

Comment Resolution Summary (ML21029A125)

Resolution of Public Comments for:
IMC 0335 Changes, Tests, and Experiments ML20325A180)
Public Meeting Date: December 1, 2020

Comment #	Source	Section #	Comment	Added	Remarks
55	NEI	04.03	<p>In the definition of MOE, the elements from NEI 96-07 rev. 1 are included however additional information that is also referenced would be useful to the inspector.</p> <p>“Changes to such methods of evaluation require evaluation under 10 CFR 50.59(c)(2)(viii) only for evaluations used either in UFSAR safety analyses or in establishing the design bases, and only if the methods are described, outlined or summarized in the UFSAR. Methodology changes that are subject to 10 CFR 50.59 include changes to elements of existing methods described in the UFSAR and to changes that involve replacement of existing methods of evaluation with alternative methodologies.”</p> <p><u>Recommendation:</u> Consider adding the additional information from NEI 96-07, 3.10 to the MOE definition.</p>	N	Section 06.19 of the IMC discusses this concept in greater detail than the definitions section. No change required.
56	NEI	04.06, page 3, Def	<p>The title should include the term “general licensees” in addition to ISFSI or MRS facility to describe all of the licensee types.</p> <p><u>Recommendation:</u> Add “general licensees” to the title.</p>	N	The definition in IMC 0335 matches the definition in NEI 12-04. No change required.

57	NEI	04.07, page 3, Definitions	<p>Final Safety Analysis Report (as updated) definition should include the UFSAR for CoC holders and for general licensees. Example: Updated Final Safety Analysis Report (UFSAR) (10 CFR 72.48) – FSAR (as updated) means:</p> <ul style="list-style-type: none"> • for specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with 10 CFR 72.70 • for general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented • for CoC holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with 10 CFR 72.248. <p>The FSAR for both specific licensees and CoC holders is the first version of the safety analysis report issued just after the initial approval of the ISFSI license or DSS design. The UFSAR for specific licensees and CoC holders is always the latest revision updated thereafter, pursuant to §72.70 or §72.248, as supplemented by changes authorized under the provisions of 10 CFR 72.48.</p> <p>The above definition of UFSAR for general licensees requires additional clarification. For general licensees, the UFSAR is owned and maintained by the CoC holder for the cask design(s) used at the ISFSI. The UFSAR for the general licensee is the UFSAR revision used to load the particular serial number cask(s) and place them into storage at the ISFSI, as revised by any applicable 10 CFR 72.48 changes made by the CoC holder and the general licensee. Once the casks loaded under a particular cask UFSAR are placed into service at a generally licensed ISFSI, the UFSAR revision and 10 CFR 72.48 changes applicable to a given serial number cask remain constant unless the CoC holder requires a change to be applied to a previously loaded cask. A general licensee also has the option to choose to apply a later CoC amendment and associated UFSAR revision to previously loaded casks pursuant to 10 CFR 72.212(b)(4). Because of this unique situation for general licensees, different casks in service at the same ISFSI under the same CoC may have different licensing bases.</p> <p><u>Recommendation:</u> Consider adding in 10 CFR 72.48 elements to this definition or having a separate definition for this aspect.</p>	Y	Revised the definition in IMC section 04.07 to include a definition for the general licensees and CoC holders.
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Comment #	Source	Section #	Comment	Added	Remarks
58	NEI	Definitions 04.13, 04.14, 04.15.	<p>Since NEI 97-04, rev. 1 Appendix B, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases" is endorsed by RG 1.186, "Guidelines and Examples for Identifying 10 CFR 50.2 Design Bases," there may be value having it referenced for NRC inspectors.</p> <p>NEI 97-04 rev. 1 Appendix B endorsed by RG 1.186 contains useful information on these design bases/function definitions.</p> <p><u>Recommendation:</u> Consider adding a note that references NEI 97-04, Rev, 1, Appendix B, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases" (endorsed by RG 1.186) for more information on these definitions.</p>	Y	NEI 97-04, Appendix B, Rev 1 and RG 1.186 have been added to the references in Section 0335-09.
59	NEI	Def	<p>06.05 describes the relationship between 50.59 & 50.155. It may be beneficial to include; "beyond the design basis events" to the definition section. This could help inspectors especially when these are described in the UFSAR.</p> <p><u>Recommendation:</u> Consider adding a definition for "beyond the design basis events" and that they are not subject to 50.59</p>	N	This comment is outside the scope of this IMC's purpose. No definition of "beyond design basis events" is needed in the IMC, which is not creating new interpretations or definitions. No change.
60	NEI	Definitions	<p>Malfunction of SSCs important to safety is missing that non-safety related (NSR) SSC need to be considered as part of this definition.</p> <p><u>Recommendation:</u> Add NSR to the definition as described in NEI 96-07 rev.1.</p>	Y	<p>NRC agrees, definition changed:</p> <p>The failure of SSCs to perform their intended design functions described in the UFSAR. For reactor licensees, this means whether or not the SSC is classified as safety-related.</p>
61	NEI	0335-06, page 5	<p>There is no information that describes the relationship between 50.59 and Surveillance Frequency Control Program (SFCP). Adding details including implementation lessons learned similar to the relationship between 10 CFR 50.59 and Fire Protection could be beneficial.</p> <p><u>Recommendation:</u> Add a section describing the relationship between 50.59 and the Surveillance Frequency Control Program (SFCP).</p>	Y	Section addressing SFCP relationship to 10 CFR 50.59 has been added.

