A PROCESS FOR RISK-INFORMED DECISION-MAKING

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SUMMARY

The use of PRA results in decision-making has been addressed in Regulatory Guide 1.174, which describes an integrated risk-informed decision-making process that was specifically developed to provide guidance to licensees on how to use risk information in a licensing submittal to change the licensing basis of a plant. While the guidance in that document was at a fairly high level, it has proved to be a useful and successful guide, and the principles of risk-informed decision-making described in RG 1.174 have been adopted for more general use in regulatory activities.

This paper describes a process developed to enable the United States Nuclear Regulatory Commission (NRC) to improve its use of probabilistic risk assessment estimates in decision-making. Recognizing that the various inputs to a decision are very different in nature, some being qualitative, and others, in particular the risk assessment, being quantitative, the guidance focuses on documenting each analysis so that its value and relevance to the decision can be clearly understood and suitably qualified to address uncertainties, and on documenting the decision so that the driving factors for the decision are identified. The process requires the use of templates to ensure that the risk estimates, uncertainties, and assumptions made in developing the estimates are fully defined, documented, and communicated to NRC decision-makers, and provides guidance to decision-makers on how to consider the relative importance, validity, and reliability of quantitative risk estimates in conjunction with other, qualitative, safety related factors.

INTRODUCTION

Since publishing its Final Policy Statement on the Use of Probabilistic Risk Assessment (PRA) Methods in Nuclear Regulatory Activities [1], the U.S. Nuclear Regulatory Commission increasingly made use of risk information in a number of its activities, including licensing actions and oversight activities. Regulatory Guide 1.174, for example, provides guidance to a licensee on the use of PRA in license amendment requests [2]. The philosophy expressed in that document had been adapted for use in other regulatory applications. The guidance in RG 1.174 is at a relatively high level, and concerns have been raised whether the approach is being applied consistently. In GAO-04-415, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," issued May 2004 [3], the U.S. Government Accountability Office (GAO) made the following recommendation with respect to the areas of risk evaluation, communication, and their use in the decision-making:

- Improve the U.S. Nuclear Regulatory Commission's (NRC's) use of probabilistic risk assessment (PRA) estimates in decision making by (1) ensuring that the risk estimates, uncertainties, and assumptions made in developing the estimates are fully defined, documented, and communicated to NRC decision makers; and (2) providing guidance to decision makers on how to consider the relative importance, validity, and reliability of quantitative risk estimates in conjunction with other qualitative safety-related factors.

In response to this recommendation, the NRC staff has developed an office instruction for the conduct and documentation of risk-informed decisions [4]. This process has been created for reactor-based risk-informed decision making, although it is considered that the basic steps can be followed for other risk-informed applications. This process is not intended to replace existing risk-informed decision-making processes (e.g., that given in Regulatory Guide (RG) 1.174 [2]; MD 8.3, "NRC Incident Investigation Program," issued March 27, 2001 [5]; and LIC-401, "NRR Reactor Operating Experience Program," issued May 17, 2005 [6]). Therefore, the guidance in this document can be supplemental to existing risk-informed processes, but was specifically developed for risk-informed decisions that are not already covered by established processes. Examples of applications in which this process could be used include the following:

- decisions involving whether an immediate effective order is needed to place or maintain the plant in a safe condition or acceptable conditions for plant re-start that are not specifically addressed in a facility's operating license or technical specifications

- decisions on an appropriate regulatory response following the discovery of potentially risk-significant generic issues

- concerns about safety margin and defense-in-depth issues with nonconservative calculations or analyses that are not specifically addressed by regulations

- instances when other risk-informed processes call for increased management attention (e.g., in RG 1.174, increased management attention is called for when the risk evaluation approaches the acceptance guidelines [2])

However, recognizing that the various inputs to a decision can be very different in nature, thus making it difficult to develop a formal process for combining them, the guidance focuses on documenting those inputs so that their contribution to the decision can be clearly understood. It also focuses on documenting the decision so that the driving factors are identified and suitably considered to address uncertainties.

OVERVIEW OF PROCESS

Figure 1 outlines the new process to be followed for risk-informed decision-making. The figure depicts three different areas— a) technical activities (information gathering and analysis), b) the risk-informed decision-making process itself (Steps 1 - 4), and c) communication of the decision (Steps 5 - 7).

