

RESOLUTIONS TO 11/30/17 NRC COMMENTS ON NEI 12-04, REVISION 1A

COMMENT NO.	SECTION	COMMENT SUMMARY	NEI RESOLUTION
1	2.1	This comment suggests changing the definition of “10 CFR 72.48 Evaluation” by quoting the complete phrase from 10 CFR 72.48(c)(2).	The affected text has been changed to better reflect 10 CFR 72.48(c)(2).
2	2.4	The comment asks for clarification of the word “transients” in Part 72.	“Transients” is a Part 50 term that was adopted from the 10 CFR 50.59 guidance, but does not translate well to Part 72. The “Discussion” section of the guidance has been clarified to replace “transients” with “anticipated occurrences (off-normal events)” to be consistent with terms used in the Part 72 regulations. In addition, the “Definition” section has been revised as a conforming change.
3	2.6	The comment asks for clarification of manual and automatic actions in the context of Part 72.	Because dry storage systems are passive, there are no “automatic means.” Therefore, this example is not accurate for Part 72 and has been deleted. The paragraph has been clarified with a simpler example of manual operator action to open a valve on a transfer cask.
4	2.8	This comment pertains to how uncertainty within an MOE is treated	Uncertainty is treated as an element of the method of evaluation (MOE). Definition 2.17 for MOE specific lists uncertainty as one example of an element of an MOE. Thus, if uncertainty is included in the MOE and is affected directly or indirectly by the proposed change to an element, it is implicitly considered in the computed results used in the Criterion 8 evaluation as to whether the results are essentially the same or conservative. New or additional uncertainty is not added to an MOE for the Criterion 8 test. In the response to Comments 38 and 39, Section 6.8.1 of NEI 12-04 has been modified to holistically address uncertainty and state that the effect of a change to an element of the MOE that involves uncertainty, needs to be clearly addressed in the 72.48 evaluation documentation.
5	2.8	The sentence indicates that results are “essentially the same” if “they are within the margin of error for the type of analysis being performed.” Many times, the margin of error in calculations is not provided in CoC holder applications or SARs.	Clarification has been added to the definition to ensure that margin of error is clearly defined and addressed in the 72.48 documentation, whether or not it is discussed in the ISFSI or cask FSAR. Because this consideration would be part of a 72.48 evaluation, it would not be included in an application that receives NRC review. Therefore the guidance addresses only the FSAR.

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6	2.8	This comment pertains to the definition of “Type of Analysis”	The definition of “Type of Analysis” from NEI 12-04, Revision 0 has been added back into the document (Section 2.22).
7	2.10	This comment suggests that fluid temperature and fluid flow rate are not used in the dry cask thermal evaluation technology.	The references to fluid temperature and fluid flow rate have been deleted.
8	2.13	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
9	2.15	Assumptions of operator actions should also be addressed as elements of a MOE (e.g., response time to alarm or timing of performance of a measurement/action).	In both the 50.59 and 72.48 guidance and in the regulations at 10 CFR 72.48(a)(6), operator actions have consistently been considered part of procedures that “perform or control a design function.” Thus, generally speaking, operator actions are considered input parameters. However, as the discussion at the end of Definition 2.17 notes, an input parameter can be considered an element of an MOE if certain criteria are met for the use of that input parameter in the calculational framework. Therefore, a new paragraph has been added to the “Discussion” section of Definition 2.15, “Input Parameters,” to specifically address operator actions.
10	2.15	This comment suggests removing the appendices to NEI 12-04 and internal references to those appendices because the NRC is not endorsing the examples.	The examples are important tools for user understanding of the guidance and have been retained. The notes at the beginning of Appendices A and B have been revised to clearly state that NEI has not requested NRC endorsement of the examples. Industry suggests that NRC exclude Appendix A and Appendix B in the endorsement language in the revision to Regulatory Guide 3.72.

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11	2.16	Add the additional sentence that is found in the first sentence from Section 6.2 (“The term “malfunction of an SSC important to safety” refers to the failure of structures, systems and components (SSCs) to perform their intended design functions— including both important to safety (ITS) SSCs and not-important to safety (NITS) SSCs when the failure of the NITS SSCs to perform their design functions could affect the ability of the ITS SSCs to perform their design functions. “) to inform the reader that relevant SSCs NITS should also be considered.	The suggested text has been added to the “Discussion” section of the definition.
12	2.18	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
13	2.18	This comment suggests changing the definition of “Procedures as Described in the FSAR, as Updated.”	The current definition is verbatim from the regulations at 10 CFR 72.48(a)(6). No change to the guidance has been made as confirmed with the NRC PM.
14	2.21	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
15	2.21	This comment pertain to the definition of “Type of Analysis”	The definition of “Type of Analysis” from NEI 12-04, Revision 0 has been added back into the document (Section 2.22).
16	3.2.3	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
17	5.1.5.1	This comment pertains to the definition of MOE and include an example that time-to-boil is not an MOE.	This was an attempt at adding an example for clarity. However, defining particular mathematical computations in the FSAR as MOEs is necessarily application-specific. The licensees and CoC holders are responsible for identifying the MOEs in their licensing bases. The example has been removed and the text reverts to what it was in NEI 12-04, Revision 0.