Comment #	Source	Section #	Comment	Added	Remarks
62	NEI	06.02, page 6	<p>Consider adding clarification when 50.59 is used as part of a TS bases change that it cannot directly conflict with the as-stated requirements of the TS.</p> <p>This will help inspectors distinguish between how 50.59 is used to support TS bases changes.</p> <p><u>Recommendation:</u> Add the following statement to the end of this section; "A TS bases change cannot be made pursuant to 10 CFR 50.59 that directly conflict with the as-stated requirements of the TS."</p>	N	The TS Admin Controls section contains the TS Bases Control Program and provides this guidance. No change.
63	NEI	06.03, page 6	<p>This section references RG 1.186, "Guidelines and Examples for Identifying 10 CFR 50.2 Design Bases" but not NEI 97-04 rev.1, Appendix B, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases"</p> <p>NEI 97-04 rev. 1 Appendix B endorsed by RG 1.186 contains useful information on these design bases/function definitions.</p> <p>Recommendation: Add NEI 97-04 rev. 1, Appendix B as a reference to this section since it is endorsed by RG 1.186.</p>	N	See response/action to Comment #58 above

Comment #	Source	Section #	Comment	Added	Remarks
64	NEI	06.05, page 7	<p>Additional clarification may be useful to the inspectors regarding this relationship.</p> <p>10 CFR 50.59 is not applicable to SSCs that have only beyond-design-basis-functions, do not interact with SSCs with design basis functions (i.e., there are physical separations and separation of power, instrumentations and controls), and credibility of adverse impact arising from modification of these beyond-design-basis SSCs to the important to safety SSCs are precluded.</p> <p>Recommendation: Consider adding the following statement at the end of the paragraph; “10 CFR 50.59 is not applicable to SSCs that have only beyond-design-basis-functions, do not interact with SSCs with design basis functions (i.e., there are physical separations and separation of power, instrumentations and controls), and credibility of adverse impact arising from modification of these beyond-design-basis SSCs to the important to safety SSCs are precluded.”</p>	N	This IMC will not provide new or revised interpretations on the scope of 10 CFR 50.59.
65	NEI	06.06, page 8, App Det	<p>This section is listed after 06.01 – 06.05 that describes regulations that contain control processes and the applicability determination process. It may benefit inspectors to have this as the header to sections 06.01-06.05 since those described applicability determinations.</p> <p>Recommendation: Consider making 06.06 and overarching section that contains the information described in 06.01-06.05 in addition to the content in 06.06.</p>	N	<p>Sections 06.01 through 06.05 discuss the relationships between various regulations and 10 CFR 50.59 and are meant to provide background insights to inspectors prior to the background on the 50.59 process. Sections 06.01 through 06.05 inform the applicability review in section 06.06 and all sections following.</p> <p>No change.</p>
66	NEI	06.06, page 8, App Det	<p>In this sections and other sections throughout. The terms “CTE” is used when “activity” may be better in describing the proposed CTE.</p> <p>Recommendation: Consider in this section (any other sections) the use of “proposed activity” versus “proposed CTE”</p>	N	<p>10 CFR 50.59 uses “change, test, or experiment” and not “activity” for what is covered by the rule.</p> <p>No change.</p>

Comment #	Source	Section #	Comment	Added	Remarks
67	NEI	06.08 page 9	<p>3rd paragraph states that; "If a change has no effect or has only beneficial effects, it does not trigger any of the evaluation criteria concerning more than minimal increase in frequency or occurrence of malfunction or higher consequences, etc"</p> <p>May be better worded as; "If a change has no effect or has only beneficial effects, it is not more than a minimal increase in frequency or occurrence of malfunction."</p> <p>This may improve clarity for the inspectors.</p> <p>Recommendation: Consider changing underlined text to "is not more than a minimal increase in frequency or occurrence of malfunction"</p>	Y	<p>The text has been changed in the following manner:</p> <p>If a change has no effect or has only beneficial effects, it does not trigger satisfy any of the evaluation criteria concerning more than minimal increase in frequency or occurrence of malfunction or higher consequences, etc. If the licensee cannot conclude that there is no adverse effect, a 10 CFR 50.59 evaluation is required.</p>
68	NEI	06.09, page 11	<p>Last paragraph in 06.09 states; "However, testing that removes an SSC from service for maintenance, if it is not a prolonged removal, does not require a 10 CFR 50.59 evaluation because it is controlled by 10 CFR 50.65(a)(4)."</p> <p>The point of this section is to ensure that inspectors understand that removing equipment from service is controlled under 10CFR50.65(a)(4). Reinforcing the point about prolonged removal doesn't seem to fit the intent of this section and is not a defined term. Considering referring to section 6.20 when assessing maintenance activities.</p> <p>Recommendation: Remove "if it is not a prolonged removal" from statement.</p>	Y	<p>Language in IMC will remain; Pointer to appropriate sub-section in 0335-06added.</p>

