

POLICY ISSUE NOTATION VOTE

December 13, 2011

SECY-11-0172

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM
COMGEA-11-0001, "UTILIZATION OF EXPERT JUDGMENT IN
REGULATORY DECISION MAKING"

PURPOSE:

To request Commission approval of the staff's recommendation in response to the Commission's direction to provide a plan for developing guidance to promote the consistent use of expert judgment in regulatory decision making throughout the agency.

DISCUSSION:

In SRM "Staff Requirements—COMGEA-11-0001," 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." In developing this response to the SRM, the staff determined that relatively significant resources would be needed to develop the intended comprehensive guidance. Therefore, the staff identified two additional options: (a) a second, less resource-intensive plan and (b) no action at this time. These three options are summarized below. The enclosure provides detailed descriptions of Options 1 and 2, and provides an expanded discussion.

Option 1—Develop Comprehensive Guidance

Option 1 establishes a hierarchical framework that would include a set of fundamental principles that provides the considerations to be addressed when using formal expert judgment in regulatory applications, followed by a set of standardized steps that address these principles. Based on this framework, Option 1 provides comprehensive and detailed implementation guidance for each of the standardized steps.

CONTACT: Susan Cooper, RES/DRA
301-251-7604

The plan for this option consists of the nine activities described below that are intended to address the Commission's direction in the SRM.

1. Define the scope of decision types to be addressed. (Level of effort: 3 staff-months)

As indicated in the SRM, the guidance should apply to regulatory decisions throughout the agency that involve the formal use of expert judgment.¹ 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.

2. Survey recent research to identify promising new approaches to consider expert judgment. (Level of effort: 2 staff-months)

The staff is aware of considerable research related to expert judgment methods and applications. Therefore, the staff would 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.

3. Identify and evaluate applications of expert judgment external to the NRC. (Level of effort: 4 staff-months)

The staff would contact selected agencies (e.g., Federal agencies with similar missions) to obtain their cooperation in the work. Meetings or workshops would be scheduled to facilitate the sharing of decision types supported by formal use of expert judgment and the associated approaches, outcomes, 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 would 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.

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. Detailed implementation guidance would be provided that describes acceptable approaches for accomplishing each standardized step.

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

¹ 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.

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). The staff would meet with internal stakeholders to solicit input on the preferred form of the guidance.

7. Obtain feedback from internal and external stakeholders. (Level of effort: 3 staff-months)

The staff would solicit feedback from internal stakeholders on the draft guidance. To facilitate this feedback, an internal workshop would take place to summarize the guidance and demonstrate its application. Subsequently, the draft guidance would receive external peer review from U.S. stakeholders and some foreign regulatory agencies.

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 would 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 would brief the Advisory Committee on Reactor Safeguards (ACRS) and request a letter to the Commission.

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 would provide the proposed final guidance document, with any associated recommendations, to the Commission.

Discussion of Option 1:

Pros: Option 1 maximizes the consistency, transparency, currency, and efficiency 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 would 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., NRC staff, NRC contacts to POCs from external agencies) and from participating external agencies. In determining resource estimates, the staff has considered the significant collaborative interactions that would be necessary for developing agency-level guidance. Given the resources needed to perform this work, implementing this option would likely result in the delay of other planned high-priority

staff work. Examples of work that may need to be delayed are given in the Resources section of this paper. Finally, because a number of NUREGs and NUREG/CRs already exist and have been utilized or referenced by the staff, and have been found to be acceptable applications of expert elicitation,² 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

Option 2 provides an intermediate approach to Option 1. In this option, the staff would develop high-level guidance for the formal use of expert judgment to support regulatory decision making. Consistent with Option 1, the staff would develop a hierarchical framework that begins with the fundamental principles and includes a set of standardized steps consistent with these principles. However, instead of providing detailed implementation guidance (as in Option 1), the staff would only provide supporting information for the standardized steps, including references to previous formal uses of expert judgment.

