**NRC INSPECTION MANUAL** IPAB

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| MANUAL CHAPTER 0308 ATTACHMENT 3, APPENDIX M |

**TECHNICAL BASIS FOR THE SIGNIFICANCE DETERMINATION PROCESS (SDP) USING QUALITATIVE CRITERIA**

1.0 OBJECTIVE

The objective of this appendix to Inspection Manual Chapter (IMC) 0308, Attachment 3, “Technical Basis for the Significance Determination Process,” is to provide a technical basis for using qualitative criteria in determining the safety significance of an inspection finding.

2.0 BACKGROUND

During the early implementation of the Reactor Oversight Process (ROP), the SDP received a significant amount of critical feedback. At the outset there was a need for more SDP tools for staff use, some of the tools available needed more refinement and benchmarking, and the overall process failed to meet timeliness expectations. As a result of these initial challenges, an SDP improvement initiative was developed by the staff of the Inspection Programs Branch (IIPB), which at the time was the lead organization for implementation of the ROP (currently the Reactor Inspection (IRIB) and Performance Assessment (IPAB) branches have replaced IIPB and perform the majority of the ROP organizational functions). Additionally, in the late summer of 2002, the Executive Director for Operations (EDO) directed the formation of a NRC task group to perform an independent and objective review of the SDP. This review was prompted, in part, by issues described in a Differing Professional Opinion (DPO) Panel Response dated June 28, 2002, (ML021830090) and an Office of the Inspector General (OIG) Audit Report dated August 21, 2002 (ML023080280). On December 13, 2002, the SDP task group finished its report and provided several recommendations, many of which were consistent with the SDP improvement initiatives developed by IIPB. Some common recommendations involved the consideration of uncertainty in the SDP, the need to improve clarity of risk-informed decision-making guidance, and the importance of making timely regulatory decisions. These common recommendations revealed the need for an alternative process (i.e., a new SDP tool) to estimate the safety significance of inspection findings that are difficult to estimate using quantitative risk tools and methods. Although previous inspection program guidance required NRC management review for findings that could not be evaluated by the SDP, a focus group led by IIPB was created to develop a new SDP tool, which eventually became IMC 0609, Appendix M, “The Significance Determination Process Using Qualitative Criteria,” initially issued on December 22, 2006.

3.0 TECHNICAL BASIS OF THE METHODOLOGY - OVERVIEW

The technical basis for using qualitative criteria to estimate the safety significance of an inspection finding involves balancing two competing objectives: accounting for uncertainty and making timely regulatory decisions. All probabilistic evaluations have an inherent level of uncertainty associated with their quantitative outcomes. However, the amount of uncertainty can vary depending on how well the risk impact of the finding can be modeled using available state-of-the-art tools (e.g., Standardized Plant Analysis Risk (SPAR) models, SDP appendices). Findings that have a high level of uncertainty with their quantitative results, typically from a lack of confidence in the state-of-knowledge, can have variably different outcomes due to their sensitivity to assumptions made in the risk analysis. For example, if an initiating event frequency has a large uncertainty band and the mitigation capability to address this initiating event is expected to be unsuccessful (i.e., a high probability of failure), then any change in the point estimate of the initiating event frequency could result in a significant change in the overall outcome. In these situations a small change in frequency could drive different levels of regulatory response; thus challenging the staff to make a timely risk-informed decision. In developing a methodology to resolve these types of situations, the staff must consider that the main objective is to balance the desire for a realistic assessment that appropriately accounts for uncertainties with the need for timely decisions on regulatory response.

3.01 Uncertainty

There are two types of uncertainty that need to be addressed when using probabilistic risk assessment (PRA) insights to make a risk-informed decision: aleatory and epistemic. Aleatory uncertainty is associated with events or phenomena being modeled that are characterized as occurring in a random or stochastic manner. Epistemic uncertainty is associated with the risk analyst’s confidence in the predictions of the PRA model itself and reflects the analyst’s assessment of how well the PRA model represents the actual system being modeled. Epistemic uncertainty is also referred to as state-of-knowledge uncertainty. Appendix M accounts only for epistemic uncertainty; aleatory uncertainty is built into the structure of the PRA model itself. It is useful to identify three classes of epistemic uncertainty that are addressed in and impact the results of PRAs: parameter uncertainty, model uncertainty, and completeness uncertainty.