Comment #	Source	Section #	Comment	Added	Remarks
69	NEI	06.10, page 11	<p>In the 1st paragraph, inspectors may benefit from language included under 72.48 section (page 37) to make it clear how the 50.59 criteria are assessed.</p> <p>If the 10 CFR 50.59 screening for the proposed activity concludes that a change to an MOE is not involved, then the 10 CFR 50.59 evaluation should reflect that 10 CFR 50.59(c)(2)(viii) is not applicable. If the 10 CFR 50.59 screening determines that the proposed activity involves only a change to an MOE, then the 10 CFR 50.59 evaluation should reflect that criteria 10 CFR 50.59(c)(2)(i) through (vii) are not applicable.</p> <p>Recommendation: Add this information to the first paragraph;</p> <p>“If the 10 CFR 50.59 screening for the proposed activity concludes that a change to an MOE is not involved, then the 10 CFR 50.59 evaluation should reflect that 10 CFR 50.59(c)(2)(viii) is not applicable. If the 10 CFR 50.59 screening determines that the proposed activity involves only a change to an MOE, then the 10 CFR 50.59 evaluation should reflect that criteria 10 CFR 50.59(c)(2)(i) through (vii) are not applicable.”</p>	Y	<p>10 CFR 50.59 requires that each element of a CTE be separately evaluated against each of the 10 CFR 50.59(c)(2) criteria. The documented evaluation should justify the applicability of each criterion. The proposed language reads that you do not need to evaluate all criteria if one is met.</p> <p>No change to Section 06.10.</p> <p>This language in Section 07.20 has been deleted.</p>
70	NEI	06.10, page 11	<p>2nd to last paragraph states; “Each element of a CTE should be separately evaluated against each of the 10 CFR 50.59(c)(2) criteria unless the elements of a CTE are interdependent.”</p> <p>The inspectors may benefit from the use of “proposed activity” versus “CTE.”</p> <p>Recommendation: Consider changing “CTE” to “proposed activity” in this paragraph.</p>	N	See response to Comment #66 above.

Comment #	Source	Section #	Comment	Added	Remarks
71	NEI	06.11, page 12	<p>This section may benefit from the reinforcement that alteration of the design basis limit for a fission product barrier (DBLFPB) requires prior NRC approval via a license amendment.</p> <p>Recommendation: Consider reinforcing the information contained on page 19 in this section that any change to the DBLFB is adverse</p>	N	<p>Section 6.11 (now 6.13) of the IMC addresses the “minimal increase principle,” which affects the four “minimal increase” criteria in 10 CFR 50.59.</p> <p>Discussion of design basis limit for a fission product barrier is outside the scope of this section.</p> <p>No change made.</p>

