

ENCLOSURE

DISCUSSION AND DETAILED DESCRIPTIONS FOR OPTIONS 1 AND 2  
IN RESPONSE TO STAFF REQUIREMENTS MEMORANDUM FOR COMGEA-11-0001,  
“UTILIZATION OF EXPERT JUDGMENT IN REGULATORY DECISION MAKING”

## Discussion and Detailed Descriptions for Options 1 and 2

### DISCUSSION:

In an SRM entitled, "Staff Requirements—COMGEA-11-0001—Utilization of Expert Judgment in Regulatory Decision Making," dated March 15, 2011, the Commission directed the staff to provide a plan for developing guidance "...that will ensure that the formal utilization of expert judgment is applied consistently in regulatory decision making throughout the Agency." The SRM specifies that development of the guidance on using expert judgment should include the following:

- a summary of past and ongoing significant NRC activities that use expert judgment to identify the lessons learned, document the approaches, and identify significant difference among the approaches
- a survey of recent research to identify promising new approaches (or techniques that can be applied within the broader approach) to expert judgment that may be appropriate for use in nuclear applications
- an evaluation of recent activities within other agencies that relied on expert judgment to identify the lessons learned, document the approaches, and identify differences among the approaches and those used in NRC activities
- options that match the approach with the nature and significance of the issue and the extent to which expert judgment is relied upon in regulatory decision making
- estimates of resources associated with each option for planning purposes
- guidance that is prescriptive enough to ensure consistent application of expert judgment within the agency, yet that is sufficiently flexible to account for the wide diversity of issues that the agency faces, such that the user can tailor the approach to be applicable to the unique issue of concern
- guidance that allows for flexibility in application and the use of highly stylized approaches by individual researchers, as long as scrutability is maintained

In the SRM, the Commission asked the staff to prepare a plan for the development of guidance to promote the consistent use of expert judgment in regulatory decision making. As indicated in COMGEA-11-0001, the two objectives of the guidance are (1) to ensure consistency when using expert judgment to support regulatory decision making and (2) to incorporate lessons learned from past major studies that relied on the use of expert judgment. Recognizing that relatively significant resources would be needed to develop comprehensive guidance, the staff considered three options for responding to the SRM:

- (1) Option 1—Develop comprehensive and detailed guidance.
- (2) Option 2—Develop high-level guidance.
- (3) Option 3 – Develop no additional guidance.

Options 1 and 2 are discussed below.

### Option 1—Develop Comprehensive Guidance

Option 1 involves a hierarchical framework that would include a set of fundamental principles that provide the considerations to be addressed when using formal expert judgment in regulatory applications, followed by a set of standardized steps that address these principles. Option 1 then provides detailed implementation guidance for each of the standardized steps. The plan for this option consists of the activities described below.

1. Define the scope of decision types to be addressed.

Level of effort: 3 staff-months<sup>1</sup>

One objective of the SRM is to gain consistency in the formal use of expert judgment. However, the SRM also states that the guidance should be flexible enough to allow for the use of highly stylized approaches. Consequently, it is imperative to gain a good understanding of the breadth of decisions and analyses that may involve the use of expert judgment, and to determine the types of techniques that have been used for each application and any unique characteristics of those applications that required adjustment of previous expert elicitation techniques.

As indicated in the SRM, the guidance should apply to regulatory decisions throughout the agency that involve the formal use of expert judgment.<sup>2</sup> As stated in COMGEA-11-0001, such approaches are appropriate when the available data or operating experiences are sparse, the subject is too complex to model accurately, and the pertinent phenomena or issues have significant safety or regulatory implications.

As such, the first activity under this option involves surveying the various NRC offices and regions to determine the range of decisions that involve the use of formal approaches for eliciting expert judgment. The staff will identify points of contact (POCs) (e.g., office- or division-level technical assistants), and the POCs will canvass their organizations to identify recent, current, and anticipated formal uses of expert judgment that supported, supports, or may support regulatory decision making, as well as to identify individuals knowledgeable about the methods used. The staff will meet with these knowledgeable individuals to glean more detailed information on the expert judgment process, the use of the results, and any insights or lessons learned from the regulatory application. This activity will include summary documentation of the decision types supported by expert judgment and the expert judgment approaches used, their significant differences, and any lessons learned.

2. Survey recent research to identify promising new approaches (or techniques that can be applied) to expert judgment.

Level of effort: 2 staff-months

Because of the importance of expert judgment in addressing subjects that involve very complex phenomena, have little applicable data, or both, the staff is aware of considerable research

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<sup>1</sup> The staff intends to apply one Full Time Equivalent (FTE) staff per year to accomplish these tasks.

