance Requirements Document* (QARD), DOE suggests that its 1995 *Principles and Guidelines* would be adequate to resolve, at the staff level, this particular open item.

The staff has reviewed DOE's *Principles and Guidelines* and has a number of concerns. The first is that DOE's QARD addresses only the subject of "peer review" (see DOE, 1995; Section 2.2.9) and does not treat the issue of elicited expert judgments (either formally or informally). Second, language in the *Principles and Guidelines*, in many places, appears to confuse the concepts of "expert judgment," "expert elicitation," and "peer review," concepts that are, in the staff's opinion, distinct. Because the staff believes there is frequent confusion in the use and application of these terms, it decided to provide the necessary clarification in its own BTP, including expanding the definition of "peer review" over that provided earlier in Altman *et al.* (1988). These three subjects are distinct and should be addressed separately. A third deficiency identified by the staff in the *Principles and Guidelines* document is that it contains no substantive discussion regarding potential procedures *per se* that would be used to conduct a formal elicitation. If DOE intends to rely on its *Principles and Guidelines* as instruction to Department management and staff, the NRC staff believes that a "how-to" statement, such as that contained in the recommended nine-step process in Section 3 of the BTP, is

needed. Lastly, the staff believes that DOE's *Principles and Guidelines* needs to acknowledge or address, as the staff did in the BTP (see Section 4), how DOE management and staff would deal with the potential for conflict of interest when conducting a formal elicitation.

With respect to the second staff SCA recommendation ". . . to modify the Site Characterization Plan (SCP—DOE, 1988), in an early update, to assure that the requisite data will be available . . . ," DOE has not modified the SCP, as first recommended. However, it is generally recognized now that DOE's repository program has evolved beyond that which was earlier described in the 1988 SCP, for a variety of reasons. As DOE prepares its future program plans for site characterization and the repository Viability Assessment, the staff fully expects DOE to provide sufficient documentation to support its decisions, including those that relate to where it might rely on formal use of expert judgment. Therefore, until the Department has had an opportunity to revise and update its site characterization plan, it may be appropriate for the staff to consider retraction of this earlier recommendation, at this time.

E-3 State of Nevada July 1995 Comments on DOE'S *Principles and Guidelines*

As noted above, and subject to specific comments and recommendations, the State has indicated that the draft BTP is "favorably responsive" to its earlier concerns expressed to the staff concerning DOE's *Principles and Guidelines* (Loux, 1995). Further, as described below, DOE is being asked to revise its *Principles and Guidelines*, consistent with the BTP. Thus, in light of this, the staff believes that further comment on the State's July 1995 letter would serve no useful purpose. However, the staff does wish to point out, as it did in its initial response to the State on these comments, that the views of DeWispelare *et al.* (1994) as well as the views of all other contractor reports (e.g., Bonano *et al.* (1990) and Senior Seismic Hazard Analysis Committee (1995)) are the views of those authors and do not, necessarily, reflect the views on regulatory positions of the NRC staff. To the extent that these or any other contractor reports are cited in this BTP, the only staff endorsement these documents receive is limited to the particular points for which they are referenced. Moreover, as regards the BTP's reference to or consistency with any other documents, the reader is reminded that for the purposes of any potential license application, the benchmark that will be used by the staff to judge the acceptability of the process of any formal elicitation is the staff's technical positions described in this NUREG.

E-4 Staff Recommendation on the Disposition of SCA Comment 3

In light of the aforementioned comments and observations, and because DOE is in "substantial agreement" with the NRC staff's technical positions in the BTP, the staff believes that there is a sufficient basis to recommend that SCA Comment 3 be closed, at the staff level, although on somewhat different grounds from those suggested by DOE in its 1996 letter to the staff (see Brocoum, 1996). However, in making this recommendation, the staff believes that DOE will need to agree to the following course of action, with the attendant commitments or, an equivalent course of action.

1. The 1995 *Principles and Guidelines* should be revised to reflect DOE's acceptance of the staff's BTP. Moreover, DOE's *Principles and Guidelines* should be revised to address the recommended changes to format and content, as noted by the staff in Section E-2, above. To summarize, these would include:

    - Correction and clarification regarding DOE's use of the terms "expert judgment," "expert elicitation," and "peer review."
    - Substantive discussion regarding the specific procedures *per se* that the Department and its contractors would follow when conducting a formal elicitation.
    - Direction to DOE management and staff regarding how to address the potential for conflict of interest when conducting a formal elicitation.