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18	5.1.5.1	This comment pertains to the definition of MOE and include an example that time-to-boil is not an MOE.	See comment resolution 17.
19	6	This comment asks, “Is this what was meant”?	Use of a new or different MOE or an MOE with a change to an element is determined solely under Criterion 8. All other proposed activities are evaluated under Criteria 1-7. Upon further review, the sentence was redundant and confusing and has been eliminated.
20	6	This comment suggests adding “A thorough evaluation is necessary to ensure that proposed activities are not linked.”	The guidance has been revised to state that a thorough evaluation is necessary to determine whether or not proposed activities are linked. This altered language was discussed in the 12/19/17 meeting between Industry and NRC.
21	6	This comment requests additional examples of “separate documents.”	The guidance has been revised to add “directions” and “design change packages, etc.” as additional examples.
22	6.1	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
23	6.1	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
24	6.1	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
25	6.1	Edit this language. Depending on design changes, the frequency of lightning events and blockage of vent events can change.” This will help in understanding that the original sentence, as written, does not reflect that a design change could affect the frequency of an accident.	The current sentence refers to “design requirements” and specifically refers to natural phenomena, such as tornadoes and earthquakes. This paragraph is focused solely on natural phenomena events, the frequency of which would not be affected by design changes. The guidance has been revised to add snow, flood and lightning strikes as another natural phenomenon event.
26	6.3	This comment pertains to how uncertainty within an MOE is treated	See comment resolution 4.

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27	6.3	This comment pertains to the type and the level of detail of information in the ISFSI or cask FSAR and the SERs	We agree that the level of detail and clarity of information in the FSARs is important to 10 CFR 72.48 program implementation. As discussed between NRC and Industry during the 12/19/18 meeting, this is a topic better included in the ongoing NRC effort to combine the Standard Review Plans (SRPs) for storage (NUREG-2215). The application review process is the opportunity to ensure the ISFSI or cask FSAR includes the appropriate level of detail for future use under the 10 CFR 72.48 program. No changes to the guidance have been made. (See also, response to Comment 34 individually below.)
28	6.3	This comment pertains to how uncertainty within an MOE is treated	See comment resolution 4.
29	6.3	<p>This comment suggests adding language to clarify that the applicant should perform analyses to ensure that 10 CFR 72.104 limits are met.</p> <p>Add: although analysis must be performed to ensure those dose limits are met.” The purpose of including analyses is to reflect the possibility that a 72.48 change affects the dose (shielding) or release (confinement) of the system. Such a change may warrant an analysis to confirm that 72.104 limits are still met.</p>	<p>Industry agrees in principle with the comment. However, Industry believes it is inappropriate to direct licensees and CoC holders to perform dose analyses. Proposed activities that may affect the 10 CFR 72.104 (or 10 CFR 72.106) dose analysis are identified as part of the design control or procedure revision process. That dose impact may or may not require an analysis or evaluation.</p> <p>The guidance has been revised to state that dose analyses or evaluations “may” be required, depending on the nature of the proposed activity.</p>
30	6.3	This section should be summarized and needs a conclusory statement about both 72.104 and 72.106.	A new paragraph has been added to the end of this section to summarize how doses impacts are to be addressed with respect to the 72.104 and 72.106 limits.
31	6.4	This comment suggests adding language to clarify that 72.104 applies as well as 72.106 as mentioned in 6.3.	A new text has been added to the end of this section to summarize how doses impacts are to be addressed with respect to the 72.104 and 72.106 limits.