72	NEI	06.12 page 13	<p>The following wording changes will help inspectors understand how the SOC's apply without limiting the use of PRA or other risk insights that would be appropriate in supporting 50.59 evaluations. The current wording appears to extend beyond the intent of the SOC's and would add additional restrictions on the use of PRA methods.</p> <p>1. "Consistent with the Commission's statements supporting the final 10 CFR 50.59 rule, inspectors should verify that licensees did not use RG 1.174 or its values for change in CDF and/or LERF as the basis for 10 CFR 50.59 evaluations."</p> <p>While we understand the intent of this statement, "its values" could be misinterpreted as meaning that the same values as described in RG 1.174 derived from another source would not be allowable.</p> <p>Recommend clarifying by stating; "inspectors should verify that licensees did not use RG 1.174 to determine values for changes in CDF and/or LERF used during 10 CFR 50.59 evaluations.</p> <p>2. "However, while the resultant CDF and LERF from the PRA are not acceptable to inform the licensee's 10 CFR 50.59 evaluation..."</p> <p>Again, inspectors could infer that the use of PRA is not acceptable versus the use of CDF and LEFF from RG 1.174 or how CDF and LERF could be used.</p> <p>Recommend clarifying by using similar wording from the Oct NRC public meeting; "However, while the resultant CDF and LERF from the PRA are not acceptable as the sole basis to inform the licensee's 10 CFR 50.59 evaluation..."</p> <p>Recommendation: The following changes would better align with the intent of the SOC and not cause confusing on how PRA may be used in support a 50.59 evaluation.</p>	Y	<p>For recommended change 1, revised to use the language in the SOC's.</p> <p>For recommended change 2, Wording changed to:</p> <p>However, while the resultant CDF and LERF from the PRA are not acceptable to inform not acceptable as the sole basis to inform the licensee's 10 CFR 50.59 evaluation, it is acceptable for licensees to use reasonable engineering practices, engineering judgement, and PRA techniques, as appropriate, to inform 10 CFR 50.59 evaluations with respect to "more than a minimal increase."</p>
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Comment #	Source	Section #	Comment	Added	Remarks
			1. Change "RG 1.174 or its values" to; "RG 1.174 to determine values" 2. Change "are not acceptable to inform" to; "are not acceptable as the sole basis to inform"		
73	NEI	06.13, page 14, (criterion i) 06.14, page 15, (criterion ii)	It would be beneficial to inspectors to include more detail on how the GDC relates to the CLB in these sections and what to expect by the licensee during the 50.59 evaluation. Recommendation: Add clarification to these sections that describes the relationship between the GDC and CLB and that a licensee's evaluation should demonstrate how the minimum performance standards continue to be met as part of the evaluation of this criterion.	N	Each licensee's CLB contains detailed descriptions of how the facility complies with the GDC. The licensee's 10 CFR 50.59 evaluation documents the impact of the CTE on the facility's CLB. This recommendation is outside the scope of the IMC, which is not adding new interpretations. No change.
74	NEI	06.15, page 15, (criterion iii & iv)	Consider adding the following statement to this section to aid inspectors with additional guidance contained in NEI 96-07 rev. 1 Sect 4.3.3 defining what is considered "more than a minimal increase." NEI 96-07 sect. 4.3.3. For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant "mission dose" exceeds applicable GDC 19 criteria. Recommendation: Add the following to section; "For changes affecting the dose to operators performing required actions outside the control room, an increase is considered more than minimal if the resultant "mission dose" exceeds applicable GDC 19 criteria."	N	"Mission dose" is not a concept discussed in the SOC's. No change.

Comment #	Source	Section #	Comment	Added	Remarks
75	NEI	06.15, page 16, (criterion iii & iv)	<p>The following statement in the 2nd paragraph appears to be misplaced.</p> <p>“Changes in methodology used to calculate radiological consequences would fail criterion (viii) of 10 CFR 50.59 and require prior NRC review regardless of how small the increase is in the calculated radiological consequences.”</p> <p>If the intent is to keep this statement, it should be modified to state;</p> <p>Changes in methodology used to calculate radiological consequences would be evaluated under criterion (viii) of 10 CFR 50.59 and require prior NRC review regardless of how small the increase is in the calculated radiological consequences.</p> <p>This terminology would better align with guidance.</p> <p>Recommendation: Delete the following statement; “Changes in methodology used to calculate radiological consequences would fail criterion (viii) of 10 CFR 50.59 and require prior NRC review regardless of how small the increase is in the calculated radiological consequences.” If intent is to keep it, consider the following for clarification; “Changes in methodology used to calculate radiological consequences would fail be evaluated under criterion (viii) of 10 CFR 50.59 and require prior NRC review regardless of how small the increase is in the calculated radiological consequences.</p>		The IMC text quoted in this comment is directly from the SOC's at 53593, specifically from the section providing examples for minimal increases. This IMC is not providing a new interpretation of 10 CFR 50.59.

Comment #	Source	Section #	Comment	Added	Remarks
76	NEI	06.17, page 18, (Criterion vi)	<p>The following information from NEI 96-07 rev. 1 Section 4.3.6 will aid inspectors with understanding aspects that describe this criterion.</p> <p>“Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the UFSAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the UFSAR.”</p> <p>Recommendation: Add the following to the beginning of 06.17</p> <p>“Malfunctions of SSCs are generally postulated as potential single failures to evaluate plant performance with the focus being on the result of the malfunction rather than the cause or type of malfunction. A malfunction that involves an initiator or failure whose effects are not bounded by those explicitly described in the UFSAR is a malfunction with a different result. A new failure mechanism is not a malfunction with a different result if the result or effect is the same as, or is bounded by, that previously evaluated in the UFSAR.”</p>	N	Section provides sufficient guidance to inspectors on criterion (vi) as is. No change.
77	NEI	06.20, page 23	<p>Adding a statement such as; “timeliness of corrective actions is evaluated under 10 CFR Appendix B, Criterion XVI.”</p> <p>This would align with the PI&R inspection guidance and what governs how timeliness of corrective actions should be assessed.</p> <p>In some cases, inspectors’ reference 50.59 when assessing timeliness of corrective actions.</p> <p>Recommendation: Consider adding a statement; “Timeliness of corrective actions is evaluated under 10 CFR Appendix B, Criterion XVI.”</p>	N	The NRC does not define or discuss “timeliness” in the manner suggested in this comment and is not creating new interpretations of requirements in this IMC. No change.