2. The current version of the QARD (DOE, 1995) should be revised to include a discussion of the treatment of "formal" expert

elicitation comparable to the discussion which already exists for "peer reviews."

3. DOE decisions on the need to use formal expert elicitations should be transparent. DOE's *Principles and Guidelines* should be revised to ensure that its management and staff prepare the necessary documentation to permit tracking of such decision-making.

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APPENDIX F
DISPOSITION OF ACNW COMMENTS

After receipt and analysis of public comments on the February 1996 draft Branch Technical Position (BTP), the staff briefed the Advisory Committee on Nuclear Waste (ACNW) on the staff's disposition of public comments and any proposed revisions to the BTP based on those public comments. As a result of that briefing, dated August 22, 1996, the ACNW submitted the following comments[1] to the Commission.

Recommendation

This BTP provides important guidance to the (potential) applicant (the U.S. Department of Energy—DOE), affected units of government, and interested parties, on the use of formally elicited expert judgment. The ACNW anticipates that the BTP will be immediately useful to the NRC staff, for example, in its evaluations of (or comments on) DOE's "Probabilistic Volcanic Hazard Analysis for Yucca Mountain, Nevada" (Geomatrix Consultants/TRW Environmental Safety Systems, Inc., 1996) and later comments on DOE's (ongoing) probabilistic seismic hazard assessment.[2] In the long term, the BTP will provide valuable guidance to the DOE in the preparation of its license application and to other parties carrying out expert elicitations in connection with the facility licensing process.

We wish to commend the NRC staff for completing the final draft BTP, which is desirably brief and nonprescriptive. The applicant is left to its own creativeness on how to handle such important issues as probabilities, methods of aggregating uncertainties, data updating, and the final form of the results. **The Committee strongly recommends the prompt completion and publication of the final draft BTP.**

Residual Concerns

Although the ACNW welcomes and supports the subject draft BTP, we have several residual concerns regarding the use of formally elicited expert judgment in the decision-making process. The Committee does not intend that these concerns delay publication of the draft BTP. We realize that these concerns could be addressed by a variety of means outside the BTP, including workshops, letters, NUREGs, technical exchanges, and so on. These concerns are discussed below. The Committee believes that these residual concerns should not delay the prompt publication of the BTP. The ACNW looks forward to working with the staff to address these concerns through other avenues.

1. Subject-Matter Experts

The Committee believes that the nomination process for selecting subject-matter experts should include organizations such as the National Academies of Sciences (NAS) and Engineering, private industry, State development and regulating bodies, and representative public interest groups.

We also believe that the process of formulating the problem to be solved, the issues to be addressed, and the detailed questions to be answered should take place, primarily, before and during the process of selecting experts. The Committee's suggested approach is that before deciding on the final panel of experts, a much larger number of experts be contacted and their input be elicited on refining the general problem that has been formulated by the generalists and the normative experts. In this way, a much larger knowledge base is available to fine tune the issues, and the opportunity exists for a very effective group of experts to evolve that will eventually make up the panel. Further refinement of the issues

[1]The indented portions of this appendix quote the ACNW comments. Moreover, the staff has responded to minor comments on the BTP made by the ACNW, as noted in the *Transcript for the 85th Meeting of the ACNW—August 21–23, 1996.*

[2]It should be noted that during the August 22, 1996, briefing of the ACNW, DOE indicated that it contemplated a series of additional expert elicitations as part of its total-system performance assessment efforts. In an October 9, 1996, public meeting with the Nuclear Waste Technical Review Board, DOE *tentatively* identified the general subject areas for these additional focused elicitations as: unsaturated zone hydrology, waste package canister degradation, thermal hydrology, waste form dissolution, and saturated zone hydrology.

and questions should be performed by the selected panel of subject-matter experts.