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32	6.5	<p>This comment asks whether there is any potential for a design change that results in a different type of accident beyond those in the SAR.</p> <p>This comment was meant for the previous sentence. <u>The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the USFAR.</u></p> <p>The NRC suggests replacing the first two sentences of the third paragraph of this section with “The evaluation for possible different accidents must consider that the proposed activity may create the possibility for accidents beyond those described in the UFSAR.”</p>	<p>Yes, there is that potential, and that is the purpose of this 72.48 question. The first two sentences of this paragraph were previously endorsed under NEI 96-07, Appendix B, Section B4.3.5, and were not proposed to be changed in NEI 12-04. Except for the examples of “random single failure and loss of offsite power” these sentences are also the same as the guidance for 10 CFR 50.59 in NEI 96-07, Revision 1, Section 4.3.5. Therefore, rather than replace the first two sentences in this paragraph, the guidance has been revised to add the NRC’s proposed sentence as a new third sentence.</p>
33	6.6	<p>This comment suggests wording to be added for clarification.</p>	<p>The guidance has been revised as suggested with the exception that the word “effect” is used in lieu of “consequences” to avoid confusion with “consequences” used in the context of Questions 3 and 4 (i.e., exclusively dose).</p>
34	6.8	<p>This comment notes the inconsistent level of detail in FSARs pertaining to MOE. Some information may reside in the calculation packages.</p>	<p>As discussed in the response to comment 27, the information contained in the FSAR is necessarily outside the scope of the 10 CFR 72.48 guidance. In response to this comment it is important to note that not all MOE information subject to 10 CFR 72.48 review is located in the FSAR. Some information may be located in the supporting calculation package. Once a calculational framework described, outlined, or summarized in the FSAR has been determined to be an MOE, the elements of, and inputs to that method may reside in the FSAR, the calculation package notes, or in a computer program used in the calculation package. Consistent with the resolution to Comment 27, not change to the guidance has been made.</p>

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35	6.8	This comment requests clarification of the last bullet in the section.	This bullet attempted to clarify the point that MOEs described, outlined or summarized in the FSAR are approved even if the language in the SER does not specifically indicate that. Given other statements in NEI 12-04 that now makes this clear (e.g., in Section 6.8.2.1), this bullet is no longer needed and has been deleted from the guidance.
36	6.8	This comment requests clarification of the last bullet in the section.	See comment resolution 35.
37	6.8.1	This comment asks for clarification of factors that would be used to determine if a change to a version of a code was so fundamental that it constituted a different MOE, rather than a change to an element of an existing MOE.	The major factor would be that the new code version computes the results in a significantly different way. An example would be the difference between MCNP-4 and MCNP-5. The guidance has been revised accordingly.
38	6.8.1.1	This comment pertains to how uncertainty within an MOE is treated	See comment resolution 4.
39	6.8.1.1	This comment pertains to how uncertainty within an MOE is treated	See comment resolution 4.
40	6.8.2.1	This comment is an editorial or administrative suggestion.	Changes to the guidance have been made as suggested. Slight alterations from the suggested language may have been made to further improve clarity.
41	6.8.2.1	This comment pertains to the definition of "Type of Analysis"	The definition of "Type of Analysis" from NEI 12-04, Revision 0 has been added back into the document (Section 2.22).
42	6.8.2.1	This comment states that the terms, conditions, and limits on an MOE's use are not usually defined in the SER.	We agree. This information should be in the FSAR and it is up to the NRC to determine how that information is reflected in the SER. This reference to the SER has been deleted from the guidance to avoid implying that the SER is a surrogate to the FSAR.
43	6.8.2.1	This comment pertains to the definition of "Type of Analysis"	The definition of "Type of Analysis" from NEI 12-04, Revision 0 has been added back into the document (Section 2.22).
44	6.8.2.1	This comment pertains to the type and the level of detail of information in the ISFSI or cask SER	We agree with the comment. For this type of MOE approval (as opposed to approval of a topical report), the MOE limitations should be described in the FSAR, not the SER. The last sentence in the fourth paragraph has been deleted