<sup>2</sup> In this context, the staff considers the formal use of expert judgment to involve a structured approach to eliciting information from experts. Common examples of structured approaches include phenomena identification and ranking table and expert elicitation processes, such as that proposed by the Senior Seismic Hazard Advisory Committee in NUREG/CR-6372, "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts," issued April 1997.

related to expert judgment methods and applications. Therefore, the staff will survey recent relevant published literature in this area to determine whether there are any recent advances in this field that are appropriate to support regulatory decision making. This survey will involve a literature search of papers and books on the use of expert judgment, as well as a review of proceedings from recent conferences on probabilistic risk assessment. The staff will compare any promising research advances found to the existing approaches and techniques identified under Activity 1 and update the project documentation.

3. Identify and evaluate applications of expert judgment external to the NRC.

Level of effort: 4 staff-months

Many organizations external to the NRC rely on expert judgment to address regulatory or technical issues that affect public, occupational, or environmental safety. These include other U.S. Federal agencies, State and local agencies, foreign regulatory agencies, international organizations, and other external stakeholders. Given the large number of such organizations, it will be necessary to establish conditions to help select organizations with which to interact. Since large Federal agencies are more likely to have developed policy or guidelines related to the use of expert judgment, the staff will give initial consideration to these agencies. The staff will further refine the selection of agencies to focus on those with similar missions to the NRC (i.e., those that have a regulatory or safety mission, or both) and that rely on formal expert judgment for applications similar to those identified during discussions with the POCs under Activity 1. The staff will address interaction with foreign entities as part of the feedback process on the draft guidance under Activity 7.

The staff will contact the selected agencies to obtain their cooperation in the work. Meetings or workshops will be scheduled to facilitate the sharing of decision types supported by formal use of expert judgment and the associated approaches, outcomes, and lessons learned. Of particular interest will be whether any of these agencies have developed guidance or policies for the use and application of expert judgment to support decision making, or whether expert judgment is applied in a more ad hoc fashion. If any of the contacted agencies does have related policy or guidance, the staff will examine this information in detail to determine its applicability to the NRC's activities.

The staff also will compare the approaches discussed to those used at the NRC and update the project documentation to address any significant differences and lessons learned.

4. Categorize decision types and develop guidance framework.

Level of effort: 5 staff-months

Based on the outcome of Activities 1–3, the staff envisions that a set of decision categories will be developed based on the nature and significance of the issue involved (e.g., whether the issue was associated with rulemaking, license review, regulatory analysis, or generic communication) and the extent to which expert judgment is relied upon to support resolution of the issue. The SRM states that the guidance should include options to match different applications, should be prescriptive yet flexible, and should allow flexibility in implementation. As such, the staff will develop a unifying framework for the application of expert judgment to

agency regulatory decisions that will provide guidance in a hierarchical manner at the following three levels:

- (1) fundamental principles
- (2) basic (standardized) steps
- (3) detailed implementation guidance

At the highest level, the framework will include a set of fundamental principles. These principles will provide the considerations to be addressed when using formal expert judgment in regulatory applications. The staff will then establish a set of standardized steps that address the fundamental principles. To ensure consistency, all formal uses of expert judgment that support regulatory decisions will include each of the standardized steps, although the level of rigor and resources applied to each step will vary depending on the characteristics of the decision being supported (i.e., the decision category, as described above). At the next level, the staff will develop detailed implementation guidance, essentially providing a list of acceptable ways to perform each of the standardized steps. The implementation guidance (which will be developed under Activity 5) will conform to the various decision categories and provide users the flexibility to account for a wide diversity of issues.

#### 5. Develop draft guidance for internal review.

Level of effort: 12 staff-months

Based on the results of Activities 1–4, and in parallel with Activity 6, the staff would develop a draft guidance document for internal review by RES. Consistent with the hierarchical structure of the guidance framework developed under Activity 4, the guidance will describe the fundamental principles and the set of standardized steps, as well as the categorization of decision types.

Detailed implementation guidance will be provided that describes acceptable approaches for accomplishing each standardized step. For different decision categories, the list of acceptable approaches may differ for some or all of the steps. By delineating acceptable approaches for different types of decisions, the guidance provides users the flexibility to account for a wide diversity of issues. This flexibility is further enhanced by offering options to accomplish each step, rather than very prescriptive instructions.

