

Resolution of NEI/Industry Comments for  
Draft IMC 0609 Appendix M (July, 2016)

No.	Comment	Added	Remarks
1	Draft appears to be more cumbersome, should be table-topped to determine if expected results were achieved and repeatable.	N.A.	Table top exercises of previous SDP cases will be performed to test the efficiency of the new version of Appendix M prior to its implementation.
2	This draft Appendix M appears to drive the user to confirm an initial bounding assessment rather than an unbiased evaluation of significance.	No	Disagree. The intent is to enable the user to reach an integrated risk informed decision with a rigorous look on realistic assumptions that should produce an objective and reliable decision.
3	Focus of Appendix M evaluations should be on Defense-in-Depth.	No	Disagree. Defense-in-depth is an important decision attribute. Depending on the context of a SDP case, other decision making attributes should also be considered for their applicability.
4	This revision of Appendix M should follow, rather than precede, the development of RG 1.174, R3.	N.A.	IMC 609 Appendix M is a "Non-Quantitative Significance Determination Process" tool and its revision is to provide improved guidance for implementation of ROP decision making. Although the development of RG 1.174, Rev. 3 is a separate NRC project for a different regulatory application, the revisions of Appendix M and RG 1.174 should not have conflicting information and concepts.
5	There is no structured guidance for reaching a conclusion. NRC should consider using guidance from NEI-00-04.	No	Disagree. The draft Appendix M document provides a framework for integrated risk-informed decision making process based on concepts described in RG 1.174 and LIC-504, Rev3. Although NEI-00-04 utilizes the Integrated Decision-Making Panel (IDP) Review for the categorization of SSCs to support implementation of 10CFR 50.69 requirements, its guidance was developed for a different regulatory application.
6	If there is a model, EPRI-3002003116 guidance should be used to determine if the [PRA] model is appropriate for use and what limitations or enhancements are needed. This should be done for all quantitative SDPs, even if App M is not used directly.	N.A.	ROP implementation documents, e.g., IMC 609 and associated IMC 308 technical basis documents, and RASP Handbook provides guidance on quantitative methods, including sensitivity and uncertainty analyses to address limitations of [PRA] models used in SDP assessments. Peer reviews of SDP assessments are also performed to ensure sufficient quality of [PRA] models. NRC guidance documents cover the general and specific guidance in EPRI-3002003116 on the limitations of PRA that may affect SDP decision making.

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7	Text of Section 1.0 goes far beyond "Purpose." The text should be simplified.....	No	Disagree. The statement of "Purpose" provides clarification on the intended use of Appendix M in specific situations. The second paragraph provides caution against unintended use.
8	Section 1.0, line 8, how does "available" apply to existing SDP appendices?	No	In the context of the sentence, "available" means that the existing SDP appendices are IMC documents issued currently for use.
9	Section 1.0, lines 10-11, "large uncertainties of modeling and other influential assumptions" are not good examples, as they are better handled by quantitative tools.	Yes	Agree. Staff will evaluate the need to clarify or revise the words "uncertainties" and "influential assumptions" as examples for this condition.
10	Section 2.0, what does the NRC plan to do to ensure Entry Criteria in the draft Appendix M are consistent with criteria for use of Appendix M presented in other documents (e.g., IMC 609 Attachment 4, "the SDP Router")?	Yes	Staff will be revising other IMC 0609 documents in parallel with Appendix M to ensure appropriate transition from other IMC 609 documents to use Appendix M.
11	Section 2.0, lines 28-29, App. M should not be used merely to ensure SDP timeliness goal is met.	Yes	Agree. Staff will evaluate rewording "timeliness" and will implement any revisions throughout the document.
12	Section 2.0.b, lines 36-39, what is the definition of "adequate?" NRC should use concepts in EPRI aggregation report.	No	In the context of the sentence, "adequate" means that the SDP tool is good enough and readily available to make an efficient risk informed decision.
13	Section 2.0.c, lines 41-43, what is the definition of "extensive?"	No	In the context of the sentence, "extensive" means that additional and extraordinary resources are required to handle a "first-of-a-kind" inspection finding with a broader range of analytical methods, including new methods that are not universally accepted.
14	Section 3.0, second paragraph, lines 18-21, meeting timeliness goal should never be the sole basis for entry into App. M.	Yes	Agree. Staff will evaluate rewording "timeliness" and will implement any revisions throughout the document. Timeliness is not the basis for entry into Appendix M; the intent is to make an efficient and objective risk informed decision.
15	Section 3.0, how is the "Applicability" section different from "Entry Conditions" section? In lines 9-16, is it appropriate to prescribe procedural steps for the SERP in App. M?	No	The "Applicability" section provides additional clarity to when App. M is applicable, and provides guidance on using a different process or appendix if Entry Conditions are not met. It is important to precaution against its unintended use.
16	Section 4.01, line 17, strike [or revise] "Attachment 1.4.1.1." Reference is incorrect.	Yes	Agree that the reference is incorrect. Staff will revise with "Attachment 4."