The first three steps in this process are common to other risk-informed decision-making processes (e.g., Ref. 2). To support these steps, information gathering and technical analyses are performed. Step 4 (i.e., integrate assessment results) is also part of the risk-informed decision-making process in RG 1.174 [2]. However, RG 1.174 only briefly discusses this important step. Therefore, reference 4 provides additional guidance for documenting assessment results.

Steps 5 - 7 have been separated to highlight the importance of communicating the decision and to emphasize the need to use recently developed guidance for risk communication [7, 8]. Feedback loops (e.g., Step 6 to Step 3) reflect the potential need for additional analyses to clarify initial results or answer questions that were not previously considered.

Underlying all steps in the process is the need for documentation. In order to make the results of this risk-informed decision-making process traceable and scrutable, and to assist in its consistency, a series of templates has been developed to formalize the form and format of such documentation.

To be effective in communicating risk-informed decisions, it is important to consider early in the process the stakeholders who need to be informed and involved, as well as who will be impacted, and to build in communication steps that encourage discussion and clarification throughout the process. This enables analysts and decision makers to be more effective in communicating the results during and at the end of this risk-informed process. Placing emphasis on communication during the process helps identify topics that require clarification and focuses attention on ensuring that all participants share an understanding of the subject, objective, terms, and assumptions at hand; this encourages discussion and prevents misunderstandings among team members and therefore enables everyone to stay on track. This is especially important when working with multidisciplinary teams that include both risk analysts and analysts from other (e.g., engineering and licensing) disciplines. The NRC's Risk Communication Guidelines [7, 8] emphasize the importance of explicitly addressing communication challenges early in a process.

DESCRIPTION OF THE PROCESS STEPS

Step 1: Characterization of the Emergent Issue

The purpose of this step is to understand the issue well enough to make an initial assessment of those organizations that must be involved and of the information needed to perform the later steps in the process (e.g., the determination of which options are viable, and which technical approaches are appropriate).

Step 2: Define Decision Options

The purpose of this step is to define the decision-making constraints, define the decision options, describe the decision criteria for acceptance/rejection, describe the factors that determine the analysis approach and options, generate a preliminary list of decision makers, and determine the need for a communication plan. To do this, the following tasks should be completed:

- **Determine the decision-making constraints.** A number of factors provide constraints on the decision-making. These include the urgency of the issue, the tools available to address it, and the resources available to conduct the analysis.

- **Define the decision options.** There may be a number of different options for resolution of the issue. These could include, for example, issuing an order shutting the plant down immediately, shutting it down within a specified time period, continuing operation with the implementation of compensatory actions (e.g. continuing operation at reduced power until the next refueling outage, or continuing operation with increased monitoring), or issuance of an immediately affective order to place or maintain the plant in a safe condition, or delaying the decision until more information is available.

