

APPENDIX X
NRC REGULATORY POSITION ON NEI 21-07, REVISION 0, “TECHNOLOGY INCLUSIVE GUIDANCE FOR NON-LIGHT WATER REACTORS SAFETY ANALYSIS REPORT CONTENT FOR APPLICANTS USING THE NEI 18-04 METHODOLOGY”

Introduction

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed Nuclear Energy Institute (NEI) 21-07, Revision 0, “Technology Inclusive Guidance for Non-Light Water Reactors Safety Analysis Report Content for Applicants Using the NEI 18-04 Methodology.” The purpose of this appendix is to supplement the Regulatory Positions discussed in Regulatory Positions C.1 through C.8 of this RG. The staff’s detailed position on that applicable portions of NEI 21-07, Revision 0 are found in the following table. The table notes areas where the staff has identified an “exception,” “clarification,” “addition,” or “comment/suggested edit.” The definition of these terms is as follows:

- **Exception** – feedback labeled as an NRC Exception is used to highlight statements, or portions thereof, in NEI 21-07 that are factually incorrect or guidance that would result in the need for an NRC Request for Additional Information (RAI) if followed by an applicant in developing a safety analysis report (SAR).
- **Clarification** – feedback labeled as an NRC Clarification is used to indicate statements or guidance in NEI 21-07 that are ambiguous and would require clarification by the NRC to limit the possible interpretations by an applicant or other stakeholder consulting NEI 21-07. An applicant relying on NEI 21-07 to develop an application in the absence of the Clarification would likely be subject to RAIs if the guidance was improperly interpreted. Similarly, stakeholders consulting NEI 21-07 in the absence of the Clarification could conclude that publicly available application information is inadequate to the extent that it could form the basis for a contention.
- **Addition** – feedback labeled as an NRC Addition is used to indicate staff regulatory guidance that should be followed by an applicant in addition to the guidance in NEI 21-07 in order to develop a SAR that addresses their safety case. Additions not related to the LMP-based affirmative safety case will be included in the ARCAP guidance.

NRC Draft NEI 21-07, Revision 0 Exceptions, Clarifications, Additions, and Comment/Suggested Edit

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)									
A.2	Background	Page 3 (last paragraph) - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that in addition to making a safety case, an applicant should also make a licensing case that focuses on compliance with applicable regulations and includes any exemptions, as necessary.	Clarification										
A.3a	Supplemental information affecting first 8 chapters of the SAR outside the scope of Industry TICAP guidance	Page 3 Clarification and addition. The staff will continue to reference in its TICAP RG the guidance that is relevant to the first 8 chapters of the SAR (e.g., siting, fuel qualification, instrumentation and control design review guide, ASME Section III Division 5). See supplemental information found in 7/8 version of TICAP RG draft white paper https://www.nrc.gov/docs/ML2119/ML21190A014.pdf	Clarification and Addition										
A.3b	Scope	Page 4 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that that an affirmative safety case should include normal operation and that applicants should also make a licensing case with respect to compliance with regulations and include exemptions, as necessary. That is, the applicant must make the case for and claim compliance with or exemptions from specific regulations. The NRC will not just review the safety case and derive from it those regulations that are met in order to makes its findings.	Clarification										
B.2	SAR Outline	Page 7 (bottom) - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that an affirmative safety case should include normal operation as well as LBEs.	Clarification										
B.3	Explanation and Use of text that is in italics	Page 9 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper clarifying the meaning of the use of the regular text and text in italics throughout the SAR content guidance in Section C of NEI 21-07. Examples of text that the staff believes should be in regular font vice in italics include:	Clarification										
		<table border="1" data-bbox="596 1052 2045 1377"> <thead> <tr> <th data-bbox="596 1052 776 1162">NEI 21-07 Section Number</th> <th data-bbox="776 1052 1104 1162">Topic</th> <th data-bbox="1104 1052 2045 1162">Issue</th> </tr> </thead> <tbody> <tr> <td data-bbox="596 1162 776 1273">1a</td> <td data-bbox="776 1162 1104 1273">Guidance in Introduction Section should be regular font.</td> <td data-bbox="1104 1162 2045 1273">The fourth, fifth, and sixth paragraphs of this section should be regular text since they provide instructions for the applicant regarding information to be included, formatting, and level of detail.</td> </tr> <tr> <td data-bbox="596 1273 776 1377">2b</td> <td data-bbox="776 1273 1104 1377">Discussion of topical reports</td> <td data-bbox="1104 1273 2045 1377">Page 21 – topical reports approved by the NRC during pre-application engagement activities should be incorporated by reference into the SAR and not simply be listed as general references. Applicants should</td> </tr> </tbody> </table>			NEI 21-07 Section Number	Topic	Issue	1a	Guidance in Introduction Section should be regular font.	The fourth, fifth, and sixth paragraphs of this section should be regular text since they provide instructions for the applicant regarding information to be included, formatting, and level of detail.	2b	Discussion of topical reports	Page 21 – topical reports approved by the NRC during pre-application engagement activities should be incorporated by reference into the SAR and not simply be listed as general references. Applicants should
		NEI 21-07 Section Number			Topic	Issue							
		1a			Guidance in Introduction Section should be regular font.	The fourth, fifth, and sixth paragraphs of this section should be regular text since they provide instructions for the applicant regarding information to be included, formatting, and level of detail.							
2b	Discussion of topical reports	Page 21 – topical reports approved by the NRC during pre-application engagement activities should be incorporated by reference into the SAR and not simply be listed as general references. Applicants should											
1a	Guidance in Introduction Section should be regular font.	The fourth, fifth, and sixth paragraphs of this section should be regular text since they provide instructions for the applicant regarding information to be included, formatting, and level of detail.											
2b	Discussion of topical reports	Page 21 – topical reports approved by the NRC during pre-application engagement activities should be incorporated by reference into the SAR and not simply be listed as general references. Applicants should											