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17	Section 4.01, line 20, bounding analysis is bounding only if it provides both worst and best estimates.	Yes	Agree. Staff will add “best” in the parenthesis before final revision.
18	Section 4.01, line 27, should refer to Step 4.02 and not Step 4.2.	Yes	Agree. Staff will change 4.2 to 4.02 before final revision.
19	Section 4.02a, line 43, where and how is “Effective Performance Monitoring Strategies” defined? What is the relationship between performance monitoring and risk significance?	No	“Effective Performance Monitoring Strategies” is defined in draft IMC 308 Attachment 3, Appendix M. Effective performance monitoring can identify industry events, operating experience, and design changes that could lead to significant safety issues. This activity enables the licensee to implement compensatory actions and perform necessary design modifications to minimize risk.
20	Section 4.02a, line 2, “Additional Relevant Decision Attributes to Consider,” where and how is this defined?	Yes	“Additional Relevant Decision Attributes” is defined in draft IMC 308 Attachment 3, Appendix M. The definition of this decision attribute may be improved through examples in table-top exercises and after receiving feedback from these exercises. Staff will document examples in the final draft.
21	Section 4.02b, line 11, compliance with regulatory guidelines should not be relevant for determining risk significance.	No	Disagree. This decision attribute is one of the fundamental principles of integrated risk-informed decision making described in RG 1.174. Eliminating this decision attribute may result in an incomplete decision making tool for unique situations where problems with regulatory compliance can affect the significance of an inspection finding from deterministic considerations.
22	Section 4.02b, line 12, the OE attribute of performance monitoring is too subjective.	No	Disagree. The criterion of OE evaluations for effective performance monitoring helps the licensee to identify potential vulnerabilities, and therefore prevents potential findings. We do not agree that this criterion is subjective.
23	Section 4.03, lines 1-3, what is the basis for this statement?	No	This statement provides an explanation to assign High Importance to a decision attribute based on assessment that one or more of its associated criteria are highly affected by the inspection finding. Staff will refine the ground rules for assigning importance, whether it is low, medium, or high, to an applicable decision attribute.
24	Section 4.04, lines 16-24, this section seems subjective and likely to foil the desired outcome of making Appendix M results repeatable.	Yes	Agree. Staff will review this entire section and revise the language to be consistent with Section 5.04 of IMC 308 Attachment 3, Appendix M to eliminate subjectivity, to the extent practicable. Feedback from table top exercises will also be reviewed to improve the draft document.

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25	Section 4.04, lines 26-29, when would the initial bounding analysis be the best reflection of risk significance?	No	The referenced statements do not imply that the bounding assessment is the best reflection of the risk significance. The referenced statements simply provide an explanation that there may not be any change in preliminary significance if the applicable decision attribute(s) is not significantly affected by the finding.
26	Section 4.04.a, line 36, if a quantitative tool is not available, how would the NRC determine the initial bounding assessment.	No	If a quantitative tool is not available, an initial bounding assessment could be performed using qualitative assessment of deterministic engineering considerations to establish a “best case and a worst case” significance.
27	Section 4.04.a.1, line 45, where is scope of defense-in-depth defined?	Yes	The scope of defense-in-depth is defined in draft IMC 308 Attachment 3, Appendix M, and will be referenced in the final draft of Appendix M. The criteria for defense-in-depth will be consistent with the new revision of RG 1.174 Rev3.
28	Section 4.04.a.2, line 11, where is scope of safety margins defined? What constitutes high, medium, and low degradation?	Yes	The scope of Safety Margins is defined in draft IMC 308 Attachment 3, Appendix M, and will be referenced in the final draft of Appendix M. The criteria for Safety Margins will be consistent with the new revision of RG 1.174 Rev3.
29	Section 4.04.a.3, lines 25-29, description of regulatory compliance issues is unclear. It should be focused on safety significance and not compliance.	No	See response to Comment #21. The scope of “Compliance with Regulatory Guideline” is defined in draft IMC 308 Attachment 3, Appendix M, and will be referenced in the final draft of Appendix M.
30	Section 4.04.a.4, lines 38-41, same comment as before on performance monitoring	No	See response to Comment #19.
31	Section 4.04.a.5, lines 45-48, what is the nexus between extent of condition and risk significance?	No	As defined in IMC 308 Attachment 3, Appendix M, “Extent of Condition” is the extent to which a performance deficiency (PD) has the potential to impact other SSCs, programs, or processes. When a PD has the potential to affect multiple SSCs, the aggregate degraded conditions have the potential for greater impact than the situation of a condition isolated to a specific SSC and therefore greater risk impact on the plant.
32	Section 4.04.a.6, lines 4-9, what is the nexus between component degradation and risk significance? How does this differ from defense-in-depth?	No	As defined in IMC 308 Attachment 3, Appendix M, “Degree of Degraded Condition” has a direct effect on the safety significance of the inspection finding. Logically, the more a condition is degraded or a program is ineffective, the more safety significant is the finding. The degree of component degradation can reduce the additional defense-in-depth barrier and/or safety margins.