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45	6.8.2.1	This comment pertains to the type and the level of detail of information in the ISFSI or cask SER	We agree with the comment. For this type of MOE approval (as opposed to approval of a topical report), the MOE limitations should be described in the FSAR, not the SER. The last sentence in the fourth paragraph has been deleted
46	Footnote to Section 6.8.2.1	This comment states that there is no implied NRC endorsement of the cited Industry/NRC Q&A document.	The footnote has been deleted.
47	6.8.2.1	This comment requests clarification of the last line in the section.	The line should say "...but not generically approved <i>for use</i> by all..." which would make it consistent with the first bullet under Section 6.8.2.3 (now 6.8.2.2). This clarification has been made in the guidance.
48	6.8.2.2	This comment pertains to the section of the guidance added to address the statements of consideration (SOC) for the 1999 10 CFR 72.48 rulemaking	Per Industry's discussion with the NRC on 12/19/17, this entire subsection has been removed from the guidance.
49	6.8.2.2	This comment pertains to the section of the guidance added to address the statements of consideration (SOC) for the 1999 10 CFR 72.48 rulemaking	See comment resolution 48.
50	6.8.2.2	This comment pertains to the section of the guidance added to address the statements of consideration (SOC) for the 1999 10 CFR 72.48 rulemaking	See comment resolution 48.
51	6.8.2.3 (now 6.8.2.2)	This comment questions use of the term "new MOE" being awkward and suggestive of using an unapproved MOE.	The term "new MOE" is used in several places in the existing 50.59 and 72.48 guidance. We agree that without the modifier "that has been approved by the NRC for the intended application" that is found in Definition 2.8, using the term "new MOE" could be confusing. Therefore, the guidance has been revised to consistently use "new or different" MOE.
52	6.8.2.3 (now 6.8.2.2)	This comment suggests specifying "under the same vendor/MOE owner" to the penultimate sentence of the second paragraph.	The guidance has been revised to change "conditions" to "restrictions" in this sentence to align it with the language in the next paragraph, which introduces those restrictions. The first bullet of the restrictions limits the use of the new or different MOE to only the same entity as the originally approved MOE, which addresses the comment. Note that this bullet has been further clarified as a result of this comment to add "or successor entity" to address the potential change to the holder of the CoC due, for example, to the sale of the company.

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53	6.8.2.3 (now 6.8.2.2)	This comment requests an explanation of the relationship of the referenced NRC meeting summary with 50.59 and states that it may be contradictory or confusing.	The guidance has been revised for clarity. The sentence beginning with “The following guidance” has been deleted and the lead-in paragraph for the list of restrictions has been revised to cite Reference 6.8.1.
54	6.8.2.3 (now 6.8.2.2)	This comment suggests expanding the bullet to add a statement that the 72.48 documents are expected to demonstrate that the different MOE is technically applicable.	As discussed in the 12/19/17 meeting, Industry agrees with the sentiment, but this bullet is nearly verbatim from the NRC’s 1999 meeting summary referred to in the lead-in paragraph. The requested information has instead been added earlier in the same section.
55	6.8.2.3 (now 6.8.2.2)	This comment suggests adding language pertaining to uncertainties and margins/assumptions to the third bullet.	As discussed in the 12/19/17 meeting between the NRC and Industry, this language is adopted directly from the NRC’s 1999 meeting summary (ML993260078). The suggested language has been added earlier in the section.
56	6.8.2.3 (now 6.8.2.2)	This comment questioned why the 4 th bullet from the NRC meeting summary was excluded from this list.	These bullets are examples. The fourth bullet in the NRC meeting summary addressed loss of offsite power for power plants, which is not an event identified in the ISFSI or cask FSAR as applicable to normal dry cask storage operations at the ISFSI. However, per the discussion between Industry and the NRC on 12/19/17, certain canister preparation auxiliary equipment requires power and loss of power may be an event identified in some ISFSI or cask licensing bases. The guidance has been revised to restore the fourth bullet to address the fact that a different MOE cannot be used to eliminate a loss of power from the licensing basis for the ISFSI/cask.
57	6.8.2.3 (now 6.8.2.2)	This comment asks for clarification of “different iodine partitioning” in the context of Part 72.	“Iodine partitioning” is a Part 50 term adopted from the 10 CFR 50.59 guidance pertaining to the amounts of each isotopic species of iodine that eventually becomes available for release to the environment after a loss-of-coolant accident. Because there are no reactor loss of coolant accidents in Part 72, the guidance has been clarified to refer to “the fractions of radioactive materials available for release from spent fuel.” This is consistent with the language used in ISG-5, Revision 1.
58	6.8.3	This comment states that there is no implied NRC endorsement of the comments submitted by industry under Reference 6.8.3.	Industry suggests that the NRC exclude this reference from endorsement in the revision to Regulatory Guide 3.72.

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59	Appendix A	This comment suggests removing the appendices to NEI 12-04 and internal references to those appendices because the NRC is not endorsing the examples.	Industry suggests that NRC exclude Appendix A and Appendix B in the endorsement language in the revision to Regulatory Guide 3.72. The note at the beginning of the appendix has been revised accordingly.
60	Appendix B	This comment suggests removing the appendices to NEI 12-04 and internal references to those appendices because the NRC is not endorsing the examples.	Industry suggests that NRC exclude Appendix A and Appendix B in the endorsement language in the revision to Regulatory Guide 3.72. The note at the beginning of the appendix has been revised accordingly.