Comment #	Source	Section #	Comment	Added	Remarks
78	NEI	06.20, page 23	<p>2nd paragraph, the use of “proposed activity” may be more appropriate than “CTE” (similar to overall note)</p> <p>The use of “CTE” doesn’t seem to fit this section as well.</p> <p>Recommendation: Consider changing “CTE” to “proposed activity.”</p>	N	See response to Comment #66 above.

Comment #	Source	Section #	Comment	Added	Remarks
79	NEI	06.20, page 23, 24	<p>The following descriptions from Part 9900 for 50.59 could aid the inspectors on considerations for determining when equipment removed from service for maintenance could become a change that would need to be assessed under 50.59.</p> <p>“Removing equipment from service (making it inoperable) for maintenance during the technical specification (TS) allowed outage time does not require application of 10 CFR 50.59. Removing non-TS equipment from service is covered by the requirements of the maintenance rule (10 CFR 50.65). 10 CFR 50.59 does not need to be applied. One way to decide if a particular activity is "maintenance" or a "change" is to determine if the plant will be returned to its as-design condition following the activity”</p> <p>“The reliance upon the Paragraph 50.65(a)(4) assessment in lieu of a section 50.59 evaluation also extends to temporary alterations (or test activities) directly related to and required in support of specific maintenance activities. This guidance also applies to temporary alterations in support of implementation of a modification (the modification itself is subject to the Section 50.59 review process with respect to operation following installation). However, if the temporary alterations (including those affecting operator actions and procedures as described in the FSAR (as updated)) are not in support of maintenance, or are expected to remain in place for more than 90 days at power, a Section 50.59 review is to be performed in addition to the Paragraph 50.65(a)(4) assessment. Refer to the regulatory guidance (for Section 50.59 and for Paragraph 50.65(a)(4)) for further information.”</p> <p>Recommendation: Consider adding additional elements from (or referencing) Part 9900, 50.59.</p>	Y	Certain elements of the 50.59 technical guidance have been incorporated in the IMC, including Section 06.20.

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80	NEI	0335-07, page 25, first bullet	<p>First bullet discusses NEI 12-04 but doesn't mention RG 3.72.</p> <ul style="list-style-type: none"> • Applicability and Screening: Licensees and CoC holders may follow these processes, as described in NEI 12-04, to determine if another process governs the CTE or if the licensee or CoC holder may need to perform a 10 CFR 72.48 evaluation. <p>RG 3.72 contains clarifications and exceptions to NEI 12-04.</p> <p>Recommendation: Add reference to RG 3.72 in this section that endorses NEI 12-04. (e.g., RG 3.72 rev. 1 endorses NEI 12-04, rev. 2)</p>	Y	Added reference to RG 3.72 and NEI 12-04 in Section 9 of the IMC.

81	NEI	0335-07, page 25	<p>Section may benefit from the following re-wording. It also has a better tie to general licensees.</p> <p>“Each 10 CFR 72 General Licensee stores spent nuclear fuel in Spent Fuel Storage Canisters/Casks in an Independent Spent Fuel Storage Installation (ISFSI) licensed to a particular amendment of a particular Certificate of Compliance (CoC). Each CoC Amendment has, appended to it, unique Technical Specifications. The CoC itself will reference the applicable UFSAR revision. The approval of a particular CoC Amendment is documented in a unique NRC Safety Evaluation Report (SER). A report, generated by the General Licensee pursuant to 10 CFR 72.212, documents the conformance of the loaded canisters/casks and the ISFSI to the requirements detailed in the applicable licensing basis. Differences between the design and operation of the loaded canisters/ISFSI and the design and operation of the canisters/ISFSI described in the UFSAR are identified within the 72.212 report and reviewed under 10 CFR 72.48. The loaded canisters/casks and ISFSI remain licensed under the same CoC Amendment, Technical Specifications (TSs), UFSAR Revision, and SERs until the loaded fuel is removed from the ISFSI (or the canisters are recertified to another CoC Amendment). Should a General Licensee later opt to store spent nuclear fuel in a canister/cask licensed under a different CoC/CoC Amendment, this different CoC/CoC Amendment will have associated with it, its own TS, UFSAR Revision, and SERs. This subsequently loaded fuel will have an associated 72.212 Report and supporting 72.48 reviews. Thus, it is feasible for a single General Licensee to have, in effect, a single ISFSI with canisters/casks loaded and stored to two or more CoC Amendments, each having separate corresponding TSs, UFSARs, and NRC SERs. For such installations, the licensee should ensure that activities are reviewed under 72.48 in light of which CoC amendment(s) etc., is(are) applicable to the activity.”</p> <p>Note - If decision to keep the original language, the next 3 comments address how to improve them as written.</p>	Y	Maintained the original language and added the suggested wording.
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			<p>2nd para. Revise the 2nd sentence to say "Licensee's and CoC holder's processes"</p> <p>In the first bullet it should be recognized that the applicability determination also decides whether no regulatory review is required at all (i.e., for editorial or administrative changes).</p> <p>2nd bullet: Prior to "(2)" add "a CoC amendment is required under."</p> <p>Recommendation: Suggested wording improvements for this overview. Or specific changes to consider if the original wording is maintained. Revise to reflect no regulatory review needed for editorial or administrative changes.</p>		
82	NEI	07.01, page 25	<p>Title references 72.78 versus 72.48 Typo.</p> <p>Recommendation: Change 72.78 to 72.48.</p>	Y	Title has been changed from "72.78" to "72.48"
83	NEI	07.01, page 25	<p>1st para.: The reference to using 0335-06 for 72.48 should be clarified by adding "consistent with the endorsed guidance in NEI 12-04."</p> <p>There are some elements of the 50.59 rule and guidance that do not apply to 72.48.</p> <p>Recommendation: Add phrase as suggested</p>	N	NEI 12-04 is a method endorsed by the NRC to demonstrate compliance with 72.48. The IMC Section 07.01 specifies the relationships between 72.48 and 50.59 as detailed in the 1999 SOC's. No change.