The staff will base the acceptable approaches identified in the guidance on the results of Activities 1–3. The guidance will assist the user in selecting the best approach to be followed for the specific decision being supported (e.g., through the use of a decision tree or matrix), based in large part on the lessons learned from previous applications of expert judgment. Illustrative examples will be used to demonstrate how the guidance should be implemented. Examples may be obtained from past NRC applications or from other agencies based on the interactions under Activity 3.

As stated in the SRM, the “guidance must allow...the use of highly stylized approaches...as long as scrutability is maintained.” Therefore, the guidance must address how the formal expert judgment process should be documented to enhance its transparency and facilitate its review.

6. Determine the form of the guidance.

Level of effort: 1 staff-months

To ensure consistent application throughout the agency, it may be desirable to include the guidance as a management directive. However, to facilitate the updating of the guidance based on lessons learned, alternatives may be preferable (e.g., documenting the actual guidance in a NUREG report or handbook that is referenced by a management directive or including it on a Web page or other suitable guidance document).

The form of the guidance will depend on which types of decisions require its use. For example, one possibility is that adherence to the guidance will be required for expert elicitations that support rulemaking, but it will be optional for decisions involving a lesser degree of regulatory significance. The staff will meet with internal stakeholders to solicit input on the preferred form of the guidance. This activity will take place in parallel with Activity 5.

7. Obtain feedback from internal and external stakeholders.

Level of effort: 3 staff-months

The staff will first solicit feedback from internal stakeholders on the draft guidance. To facilitate this feedback, an internal workshop will take place to summarize the guidance and demonstrate its application. Participants will provide oral feedback during the workshop, and the staff will solicit written comments afterwards.

Subsequently, or in parallel, the draft guidance will receive external peer review. Some foreign regulatory agencies will be selected for this review, along with other U.S. stakeholders. The staff also will present the draft guidance to the Advisory Committee on Reactor Safeguards (ACRS). The staff will review all feedback and prepare a draft final version of the guidance.

8. Submit the draft final guidance for internal concurrence and public comment.

Level of effort: 6 staff-months

Once the staff completes the draft final version of the guidance, the staff will submit it for internal concurrence and then release the draft final guidance for public comment. After addressing the public comments and revising the draft final guidance as needed, the staff will brief ACRS and request a letter to the Commission. Depending on the extent of changes to the guidance, reconcurrence may be needed.

9. Submit the proposed final guidance document to the Commission.

Level of effort: 3 staff-months

Once the staff addresses any final comments from ACRS and office management, the staff will provide the proposed final guidance document, with any associated recommendations, to the Commission.

#### Discussion of Option 1:

Pros: Option 1 maximizes the consistency, transparency, and efficiency that can be expected in future applications that use formal expert judgment to support NRC decision making, while still affording flexibility to account for the wide diversity of issues that the agency faces. This option explores methods previously used by the agency and investigates improvements or alternatives to those methods developed by external agencies and research institutions. The objective of this option is to provide NRC staff with additional formal guidance on appropriately selecting methods, and on developing and applying results based on expert judgment. Consequently, the expected result of this option is a guidance document that addresses how to conduct the expert elicitation for a given application. Such guidance would provide a spectrum of approaches and guidance on selecting the appropriate approach for a given type of decision, based in large part on the lessons learned from previous applications of expert judgment. In addition, the guidance will facilitate the review of analyses submitted to the NRC that involve the use of expert judgment.

Cons: This option requires significant resources within the NRC (e.g., RES staff, POCs in other offices, NRC contacts to POCs from external agencies) and from participating external agencies. Given the limited resources available to perform this work, implementing this option will result in the delay of other work. Also, the benefits of expected improvements in expert elicitation applications (e.g., consistency) may not justify the resources needed for Option 1. Finally, because a number of NUREGs and NUREG/CRs already exist on this topic<sup>3</sup> and have been found to be acceptable applications of expert elicitation, gaining widespread staff consensus on any new methods resulting from the extensive literature search and outreach to other agencies required in Option 1 would be challenging.

#### Option 2—Develop High-Level Guidance

Under this option, the staff will develop high-level guidance for the formal use of expert judgment to support regulatory decision making. Consistent with Option 1, the staff will develop a hierarchical framework that begins with the fundamental principles and includes a set of standardized steps that address these principles. However, at the next level, instead of providing detailed implementation guidance (as in Option 1), the staff will only provide supporting information related to the standardized steps. This information will consist primarily of a summary of previous formal uses of expert judgment at the NRC (focusing on how the approach addressed each of the standardized steps) and references to additional information.<sup>4</sup>

While this option provides users the flexibility to account for a wide diversity of issues, it may not provide the same level of consistency as Option 1. To further limit the amount of resources required, Option 2 focuses only on internal NRC experience with the formal use of expert

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<sup>3</sup> Examples include NUREG/CR-6372; NUREG-1624, "Technical Basis and Implementation Guidelines for A Technique for Human Event Analysis (ATHEANA)," Revision 1, issued May 2000; NUREG/CR-5424, "Eliciting and Analyzing Expert Judgment: A Practical Guide," issued January 1990; NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program," issued November 1996; and NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process," issued April 2008.