Response

Regarding the first portion of the ACNW's comment, the staff's intent behind Step No. 2 ("Selection of Experts") of Technical Position No. 2 ("A Consistent and Systematic Process for Elicitation Should be Applied") of the BTP was to encourage the enlistment of qualified individuals representing or affiliated with the organizations/ entities identified by the ACNW in its comment. To make the staff's intent clearer, the first two sentences of the fifth paragraph of the "Discussion" section (Section 4) behind Technical Position No. 2/Step No. 2 have been modified as follows:

> In selecting each of the three types of experts, especially the subject-matter experts, it may be useful to seek qualified nominations from outside sources, or recognized peers in the field. This would include, for example: the National Academies of Sciences and Engineering; academia; recognized professional societies (e.g., *Sigma Xi*, The Geological Society of America, the American Society of Civil Engineers); National laboratories; knowledgeable Federal Agencies and International Organizations; private industry; State development and regulating bodies; representative public interest groups; and interested stakeholders.

Apropos the second portion of the ACNW's comment, regarding the timing of final subject-matter expert selection and problem formulation (Step No. 3—"Identification of Issues and Problem Decomposition" of Technical Position No. 2), the staff believes that the BTP is compatible with the ACNW's views on this issue. Although the BTP may not state so in the same way the ACNW has, the staff believes that the BTP recognizes that it may be appropriate to "iterate" on problem formulation (Step No. 3) before subject-matter expert selection (Step No. 1) is finalized, as noted in the third introductory paragraph (in Section 4, "Discussion") to Technical Position No. 2:

> In addition, although the process steps are listed in numerical order, it is not necessary that the individual steps be performed in the exact sequence presented. In fact, it is expected that several of these process steps will proceed or can be initiated concurrently, subject to repeated iterations and opportunities for feedback from the subject-matter experts. This may be especially true for Step Nos. 2, 3, and 4, which are depicted as parallel process steps with feed-backs, as shown in the preceding figure. What this figure shows, for example, is that once the subject-matter experts are identified (in Step No. 2), they can help to better define the objective of the elicitation (Step No. 1) and thus aid in the decomposition of the elicitation issue into its constituent parts (Step No. 3). Moreover, the subject-matter experts can also aid in the identification of additional information that could facilitate the elicitation (Step No. 4).

However, the staff's intent here may not be clear to all readers. Accordingly, the staff has added the following footnote to the paragraph in question:

> Alternatively, before deciding on the final panel of subject-matter experts (Step No. 1), in contacting candidate experts, it might be useful to solicit their input on refining the general problem (Step No. 3) that was previously formulated by the generalists and the normative experts. In this way, a much larger knowledge base is available to fine-tune the issues that will ultimately be addressed by the final group of subject-matter experts. Further, final refinement of the sub-issues (and questions—Step No. 3) should be performed ultimately by the selected panel of subject-matter experts.

Moreover, the staff has revised the title of Step No. 3—"Identification of Issues and Problem Decomposition" of Technical Position No. 2 to read as "Refinement of Issues and Problem Decomposition" to better reflect the staff's intent in this particular process step.

2. Aggregation of Results

> The Committee believes that the results from expert elicitation should clearly display the uncertainties in the chosen performance measures for a particular issue. Therefore, the aggregation of the results of the expert panel should also be clear in terms of the

uncertainties in the individual judgments of the panel members and the method of aggregation and integration of bottom-line results that include the quantification of uncertainties. This property of the elicitation process becomes especially important to the regulators in the consideration of multiple elicitations covering similar or identical issues. The scientific process considers a full range of alternatives on the basis of the technical knowledge base of each and the associated reasoning processes, all of which should be exposed in the decision-making process. This documentation will facilitate the regulator's ability to discriminate between different alternatives on the basis of the evidence presented.

In this regard, major guidance would come from an illustration of the aggregation process that embraces the notion of combining and integrating probability distributions. The idea would not be to prescribe a process but rather to illustrate in graphical and analytical terms an example of what is meant by the aggregation process. It is believed that such an aid would greatly facilitate and add meaning to the use of probability methods in the licensing process in general, and in expert elicitation in particular.

Response

The staff agrees with this comment and notes that the BTP is not inconsistent with the ACNW's views. The BTP emphasizes the importance of an individual expert's opinion. In this regard, the BTP, as part of the "Documentation" process step (Step No. 9 of Technical Position No. 2), notes that the documentation associated with any formal elicitation should be adequate insofar as it accurately reflects the subject-matter expert's opinion but also captures the rationale for that opinion. This would include the preliminary and constituent opinions that are used to form a final opinion. If, during the feedback process (Step No. 7), a subject-matter expert modifies his or her opinion, then the staff believes that both the original (Step No. 6) and modified opinions (Step No. 6), along with the rationale for any change, should be included as part of the elicitation record (Step No. 9).