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84	NEI	07.01, page 25	<p>The 2nd paragraph, 2nd sentence should also be included in 0335-06, with appropriate re-wording for the 50.59 program because changes made to SSCs under 50.59 can also affect the ISFSI and require 72.48 review.</p> <p>Recommendation: Add sentence in 07.01 to the language in 0335-06 to reflect interplay between 50.59 and 72.48.</p>	Y	<p>Agree. IMC has been revised to add the following to 0335-06:</p> <p>RELATIONSHIP BETWEEN 10 CFR 50.59 AND 10 CFR 72.48</p> <p>As a part of rulemaking in 1999, the staff revised the regulations in 10 CFR 72.48 to conform with the revised 10 CFR 50.59 rule in order to provide consistent implementation of these two regulations.</p> <p>Other sections of this IMC discuss key definitions, provide guidance for reviewing the licensee's and CoC holder's processes for applicability and screening, and performing an assessment of 10 CFR 72.48 evaluations. Inspectors should be aware that changes in the ISFSI and spent fuel storage cask design may affect the Part 50 license if co-located and may require analyses in 10 CFR 50.59 and 10 CFR 72.48.</p>

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85	NEI	07.02, page 25	<p>1st para: a) It is not clear why Part 71, Subpart H is included here. Seems like Part 72, Subpart G is all that should be referenced. Suggest deleting this discussion to avoid confusion and inappropriate mixing of Part 71 and 72 requirements. b) Change “or implementation of 10 CFR 72.212 evaluation” to “or implementation of a Part 72 general license.”</p> <p>Recommendation: a) Suggest deleting Subpart H. (b) Revise wording as suggested</p>	Y	Licenseses and CoC Holders may use a previously approved program under Part 71, Subpart H or Appendix B to Part 50 to satisfy the requirements of an established program under Part 72. There was no change as suggested from recommendation (a). Revised wording to the suggested language as described in recommendation (b).
86	NEI	07.03, page 26	<p>The purpose of this section is not clear. It provides discussion of dual-purpose systems but then concludes Part 71 is outside the scope of the IMC. Suggest deleting this section to avoid confusion and inappropriate mixing of Part 71 and 72 requirements.</p> <p>Is the intent to reinforce this aspect? “Inspectors should be aware of changes to activities that affect Part 71 design and licensing bases and will need to be assessed and controlled under Part 71 requirements.”</p> <p>Recommendation: Consider removing this section or add additional information on what it is included for the inspector.</p>	N	The purpose of this section was to provide the inspector information above dual-purpose systems and how changes made to Part 72 may impact Part 71 requirements. There was no change to this section as recommended.
87	NEI	07.05, page 27	<p>1st para.: Suggest deleting the last sentence. This may be colloquially true, but there are too many differences between a 212 report and a specific ISFSI license UFSAR to make this statement.</p> <p>Recommendation: Suggest deleting section as unnecessary and to avoid confusion.</p>	Y	Revised the IMC to delete the last sentence in the first paragraph.