Parameter uncertainty recognizes that the value of such parameters as initiating event frequencies, component failure probabilities or failure rates, and human error probabilities cannot be known with precision. PRAs are capable of addressing parameter uncertainty explicitly; however, the estimated mean value and spread of the uncertainty distribution can vary depending on the availability, quality, and source of data, the type of parameter that is being estimated, and other factors. Model uncertainty recognizes that the relationship between the real plant and its mathematical representation may differ. Model uncertainties that underlie the development of the PRA model are typically handled by making assumptions that then become part of the definition of the PRA model. When there are multiple assumptions that are equally plausible, sensitivity analyses may be conducted using different assumptions to assess their impact on the overall results. A common and significant example of model uncertainty is the determination of degraded conditions and exposure time. Often it is difficult to pinpoint the exact period of time a

component was in a failed state and whether or not the component was capable of performing its intended function (i.e., the exact physics of failure). Completeness uncertainty, which can be regarded as a type of model uncertainty, recognizes that the model may not represent every aspect of the as-built as-operated plant, either because it may relate to an unknown dynamic or because accurate models do not exist for some systems or phenomena. The incompleteness of the model includes those aspects the analyst is aware are missing from the model and those that are not known given the current state-of-knowledge. Completeness uncertainties cannot be addressed analytically since, by definition, they stem from risk contributors that are missing from the model.

3.02 Timeliness

Timeliness is one of the key objectives of the ROP. The safety significance of inspection findings (i.e., SDP outcomes) yields direct inputs into the ROP action matrix. When these inputs are of White, Yellow, or Red significance they have the potential to result in a supplemental inspection and other actions by both the regulator and licensee depending on the number, significance, and applicable cornerstone(s) of the finding(s). Prompt licensee and NRC staff response to identified findings ensures timely corrective actions to address the cause and to prevent recurrence.

4.0 TECHNICAL BASIS OF THE BOUNDING ASSESSMENT AND DECISION ATTRIBUTES

The results from the bounding evaluation, as practical, and decision attributes are used to provide technical staff and management with a framework to document qualitative information to support the determination of inspection finding safety significance. The bounding evaluation can vary in scope and complexity depending on the nature of the situation. In cases where there are tools available to provide quantitative estimates, but there are large uncertainties associated with the estimated parameters, the bounding evaluation can become quite comprehensive and require a significant amount of resources to complete. In complex systems it can be challenging to determine which assumptions lead to conservative results. Sometimes assumptions that appear to maximize a certain result or outcome could reflect a local maximum instead of a global maximum. In other cases where the available tools are not capable of providing a robust quantitative basis, a simple quantitative approach supplemented with qualitative inputs, as appropriate, can provide a reasonable bounding assessment. When the available tools are unable to provide any quantitative estimate, a completely qualitative approach is also an acceptable method. Once the bounding assessment has been established, as practical, the decision attributes are reviewed for their applicability to the finding. If applicable, each decision attribute should have a basis, quantitative and/or qualitative, to justify its use as an input to the decision-making framework. After all the applicable decision attributes have been established with an appropriate basis, the bounding assessment and decision attributes should be evaluated as a whole to arrive at a risk-informed decision.

4.01 Bounding Evaluation

To the extent possible, given the circumstances of the finding, quantitative tools should be used to frame the risk impact of the finding. A quantitative bounding evaluation may

provide an upper and lower limit (i.e., worse case and best case analysis) to reduce the range of potential outcomes. If a quantitative bounding evaluation is not possible, then an appropriate qualitative bounding evaluation can be used to establish an upper and lower limit.

4.02 Decision Attributes

4.02.01 Defense in depth – The defense-in-depth philosophy has traditionally been applied in reactor design and operation to provide multiple means to accomplish safety functions and prevent the release of radioactive material. It has been and continues to be an effective way to account for uncertainties in equipment and human performance and, in particular, to account for unknown and unforeseen failure mechanisms or phenomena, which (because they are unknown or unforeseen) are not reflected in either the PRA or traditional engineering analyses (Ref 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 the NRC’s deterministic approach and supports the NRC’s traditional defense-in-depth philosophy (Ref 3).

Defense-in-depth consists of a number of elements, and consistency with the defense-in-depth philosophy is maintained if the following occurs (Ref 1):

* A reasonable balance is preserved among prevention of core damage,

prevention of containment failure, and consequence mitigation.