<sup>4</sup> In addition to the NRC reports already cited, additional guidance is currently under development and issued for public comment: NUREG-XXX, "Practical Implementation Guidelines for SSHAC Level 3 and 4 Hazard Studies." This new work also captures lessons learned from applications of NUREG/CR-6372 in various US and international projects that characterized seismic hazards.

judgment and does not involve collaborating with other agencies or organizations. In addition, this option does not include a survey of recent research to identify new approaches or techniques.

Option 2 provides an intermediate approach to Option 1. The level and detail of the guidance developed under this option can be adjusted based on the availability of resources. Based on the above considerations, the following differences would exist from the activities described under Option 1:

1. Define the scope of decision types to be addressed.

Level of effort: 3 staff-months

This activity is essentially unchanged from Option 1.

2. Survey recent research to identify promising new approaches (or techniques that can be applied) to expert judgment.

This activity will not be performed under Option 2.

3. Identify and evaluate applications of expert judgment external to the NRC.

This activity will not be performed under Option 2.

4. Categorize decision types and develop guidance framework.

Level of effort: 5 staff-months

This activity is essentially unchanged from Option 1.

5. Develop draft guidance for internal review.

Level of effort: 7 staff-months

Based on the results of Activities 1 and 4, and in parallel with Activity 6, the staff will develop a draft guidance document for internal review by RES. Consistent with the hierarchical structure of the guidance framework, the guidance will describe the fundamental principles and set of standardized steps developed under Activity 4, as well as the categorization of decision types.

For each standardized step, supporting information will be provided that consists primarily of a high-level summary and lessons learned from previous formal uses of expert judgment at the NRC as they relate to that step. This will provide an array of options for the user to choose from, but they will not include specific guidance on implementation. However, the guidance will identify references that provide more detailed information to support implementation. Also, while Option 2 will not include formal guidance to assist the user in selecting the best approach, the high-level summaries and lessons learned from previous applications will help inform the decision of which approach or technique to pursue. The set of standardized steps also will serve as general guidance on what areas of the analysis should be documented and the level of detail of this documentation.



6. Determine the form of the guidance.

Level of effort: 1 staff-months

This activity is essentially unchanged from Option 1.

7. Obtain feedback from internal and external stakeholders.

Level of effort: 1 staff-months

Because of reductions in the scope of the guidance under Option 2, the level of effort for this activity is expected to be somewhat less. It should be noted that obtaining feedback from external stakeholders will help compensate for the more limited amount of information gathered under Option 2.

8. Submit the draft final guidance for internal concurrence and public comment.

Level of effort: 6 staff-months

This activity is essentially unchanged from Option 1.

9. Submit the proposed final guidance document to the Commission.

Level of effort: 3 staff-months

This activity is essentially unchanged from Option 1.

Discussion of Option 2:

Pros: This option requires significantly fewer resources to implement than Option 1, but it should still enhance consistency in applying the formal use of expert judgment in agency decision making. Prospective users of this guidance will receive high-level guidance, a spectrum of approaches to consider based on previous applications at the NRC (thereby making the guidance flexible to account for diverse issues), and references to documents that provide more detailed guidance. The list of standardized steps also will provide an outline for the documentation of expert judgment applications, which could enhance consistency and transparency, as well as for the review of analyses submitted to the NRC that involve the use of expert judgment.

It should be noted that the majority of the work performed under Option 2 also is performed under Option 1. Therefore, as future resources and priorities allow, the Option 2 guidance can be expanded to include more detailed implementation guidance, and to consider experience at external organizations and research advances that are appropriate to support regulatory decision making. As such, over time, the guidance developed under Option 2 can evolve to the level of detail associated with Option 1.

Cons: This option provides only high-level guidance and documents various approaches that have been previously applied at the NRC for different types of regulatory decisions. Option 2 does not explicitly assist users in determining the best approach for the specific decision being

supported. Also, to limit the amount of resources required, Option 2 focuses only on internal NRC experience with the formal use of expert judgment and does not involve collaborating with other agencies or organizations. In addition, this option does not include a survey of recent research to identify new approaches or techniques. Although less resource-intensive than Option 1, the resources necessary also would result in the delays of other planned staff work.