Comment #	Source	Section #	Comment	Added	Remarks
88	NEI	07.05, page 27	<p>2nd para.:</p> <p>a) Add clarification as to whether parts of the 212 report not governed by 72.212(b)(5) and (b)(6) are or are not governed by 72.48. The 212(b)(7) regulation seems to be narrowly written to apply to just these sections of the 212 report.</p> <p>b) Suggest adding a reference to RIS 2012-05.</p> <p>c) Implementation of 212(b)(7) has been the source of recent enforcement action for general licensees. Suggest adding more clarity as to how the NRC interprets a “deviation” from the cask UFSAR with respect to evaluations in the 212 report. Consult RIS 2012-05 in this regard.</p> <p>Recommendation: (a) Clarify as suggested. (b) Add reference as suggested. (c) Add clarification on how NRC interprets a “deviation” from a cask UFSAR with respect to evaluations in the 212 report.</p>	Y	<p>This IMC is intended to assist the staff when reviewing changes in the facility or spent fuel storage cask design as described in the final safety analysis report as updated. This document does not provide any new interpretations or rules pertaining to 10 CFR 50.59 or 10 CFR 72.48. This includes no new interpretations of other regulations identified in this document such as 10 CFR 72.212. The staff reviews regulations, generic communications and other documents as applicable for related staff positions to obtain additional information (e.g. Regulatory Guides and Regulatory Information Summaries).</p> <p>The recommendation to add the suggested reference of RIS 2012-05 is included in Section 9 of this IMC.</p>
89	NEI	07.05, page 27	<p>3rd para.: The point being made in the penultimate sentence is not clear and the sentence seems to be misplaced. General licensee site-specific deviations from the cask FSAR authorized under 72.48 are not included in a modification to the generic cask FSAR. Each general licensee tracks these independently. Suggest deleting this sentence. The relationship between the cask UFSAR, the 212 report, and 72.48 is adequately addressed in the previous paragraph.</p> <p>Recommendation: Delete sentence as suggested.</p>	Y	Revised the IMC to include the recommendation to delete sentence as suggested and revise paragraph since the previous paragraph adequately addressed the concepts.

Comment #	Source	Section #	Comment	Added	Remarks
90	NEI	07.06, page 27	<p>For general licensees, other regulations (e.g., 10 CFR 50.54) also applies for some programs. While only some examples of these regulations that contain a change control process in Part 72 regulations are listed in this section, NEI 12-04 list is more comprehensive.</p> <p>Recommendation: Suggest either adding the additional regulations or referencing back to NEI 12-04 Sect. 4.1.</p>	N	As stated in Section 07.06, the examples provided are not meant to be exhaustive. No change.
91	NEI	07.08, page 28	<p>5th paragraph states that “Inspectors should recognize that changes reducing an SSC’s capability, performance, qualification, or reliability are adverse.”</p> <p>May be better worded as; ““Inspectors should recognize that changes reducing an SSC’s capability, performance, qualification, or reliability in the accomplishment of its as-credited design function is adverse.</p> <p>This will help improve clarify for the inspector to distinguish between credited design functions from those that do not.</p> <p>Recommendation: Add; “in the accomplishment of its as-credited design function” to distinguish between changes that do not affect a credited design function from ones that do.</p>	Y	Revised the IMC to include the recommendation to add the suggested language.
92	NEI	07.08, page 29	<p>Last para.: The term “unintended change” is not in the regulations, RG 3.72 or NEI 12-04.</p> <p>It would not be clear to inspectors what this is intending.</p> <p>Recommendation: Suggest explaining the term using existing definitions, providing a new definition in the appropriate document, or otherwise more fully explaining the issue and the process to be followed</p>	N	The paragraph discussed in this comment is from the Inspection Manual Part 9900 10 CFR Guidance on 10 CFR 50.59. This IMC is not providing new guidance interpreting 10 CFR 50.59.

Comment #	Source	Section #	Comment	Added	Remarks
93	NEI	07.10, page 29	<p>In the 1st paragraph, inspectors may benefit from language included later under 72.48 section 07.20 (page 37) to make it clear how the 72.48 criteria are assessed.</p> <p>If the 10 CFR 72.48 screening for the proposed activity concludes that a change to an MOE is not involved, then the 10 CFR 72.48 evaluation should reflect that 10 CFR 72.48(c)(2)(viii) is not applicable. If the 10 CFR 72.48 screening determines that the proposed activity involves only a change to an MOE, then the 10 CFR 72.48 evaluation should reflect that criteria 10 CFR 72.48(c)(2)(i) through (vii) are not applicable.</p> <p>Recommendation: Add this information to the first paragraph;</p> <p>“If the 10 CFR 72.48 screening for the proposed activity concludes that a change to an MOE is not involved, then the 10 CFR 72.48 evaluation should reflect that 10 CFR 72.48(c)(2)(viii) is not applicable. If the 10 CFR 72.48 screening determines that the proposed activity involves only a change to an MOE, then the 10 CFR 72.48 evaluation should reflect that criteria 10 CFR 72.48(c)(2)(i) through (vii) are not applicable.”</p>	Y	<p>10 CFR 72.48 requires that each element of a CTE be separately evaluated against each of the 10 CFR 72.48 criteria. The evaluation should justify the applicability of each criterion. The proposed language appears to read that you do not need to evaluate all criteria if one is met. No change.</p> <p>This language has been removed from Section 07.20.</p>
94	NEI	07.10, page 29	<p>1st para.: Delete “or CoC holder” from the last sentence.</p> <p>CoC holders do not request license amendments per 72.56.</p> <p>Recommendation: Delete phrase as suggested</p>	Y	Revised the IMC to include the recommendation to delete the suggested language.
95	NEI	07.10, page 29	<p>3rd para.: At the beginning of the 2nd sentence, add “While the SER does not impose requirements on the licensee or CoC holder, inspectors...”</p> <p>Improves guidance.</p> <p>Recommendation: Add phrase as suggested.</p>	N	The paragraph as written provides sufficient guidance to inspectors. No Change.

