

APPENDIX M

SIGNIFICANCE DETERMINATION PROCESS USING QUALITATIVE CRITERIA

1.0 SCOPE

This Appendix provides **deterministic** guidance for assessing the significance of inspection findings, identified through the cornerstones of **Reactor Safety and Radiation Safety in the Reactor Oversight Program (ROP)**, when the probabilistic risk assessment (PRA) methods and tools, including **the existing** significance determination process (SDP) **appendices, cannot adequately address the finding's complexity or provide a reasonable estimate of the significance due to modeling and other uncertainties** within the established SDP timeliness goal of 90 days or less. **Appendix M should not be used by decision makers when the results of another SDP appendix do not appear to be appropriate (i.e., the significance is too high or too low).** In these cases, the appropriate SDP should be used and a deviation from the Reactor Oversight Process (ROP) Action Matrix should be pursued in accordance with Inspection Manual Chapter 0305, "Operating Reactor Assessment Program."

2.0 BASIS

Occasionally an inspection finding can challenge the staff in making a timely risk assessment. Sometimes an appropriate SDP tool does not exist to determine the risk impact of a finding, in which case the safety significance of a finding is ultimately determined using qualitative engineering judgment and regulatory oversight experience, which is acceptable in a risk-informed process. In other cases, the significance evaluation of a finding attempts to determine **the risk** significance using PRA tools that **are** not well suited for the specific application **because the finding is complex, cause and effect relationships cannot be modeled in the PRA, or core damage frequency (CDF) and large, early release frequency (LERF) may not be applicable metrics.** In some instances, the uncertainties associated with **a risk evaluation** using an existing SDP **are** too broad for decision-making. Thus, the **risk** evaluation process **can take** significantly more time than **is necessary or reasonable for most ROP applications.** This Appendix provides guidance to allow the NRC to apply a consistent process using qualitative and quantitative attributes for risk-informed management decision making.

3.0 APPLICABILITY

In all cases, a clear and well understood **inspection finding** must be established in accordance with the guidance in IMC 0612. **Appendix M may be used if the staff has determined that existing SDP methods and tools are not available or are not adequate to determine the significance of the finding within the established SDP timeliness goal of 90 days.**

Unless explicitly directed to use Appendix M by SDP guidance, the staff should conduct a planning Significance and Enforcement Review Panel (SERP) to determine if Appendix M is an appropriate tool for characterizing the significance of a finding. Careful consideration is warranted in considering this tool, especially if another SDP tool or method provides a suitable approach. For example, a degraded condition may be specifically modeled or uncertainties associated with an initiating event frequency or failure rate probability may not

exist. In these cases, an existing SDP tool may provide a suitable characterization of significance within the established SDP timeliness goals. Application of Appendix M is appropriate when another SDP tool is not applicable or involves extensive study or analysis that cannot be completed within established SDP timeliness goals. When assessing a finding with Appendix M, the intent is not to develop new models, perform experiments, or seek in-depth expert elicitation. Findings should be assessed using deterministic engineering judgment relying upon in-house engineering knowledge and expertise and regulatory oversight experience.

4.0 EVALUATION PROCESS

4.1 Initial Bounding Evaluation

4.1.1 A bounding quantitative and/or qualitative evaluation (i.e., worst case analysis) should be initially performed, if feasible, using best available information to determine the significance of the finding. If the bounding evaluation shows that the finding is of very low safety significance (i.e., Green) the finding can be documented in accordance IMC 0612 and the guidance provided in Step 4.3 of this appendix.

4.1.2 If the bounding evaluation indicates that the risk significance of the finding could be greater than Green, then proceed to Step 4.2.

4.2 Attributes

4.2.1 For findings in which the risk significance could be greater than Green, evaluate the following attributes to determine the significance of the finding. Consider attributes which relate directly to the significance of the finding and document the basis for the consideration.

4.2.1.1 The effectiveness of one or more Defense-in-Depth elements impacted.

4.2.1.2 A reduction in Safety Margin can be quantified.

4.2.1.3 The extent to which the condition of the performance deficiency affects other equipment (e.g., downstream equipment affected; identical or similar equipment affected).

4.2.1.4 Degree of degradation of failed or unavailable components (assess in terms of functionality, if mission time can be met).

4.2.1.5 Period of time the performance deficiency existed (exposure time); and if opportunity to identify the finding during such period was missed (operating experience, licensee's programs such as surveillance testing).

4.2.1.6 The likelihood that the licensee's recovery actions would successfully mitigate the performance deficiency.

4.3 Process and Documentation

4.3.1 If the results of the Appendix M evaluation indicate a greater than green finding, the decision-making logic should be documented using Table 4.1, "Qualitative Decision-Making Attributes for NRC Management Review," and should be included in the SERP package as described in IMC 0609, Attachment 1, "Significance and Enforcement Review Panel."

4.3.2 If the results of the Appendix M evaluation indicate a green finding, document the quantitative or qualitative method used including the results in the inspection report.

5.0 REFERENCES

IMC 0609, Attachment 1, "Significance and Enforcement Review Panel Process"

IMC 0612, "Power Reactor Inspection Reports"

END

TABLE 4.1
Qualitative Decision-Making Attributes for NRC Management Review

Decision Attribute	Applicable to Decision?	Basis for Input to Decision - Provide qualitative and/or quantitative information for management review and decision making.
Finding can be bounded using qualitative and/or quantitative information?		
Defense-in-Depth affected?		
Performance Deficiency effect on the Safety Margin maintained?		
The extent the performance deficiency affects other equipment.		
Degree of degradation of failed or unavailable component(s)		
Period of time (exposure time) affect on the performance deficiency.		
The likelihood that the licensee's recovery actions would successfully mitigate the performance deficiency.		
Additional qualitative circumstances associated with the finding that regional management should consider in the evaluation process.		

Result of management review (COLOR): _____

Attachment 1

Revision History For
IMC 0609 Appendix M

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number
N/A	12/22/06 CN 06-036	This new document has been issued to provide guidance to NRC management and inspection staff for assessing significance of inspection findings.	This procedure was developed by involved stakeholders. No training on the procedure recommended at this time. However, additional guidance may be developed based on experience gained.	ML063050646
N/A	ML101550365 04/04/12 CN 12-005	Provided clarification in the Scope and Applicability sections to articulate the Appendix M entry conditions and that Appendix M is not intended to be used to develop new models or acquire in-depth expert elicitation. In addition, ROPFF 0609M-1412 was incorporated to clarify that Appendix M applies to all the safety cornerstones of the ROP.	None	N/A