Based on the above considerations, the following summarizes the activities for Option 2 compared to that for Option 1:

- Activities that are essentially unchanged: 1, 4, 6, 8, 9
- Activities that are not performed: 2 and 3
- Activities that are changed in scope: 5 and 7

The descriptions of activities 5 and 7, as implemented under Option 2, are given below.

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 would develop a draft guidance document for internal review. Consistent with the hierarchical structure of the guidance framework, the guidance would 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, a high-level summary, lessons learned from previous formal uses of expert judgment at the NRC, and references that provide more detailed information to support implementation would be provided.

7. Obtain feedback from internal and external stakeholders. (Level of effort: 1 staff-month)

Because the level of detail of the guidance is reduced, as compared to Option 1, the level of effort for this activity for Option 2 also is reduced. Discussion of Option 2:

² Examples include NUREG/CR-6372, "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on Uncertainty and Use of Experts"; 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.

Pros: This option requires fewer resources to implement than Option 1, but it still enhances consistency in applying the formal use of expert judgment in agency decision making. Prospective users of this guidance would receive high-level guidance, a spectrum of approaches to consider based on previous applications at the NRC, and references to documents that provide more detailed guidance. The list of standardized steps also would provide an outline for the documentation of expert judgment applications, which could enhance consistency and transparency.

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. Also, to limit the amount of resources required, Option 2 focuses primarily 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 development of the guidance may also result in the delay of other high-priority planned staff work, examples of which are given in the Resources section of this paper.

Option 3—Develop No Additional Guidance

This option is based on the following staff considerations: (1) formal elicitation methods for expert judgment have been used acceptably in support of previous agency decisions, (2) the use of alternate formal approaches likely would not have affected the outcomes of those decisions or the transparency of the method and how it was applied, (3) adequate guidance exists for implementing existing approaches, and (4) the staff will continue to consider uncertainties and conduct sensitivity analyses, as appropriate and as they affect regulatory decision making. This option allows the staff to choose the expert judgment approach most appropriate for the decision being supported. Therefore, under this option, the staff will continue to use expert judgment consistent with past practice.

Discussion of Option 3:

Pros: This option requires no additional effort or resources and, therefore, does not negatively impact any current or planned agency work. It allows the staff flexibility to choose a more or less formal approach that accounts for diverse issues and decision circumstances.

Cons: This option does not improve the current state of practice in the formal use or standardization of expert judgment in support of regulatory decision making. This option does not provide any additional formal guidance, or any potential enhanced consistency in expert judgment applications. This option also does not document, in one place, the range of available approaches for expert judgment or the types of decisions those approaches have historically supported.

The staff also considered other options such as joint development of guidance with industry and other stakeholders. However, there were significant disadvantages to these other options (e.g., long timeframes needed to develop consensus with industry and the inability to optimize for NRC's use), so they were not developed.

SUMMARY OF RESOURCES AND SCHEDULE:

The following chart summarizes the estimated resources associated with preparing the proposed final guidance for Options 1 and 2, and activities described above. Option 3 involves no additional resources, so is not included here. The staff estimates that, given other planned work priorities and process times to complete each step, completing the guidance would likely require spreading out the development of guidance over at least 5 calendar years for Option 1 and 3 years for Option 2. The staff would need to reassess the schedule and resource needs annually through the Planning, Budgeting, and Performance Management process. Because no resources have been previously budgeted for this work, resources would need to be reallocated from ongoing and planned work.