Accordingly, given the underlying "transparency" theme of the BTP, the staff expects that the documentation of the aggregation method used (Step No. 8), whatever that aggregation method might be, must adequately record, among other things, the individual subject-matter expert's opinions, and their attendant effect on results of the elicitation itself, so that they are also traceable, within the aggregate. As noted in the BTP, the staff expressed no opinion regarding what type of aggregation should be used in a formal elicitation because this issue is considered beyond the scope of this guidance. Furthermore, providing an example on this aspect of an expert elicitation is inconsistent with the level of detail sought in this particular guidance document. However, the Center for Nuclear Waste Regulatory Analyses' climate elicitation (DeWispelare *et al.*, 1993) does provide a graphical example illustrating one type of *mechanical* aggregation. NUREG–1489 (PRA Working Group, 1994; pp. C–139—C–142) also provides some detailed discussion regarding the *mathematical* aggregation of expert's judgments.

3. Interpretation of the Results

The Committee wishes to emphasize that as a result of the flexibility of the process, the applicant should not conclude that following the guidance implies automatic acceptance of the results. The results, and the detailed bases thereof, are the desired outcome of the elicitation process. The credibility of the results has to be principally based on the individual's reasoning process, the method of aggregation, and the supporting knowledge base, including the use of specific data wherever possible.

Response

The staff agrees with this comment and notes that the BTP, in particular, the sixth and seventh paragraphs in "Purpose of the BTP" (Section 1.4), address this issue.

4. Application of Expert Elicitation

Although the Committee was pleased that the BTP was not overly prescriptive on the matter of how to conduct expert elicitations, there is a need for additional guidance on candidate issues for application. A discussion

of appropriate applications would illustrate the limitations and the general intent of the process.

Response

As noted in the staff's response to DOE's second overall comment (in Appendix D), on the need for additional guidance in the area of performance assessment, the staff will take this comment into account in due course but has made no decision as yet on this option. In view of the possibility that new performance measures may be established for a potential repository at Yucca Mountain, pursuant to the Energy Policy Act of 1992, and consistent with the findings and recommendations of the recent NAS report (see National Research Council, 1995), the staff wishes to provide for the possibility that site-specific standards may necessitate the development of additional implementing guidance. The staff, therefore, continues to leave open this option, as noted in Section 1.4, paragraph 3 of the BTP (e.g., that it ". . . is considering the potential need for future guidance to identify those specific aspects of a performance assessment for which the application of expert judgment may or may not be appropriate. . . ."). Currently, the staff has no plans for, or resources devoted to, preparing any additional guidance in this area. If the staff decides that additional guidance should be considered, it will explain its reasons and offer the opportunity for comment by the ACNW (and others).

Observation

Additionally, the Committee believes that the Commission, consistent with its *Policy Statement* on probabilistic risk assessment (see NRC, 1995; 60 FR 42623), may wish to examine the decision-making process to take greater advantage of results developed through state-of-the-art expert elicitations. For example, there may be an impact on the admissibility for testimony of a valid elicitation resulting from the unavailability of one or more subject matter experts. Although there are legal arguments for the need for a "sponsoring witness," such an individual may not be able to represent, as his or her own, the full range of the technical arguments contained in the original elicitation.

Response

This comment concerns Commission policy and adjudicatory issues that are beyond the scope of the BTP.

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11. ABSTRACT (200 words or less)

The U.S. Nuclear Regulatory Commission staff expects that subjective judgments of individual experts and, in some cases, groups of experts, will be used by the U.S. Department of Energy (DOE) to interpret data obtained during site characterization and to address the many technical issues and inherent uncertainties associated with predicting the performance of a repository system for thousands of years. NRC has traditionally accepted, for review, expert judgment to evaluate and interpret the factual bases of license applications and is expected to give appropriate consideration to the judgments of DOE's experts regarding the geologic repository. Such consideration, however, envisions DOE using expert judgments to complement and supplement other sources of scientific and technical information, such as data collection, analyses, and experimentation. In this document, the NRC staff has set forth technical positions that: (1) provide general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert; and (2) describe acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic disposal regulation, currently set forth in 10 CFR Part 60.

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