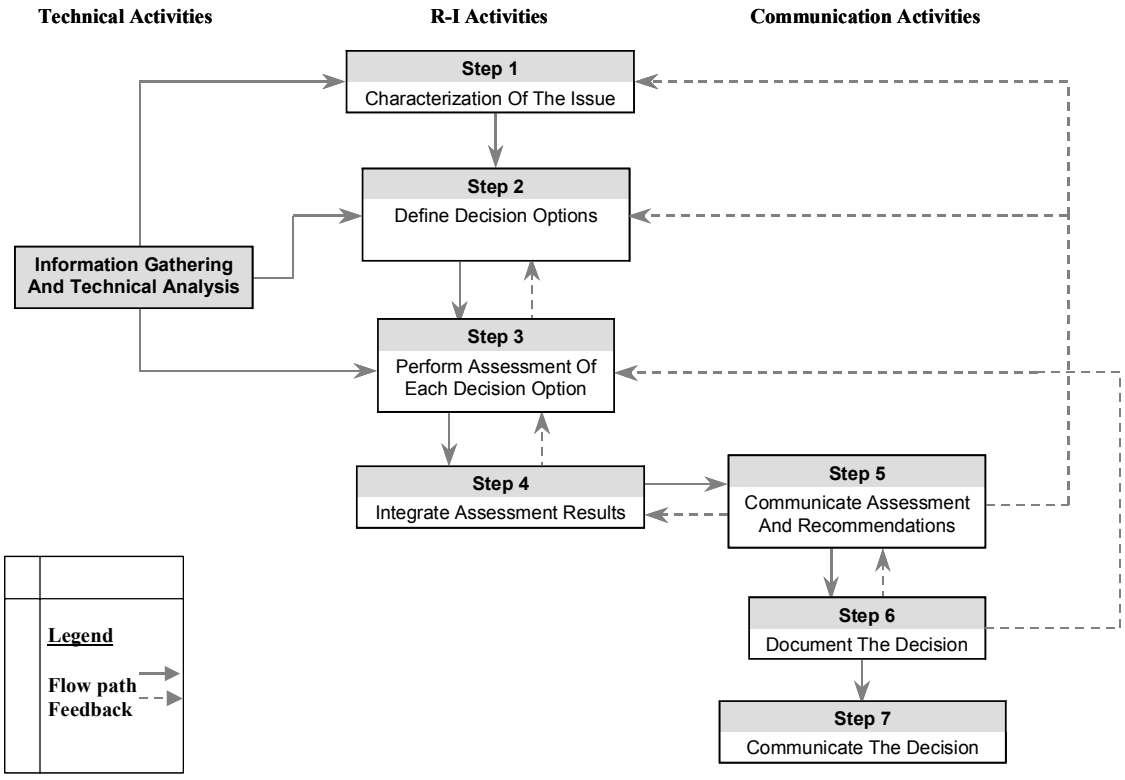

FIGURE 1: RISK-INFORMED (R-I) DECISION MAKING PROCESS

- **Describe the guidelines or criteria for acceptability or rejection of each decision option.** Examples of such guidelines include: meeting the acceptance guidelines of RG 1.174 [2]; or showing the compensatory actions to be effective in minimizing the risk impact.

- **Describe the factors that determine the approach to the analysis of the issue and the selection of options.** A variety of factors, technical and nontechnical, can influence this decision. For example, resource limitations, particularly those related to the time available to make a decision, can be an important factor in determining the available options.

- **Identify the potential primary decision makers.** Depending on the decision, potential decision makers include branch chiefs, division directors, the Risk-Informed Licensing Panel, office directors/regional administrators, or the NRC Executive Director for Operations.

- **Determine the need for a communication plan.** If an issue is potentially controversial (internally or externally to the NRC), a communication plan would focus on developing and delivering key messages about the subject to all stakeholders, and assure ongoing open discussion.

Step 3: Perform Assessment of Each Decision Option

In this step, technical staff assigned to work on this issue analyze and document the assessment of each option. The template provided in the office instruction [4] provides the documentation of the analysis of each input to the decision in a similar manner, by addressing the following:

- what is affected by the issue
- how the option addresses the issue
- the uncertainties associated with the analysis
- the assumptions made to deal with those uncertainties
- the degree of confidence in the conclusion of the analysis

Step 4: Integrate Assessment Results

In this step, the results of the analyses are summarized for each decision option. Each of the principal analysts in each discipline (e.g., PRA, engineering, licensing, etc.) participates in the integration process by documenting his individual analysis using the templates provided and sharing it with other technical staff through a facilitated discussion. The goal of this step is to come to agreement on a recommendation to take forward to decision makers. The integration team works to achieve consensus through the following process:

- Summarizing the results of individual assessments and presenting them to the group.
- Led by a team leader, discussing the results and evaluations of individual assessments. It is critical during this discussion to raise issues, ask questions, and raise and address concerns about risk information, data sources, and other related subjects. The group discussion may identify the need for additional analyses, reframing of the issue, the involvement of additional staff, or other issues.
- With the help of the team leader, deciding upon a decision option to recommend to decision makers.

Step 5: Communicate Assessment and Recommendations

The purpose of this step is to provide a framework for communicating the preferred decision option selected by the integration team to decision makers. Decision makers typically need information presented in summary format for rapid assessment and ease of understanding the impacts and complexity of an issue. Decision makers need narrative descriptions that provide qualitative insight into causes, uncertainties, assumptions, and affected outcomes for a given situation. Less information is needed regarding the details of numerical results, statistical methods, and analyses. This background information must be available, but it should be presented after the recommendations.