<u>Activity</u>	<u>Option 1</u>	<u>Option 2</u>
1—Scope	3 staff-mos.	3 staff-mos.
2—Literature search	2 staff-mos.	N/A
3—External applications	4 staff-mos.	N/A
4—Guidance framework	5 staff-mos.	5 staff-mos.
5—Draft guidance	12 staff-mos.	7 staff-mos.
6—Form of guidance	1 staff-mos.	1 staff-mos.
7—Feedback	3 staff-mos.	1 staff-mos.
8—Concurrence/public comment	6 staff-mos.	6 staff-mos.
9—Final guidance	3 staff-mos.	3 staff-mos.
Total	39 staff-mos. (4.5 FTE ³)	26 staff-mos. (3.0 FTE)

The following projects are examples of existing and planned RES activities in FY 2012⁴ and FY 2013 that may be delayed or deferred due to the potential impact of implementing Option 1 or 2. In particular, activities related to human reliability analysis (HRA) and its support to larger probabilistic risk assessment (PRA) studies could be impacted, such as:

- Level 3 HRA/PRA⁵ or HRA data collection
- U.S. bench-marking project⁶
- WGRisk bench-marking⁷
- Response on HRA model differences (SRM-M061020)⁸

As the budget for FY 2014 has not been created, specific resource implications beyond FY 2013 are yet to be determined.

³ For estimation purposes, staff used 1 Full Time Equivalent staff = 1400 hrs, 1 staff-month = 160 hrs.

⁴ Resources would be addressed during the PBPM process.

⁵ Sep. 21, 2011 - (SRM M100218) - Staff Requirements - SECY-11-0089 - Options for Proceeding with Future Level 3 Probabilistic Risk Assessment (PRA) Activities

⁶ Feb 18, 2009 - (SRM M090204B) - Staff Requirements - Briefing on Risk-Informed, Performance-Based Regulation, 1:30 p.m., Wednesday, February 4, 2009, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)

⁷ Nuclear Energy Agency Working Group on Risk Assessment (WGRisk) benchmarking support

⁸ Response to SRM-M061020, "Meeting with Advisory Committee on Reactor Safeguards, 2:30 p.m., Friday, October 20, 2006, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," dated November 8, 2006 (i.e., follow-up projects on HRA model differences)

RECOMMENDATIONS:

Although the staff agrees that improvements to existing expert judgment approaches could be made, existing expert judgment approaches previously utilized by the staff are considered to be acceptable to meet their regulatory purpose. Due to the relatively high resource implications of Options 1 and 2 and the overall prioritization of existing ongoing work, the staff recommends Option 3 (i.e., no further action at this time). If Option 3 is selected, the staff will continue to consider improvement initiatives going forward as resources permit. Also, by not proceeding at this time, the staff would be better positioned to support high-priority activities (e.g., implementation of recommendations identified in the Fukushima Dai-ichi Task Force Report,⁹ site-wide, Level III PRA studies,⁴ and the HRA model differences project⁷). Should the Commission direct the staff to proceed with Options 1 or 2, the staff would develop and provide to the Commission a detailed plan, schedule, and specific resource impacts associated with this activity.

COORDINATION:

The Office of the General Counsel has reviewed this Commission paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

/RA by Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosure: As stated

⁹ USNRC, "Recommendations for Enhancing Reactor Safety in the 21st Century, Review of Insights from the Fukushima Dai-ichi Accident," July 12, 2011, ML111861807.

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OFFICE	RES/DRA/HFRB	QTE	RES/DRA/HFRB	RES/DRA	NRR	NRO
NAME	S. Cooper (via email)	K. Azariah-Kribbs (via email)	S. Peters	R. Correia	E. Leeds (BBoger for via email)	M. Johnson (CAder for via email)
DATE	8/12/11	7/27/11	8/12/11	8/18/11	10/4/11	9/23/11
OFFICE	NSIR	NMSS	FSME	CFO	OGC	RES
NAME	J. Wiggins (CJones for via email)	C. Haney (NJordan for via email)	C. Carpenter (GDeegan for via email)	J. Dyer (JGolder for via email)	C. Martin	B. Sheron
DATE	10/5/11	9/30/11	9/23/11	9/23/11	9/23/11	10/14/11
OFFICE	EDO					
NAME	R. Borchardt (MWeber for)					
DATE	12/13/11					

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⁹ USNRC, "Recommendations for Enhancing Reactor Safety in the 21st Century, Review of Insights from the Fukushima Dai-ichi Accident," July 12, 2011, ML111861807.