* Over-reliance on programmatic activities as compensatory measures is avoided.
* System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).
* Defenses against potential common-cause failures are preserved, and the potential for the introduction of new common-cause failure mechanisms is assessed.
* Independence of barriers is not degraded.
* Defenses against human errors are preserved.
* The intent of the plant’s design criteria is maintained.

In addition, the introduction to the general design criteria in 10 CFR 50, Appendix A, asserts that designers of nuclear power plants consider (1) the need to design against single failures of passive components (as defined in 10 CFR 50, Appendix A) and (2) redundancy and diversity requirements for fluid systems (Ref 1). The concept of defense-in-depth from a mitigating systems perspective should take into account the expected frequency of applicable initiating events and associated uncertainties.

4.02.02 Safety Margin – The impact of a finding is typically minimized if sufficient safety margins are maintained. In general, safety margins are considered sufficient if:

* Codes and standards or their alternatives approved for use by the NRC are met. Other codes and standards may be given credit on a case by case basis.
* Safety analysis acceptance criteria are met and provide sufficient margin to account for analysis and data uncertainty (Ref 1).

4.02.03 Extent of condition – If a finding is not isolated to a specific occurrence, condition, or event, its safety significance is typically greater. When a finding is capable of affecting multiple structures, systems, and components (SSCs), the number of degraded conditions has the potential to be greater than a case in which a finding is isolated to a specific SSC. The identified extent of condition should have a reasonable and sound technical basis to justify the scope.

4.02.04 Degree of degraded condition (or programmatic weakness) – The magnitude and detailed circumstances of the degraded condition (or programmatic weakness) have a direct effect on the safety significance of the finding. As stated in IMC 0308, Attachment 3 “Technical Basis for the SDP,” the finding (i.e., more than minor performance deficiency) is the proximate cause of the degraded condition or programmatic weakness. Logically, the more a condition is degraded or program is weakened, the more safety significant the finding.

4.02.05 Exposure time – Generally, the longer a finding is left uncorrected the more opportunities the finding has to manifest itself (i.e., act as the proximate cause of a degraded condition or programmatic weakness). As such, the longer the exposure time the more safety significant the finding.

4.02.06 Recovery actions – Even if the extent of condition, degree of the degraded condition (or programmatic weakness), and exposure time increased the safety significance of a finding, crediting established recovery actions or mitigation strategies should be appropriately considered to determine the overall significance of the finding.

4.02.07 Additional Qualitative Circumstances for Management Consideration – Depending on the situation, the previous six attributes may not capture all of the qualitative attributes that may apply to the finding. Therefore, additional qualitative circumstances, as appropriate, may be considered in the decision making process. Any additional qualitative circumstances for management consideration should have a clear and reasonable nexus to the safety significance of the finding.

4.03 Integrated Risk-Formed Decision Making Process Based On The Bounding Evaluation And Decision Attributes

After the bounding evaluation and decision attributes are established, the final step of the process is to evaluate all the inputs affecting the safety significance of the

finding and make an integrated risk-informed decision. Overall, these decision-making inputs are integral to an overall picture of the safety significance of the finding. Even though the different inputs (i.e., pieces of evidence) used to describe the safety significance of the finding may not be combined in a structured manner, the integrated, risk-informed decision should clearly document the synergistic effect of the inputs as a whole. The basis for the integrated, risk-informed decision is a function of the confidence the NRC staff has in the combined effect the bounding evaluation and decision attributes have on the safety significance of the finding (Ref 1).

1. REFERENCES
2. Regulatory Guide 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis”, Revision 2, May 2011.
3. SDP Task Group Report December 13, 2002 (ML023470613)
4. 60 FR 42622, “Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement,” *Federal Register,* Volume 60, Number 158, p. 42622, Washington, DC, August 16, 1995.
5. NUREG-1855, “Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision Making,” Volume 1, March 2009.
6. The Office of Nuclear Reactor Regulation Office Instruction, LIC-504, “Integrated Risk-Informed Decision-Making Process for Emergent Issues,” Revision 3, April, 2010.
7. Inspection Manual Chapter 0609 “The Significance Determination Process”
8. Inspection Manual Chapter 0308, Attachment 3, “Technical Basis for the Significance Determination Process”

END

Attachment 1 – Revision History for IMC 0308, Attachment 3, Appendix M

| Commitment Tracking Number | Accession Number  Issue Date  Change Notice | Description of Change | Training Required and Completion Date | Comment and Feedback Resolution Accession Number |
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