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33	Section 4.04.a.7, line 14, what is the criteria for defining "significantly affects" as related to exposure time?	No	As defined in IMC 308 Attachment 3, Appendix M, the "Exposure Time" criterion of more than six months, approximately one year, or greater than 1 year would be considered to have a significant effect on the risk significance of the finding.
34	Section 4.04.a.9, lines 27-33, the cross-cutting issue attribute should be eliminated.	No	Disagree. As defined in IMC 308 Attachment 3, Appendix M, "Cross-Cutting Issues" address cross-cutting areas containing the fundamental performance characteristics that extend across all of the ROP cornerstones of safety. The safety significance of a cross-cutting issue (CCI) should be evaluated when it impacts licensee performance in other ROP cornerstones that may be an indication of programmatic weaknesses. This decision attribute was specifically included in Appendix M per NRC staff recommendation.

No.	Comment	Added	Remarks
35	Attachment 2, Part 1, provides no definitions or examples of low, medium, or high degradation.	Yes	Definitions are provided in IMC 308 Attachment 3, Appendix M.
	Will documentation be provided to the public?	Yes	Documentation of SDP assessment(s) using the new IMC 609 Appendix M will be made available to the licensee and public stakeholders.
	Block 1A – what is meant by “balance?”	No	In the context of the sentence, “balance” means there is defense-in-depth that protects against core damage, containment failure, and consequence mitigation. Any PD in an SSC or program that reduces the licensee’s ability to protect the core, containment, and environment have degraded balance and therefore degraded defense-in-depth.
	Block 1B – what criteria are used?	No	There is no reliance on compensatory measures and program assumptions.
	Block 1C – what criteria are used?	No	An SSC or program is fully able to perform its design function with no adverse impacts, and the PD does not result in unnecessary out-of-service time, reduced performance, etc.
	Block 1D – why are two questions being asked?	No	The intent is to determine if the PD impacts current and known common cause failure mechanisms, or if it introduces new failure mechanisms.
	Block 1E – how will the NRC measure this?	No	If the PD is a result of HU errors, or causes additional HU errors, then this criteria is applicable.
	Block 1F – Does this relate to GDC? What about plants not licensed to GDC?	No	Yes, plants not licensed to the GDC will be N/A for this criteria.
Will each element be weighted equally?	Yes	Yes, each applicable decision attribute should be considered as having equal weight to avoid subjective judgment on the importance of one decision attribute from another.	

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36	<p>Attachment 2, Part 2, Block 2A – what constitutes “significant reduction?”</p> <p>Block 2B – How does this element differ from previous compliance criterion?</p> <p>Block 2C – What constitutes “significant reduction?”</p>	<p>No</p> <p>No</p> <p>No</p>	<p>Significant reduction means all margin has been lost, or sufficient margin has been lost to impact performance.</p> <p>Acceptance criteria has built in margin, if the system or program does not meet acceptance criteria, then safety margin is lost.</p> <p>See remarks to comment on Block 2A.</p>
37	<p>Attachment 2, Part 3, Block 3A – How does this differ from previous compliance criterion?</p> <p>Block 3B – How is this related to risk significance?</p> <p>Block 3C – If the plant remained within code requirements, what is the concern?</p> <p>Block 3D – If SSC continued operating in accordance with the license, what is the PD? What is its significance?</p> <p>Block 3E – What is the connection to safety?</p>	<p>No</p> <p>No</p> <p>No</p> <p>No</p> <p>No</p>	<p>Non-compliance with Tech Specs, whether intentional or unintentional, is potentially risk significant. This is intended to be aggregated with the defense-in-depth and safety margins attributes.</p> <p>An unanalyzed condition is outside the licensing basis and may have a complete loss of defense-in-depth and/or safety margin, and could challenge design and operational limits.</p> <p>There is no concern if the plant remained within the code requirements, but if the code is challenged or exceeded, then this noncompliance possibly impacts defense-in-depth and safety margins.</p> <p>Same as above – this pertains to SSCs operating outside of their intended function.</p> <p>See previous remarks to regulatory compliance above - current degraded regulatory compliance that leads to a current finding may have risk significance. It is also a principle of risk informed decision making as defined in RG 1.174.</p>
38	Attachment 2, Part 4, same comments as Part 3.		Same remarks as Part 3 above.