The following summary information should be presented in the order shown, in brief sentences or bullet format. The summary should start with the most important information first, such as a recommendation or conclusion, and follow with supporting evidence or data. The information presented includes the following:

- a description of the issue and its characterization, and the type of decision needed
- the recommendation for the preferred option, including driving factors, important assumptions, and potential impacts
- the range of options and the criteria that were considered
- summary of the technical approach used to address the issue
- summaries of technical analyses (especially those that were critical to any recommendations), including any technical or data limitations
- other relevant information, such as generic implications, stakeholder concerns, or known or anticipated impacts of a decision on other regulations

When the above information is presented to decision makers, they may request additional information or other inputs. In particular, this may occur if the technical group could not reach a consensus recommendation in Step 4 for a preferred option. If decision makers identify the need for additional information or analyses, integration team staff should return to the appropriate step in the process to refine or supplement the decision inputs.

Step 6: Document the Decision

When decision makers decide that they have adequate and appropriate information to make a decision in Step 6, the integration team should prepare a document that summarizes the decision inputs.

Step 7: Communicate the Decision

Although a communication plan is not required for every NRC activity, it is likely the issues addressed in this risk-informed process will generate enough interest and impact that the technical staff and decision makers would benefit from a plan to convey the process and its outcomes to internal and external stakeholders

DOCUMENTATION

One of the major objectives of developing this office instruction was to provide a more transparent and consistent approach to the risk-informed decision-making. An essential part of this process is the documentation of the decisions. To facilitate this aspect of the process a set of templates has been developed, and is presented in the office instruction [4]. Table 1, the template for the documentation of step 4, "integration of the assessment results" is included here as an example.

CONCLUSION

A formal process for risk-informed decision-making has been developed for use in regulatory decisions related to reactor operations. This process focuses on a clear definition of the options, and on documenting the information used to reach the decision in such a way that the assumptions made, and the uncertainties associated with each input to the decision are considered.

REFERENCES

[1] USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement," *Federal Register*, Vol. 60, p. 42622 (60 FR 42622), August 16, 1995.

[2] U.S. Nuclear Regulatory Commission, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.174, Revision 1, November 2002.

[3] U.S. General Accounting Office, "Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant's Shutdown," GAO-04-415, May 2004.

[4] U.S. Nuclear Regulatory Commission, "Integrated Risk-Informed Decision-Making Process for Emergent Issues", LIC-504, December 2005, ADAMS accession number ML052060376.

[5] U.S. Nuclear Regulatory Commission, "NRC Incident Investigation Program," MD 8.3, March 27, 2001.

[6] U.S. Nuclear Regulatory Commission, "NRR Reactor Operating Experience Program," LIC-401, May 17, 2005.

[7] U.S. Nuclear Regulatory Commission, "Effective Risk Communication—Guideline for Internal Risk Communication," NUREG/BR-0318, December 2004.

[8] U.S. Nuclear Regulatory Commission, "Effective Risk Communication—The Nuclear Regulatory Commission's Guideline for External Risk Communication," NUREG/BR-0308, January 2004.

TABLE 1 Template for Documenting Risk-Informed Decisions—Step 4, Integrate Assessment Results

Option #: **Description**: Preferred □ Acceptable □ Not acceptable □			
Driving factor (Note 1)	**Key technical input** (Note 2)	**Characterization of the representation of the key technical input**	**Characterization of confidence in the assessment of the driving factor**
Driving factor 1 - description	1) ……	Include, for example, • Limitations of the analysis • Sources of uncertainty • Assumptions made to address uncertainties	• Impact of uncertainty on the conclusion, taking into account the uncertainties in the key technical inputs
	2) ……		
	3) ……		
	4) ……		
	(Include as many rows as are needed)		
Driving factor 2 – description (Include as many driving factors as are needed)			

Note 1: The driving factors are the assessment of those principles of integrated decision making that play the most significant role in the decision (i.e., defense-in-depth philosophy is maintained, sufficient safety margin is maintained, any changes to risk are small and consistent with the Commission's Safety Goal Policy Statement). Monitoring is assumed to be part of the definition of the option when applicable. When the option is not acceptable, there may only be one driving factor. When an option is acceptable, all principles must be met. When several options are acceptable but one option is preferred over another, one of the principles may be the tie-breaker.

Note 2: A key technical input is an essential input to the analysis that enables the conclusion of acceptability or non-acceptability to be reached. There may be several key technical inputs. For example, when assessing the acceptability of monitoring degradation to maintain power operation, the technical inputs would be those associated with the degree and rate of degradation, and the efficacy of the monitoring process.