Comment #	Source	Section #	Comment	Added	Remarks
96	NEI	07.10, page 30	<p>4th para.: The 2nd bullet does not clearly describe the two separate types of MOE changes as described in the definition of a departure from an MOE in the regulations. Suggest revising to refer to 1) A change to an element of a method described in the UFSAR or 2) a different method from that described in the UFSAR.</p> <p>This will provide better guidance in this area.</p> <p>Recommendation: Revise as described.</p>	Y	Revised the IMC to include the recommendation to add the suggested language.
97	NEI	07.11, page 30	<p>Most ISFSIs and cask designs were not licensed per NUREG-2215. Suggest replacing this reference with a reference to the applicable SRP for the ISFSI license or cask design CoC.</p> <p>Improves inspector guidance.</p> <p>Recommendation: Replace reference as suggested.</p>	Y	Revised the IMC to include the recommendation to add the suggested language.
98	NEI	07.12 page 30	<p>The blanket reference to Section 06.12 is not applicable for 72.48. PRA does not apply to Part 72 and the NRC asked that we remove references to PRA from NEI 12-04. Suggest adding Part 72-specific guidance to inspectors for licensee use of probabilistic analysis techniques, including any limitations.</p> <p>May cause confusion to inspectors as written.</p> <p>Recommendation: Suggest adding Part 72-specific guidance on use of PRA.</p>	N	Agree. Section has been changed to address licensees who are committed to RG 3.72, Revision 0, versus Revision 1.
99	NEI	0335-07.13 thru 20	<p>Reg Guide 3.72, Revision 1 has exceptions and clarifications that apply to the 72.48 criteria that should be recognized in the appropriate sections to help the inspectors during the inspection activity.</p> <p>This will aid inspectors during inspection activities</p> <p>Recommendation: Consider a broad review of these sections to include applicable exceptions and clarifications form RG 3.72, Rev.1.</p>	Y	Reference added to RG 3.72, Rev 0 and 1. Additionally, the staff has integrated the applicable exceptions and clarifications within the IMC as necessary.

Comment #	Source	Section #	Comment	Added	Remarks
100	NEI	0335-09, page 40	<p>The following guidance documents are not listed in the references.</p> <ul style="list-style-type: none"> • 10 CFR 72.48, "Changes, Tests, and Experiments." • Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, tests, and experiments." • NEI 97-04. rev. 1 Appendix B, "Guidance and Examples for Identifying 10 CFR 50.2 Design Bases" • NUREG-1536 & 1537 (precursors to NUREG-2215 that were the governing SRPs for most ISFSAs and cask designs) • RIS 2012-05, "Clarifying the Relationship Between 10 CFR 72.212 and 10 CFR 72.48 Evaluations" <p>Recommendation: Consider adding additional references as described.</p>	Y	Reference list fully updated.
101	NEI	General Comment	<p>Use of NEI 96-07 should reference revision 1 to ensure clarity of endorsed guidance.</p> <p>OR</p> <p>If revisions were not intended to be use, statements that reflect that the latest endorsed guidance should be used.</p> <p>Minimize the potential for inspectors to reference outdated information</p> <p>Recommendation: Add revision 1 when NEI 96-07 is referenced.</p> <p>OR</p> <p>Include a statement that the inspectors should reference the latest endorsed references for their use.</p>	Y	Agree. IMC was changed to reference revisions.

Comment #	Source	Section #	Comment	Added	Remarks
102	NEI	General Comment	<p>Since this inspection manual is to inspect all activities related to 50.59, including information from NEI 96-07 Appendix D and associated rev. 2 of RG 1.187 would benefit inspectors inspecting areas associated with digital I&C.</p> <p>Recommendation: Add information and references to reflect digital I&C 50.59 related activities.</p>	Y	Section added related to digital I&C activities.
103	NEI	General Comment	<p>In Section 6.13 and 6.14, the examples in NEI 96-07 rev.1 are not included. This is ok but it would be good to make a statement in the IMC similar to RG 1.187 that the examples in NEI 96-07 are meant to illustrate and reinforce the concepts contained in the body of the document. Examples may not apply in all cases and other approaches not described by an example are allowed. In either case, inspectors should ensure the approach taken is applicable to its particular circumstance as described in the content of NEI 96-07 rev.1.</p> <p>Recommendation: Add info to ensure the inspectors understand how to consider examples referenced in 50.59 evaluations such as;</p> <p>Rev. 1 of NEI 96-07 includes examples to illustrate and reinforce the guidance. Inspectors should consider that the examples are not always applicable for all licensees. If a licensee uses an example described in NEI 96-07 rev. 1 or another approach as part of the evaluation, the inspector should ensure that the approach is applicable to its particular circumstance as described in the content of NEI 96-07 rev. 1.</p>	N	This concept will be addressed in inspector training. Additional information on this point can be found in RG 1.187, Rev. 2.