NEI 21-07 Section Number ID	Topic	Discussion		Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
				specifically identify documents IBR'd into the SAR. The staff also believes the sentence should be in regular text.	
		3	Guidance regarding licensing basis events should be regular font	Page 27 - The third paragraph should be in regular font because it provides guidance regarding LBEs.	
		3.6	DBA guidance should be regular font.	Page 35 – The fourth paragraph in this section should be regular font because it provides guidance regarding the documentation of conservative deterministic DBA analyses that is generally modeled after accident analysis descriptions found in Chapter 15 of SARs for current LWRs.	
		4.2a	Guidance regarding DID should be regular font.	Page 38- the final sentence in the first paragraph of Section 4.2 should be in regular font because it provides guidance.	
		4.2b	Defense in depth discussion and clarification that some of the guidance should be in regular text	<p>Page 39 – the second paragraph of Section 4.2 and the bulleted list immediately below it should be in regular font and not in italics since it provides guidance.</p> <p>The sixth bullet of this list should be modified to read, “Evaluation of single features that are risk significant to assure no overdependence on that feature”</p> <p>The first sentence of the paragraph following these bullets in Section 4.2 should be revised to state: “Note that the information responsive to this bulleted list should be provided in either this chapter or in Chapters 3, 5, 6, 7, and 8.”</p>	
		4.2.1	DID plant capability summary	Page 40 – portion of second paragraph should be in regular font because it provides guidance	
		4.2.1.2	DID guidance should be regular font.	Page 41 – The first paragraph in this section should be regular font because it provides guidance regarding the DID evaluation.	

NEI 21-07 Section Number ID	Topic	Discussion			Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		4.2.2a	Defense in Depth Summary discussion in the SAR	Page 42 and 43, the second paragraph in Section 4.2.2, which starts with “Programmatic DID should be used ...” should be in regular font and not in italics since it provides guidance.		
		4.2.3b	Integrated defense in depth discussion in the SAR	Page 44, the following text should be in regular font and not in italics since it provides guidance: The baseline DID evaluation results in the SAR reflect the finalization of all DID adequacy evaluations. The evaluation in this section determines that incremental evaluations of DID outlined in NEI 1804 Section 5.9.3 for plant capability are collectively complete, programmatic actions are appropriate to sustain identified safety significant performance requirements and residual risks are very low.”		
		4.2.2.1	Evaluation of Significant Uncertainties	Page 44 – Further discussion in needed in either NEI 21-07, Revision 1 or the TICAP draft RG white paper to document that “The consideration of uncertainties may also identify some sources of uncertainty that may be safety significant and lead to specific actions for DID purposes. A summary of the sources of significant uncertainty should be describe in the SAR. The details of these analyses should be documented in plant records.” This text should be in regular font		
		4.2.3	Integrated DID evaluation	Page 45 - the following text should be in regular font and not in italics since it provides guidance: The baseline DID evaluation results in the SAR reflect the finalization of all DID adequacy evaluations. The evaluation in this section determines that incremental evaluations of DID outlined in NEI 18--04 Section 5.9.3 for plant capability are collectively complete, programmatic actions are appropriate to sustain identified safety significant performance requirements and residual risks are very low.		
		5.4	Safety Related Structures, Systems, and Components (SSC) description in the SAR	Page 49 - Section 5.4 first paragraph text should be in regular font vice in italics since it provides guidance. The staff will also revise the following text in the TICAP RG regarding Safety-related SSC discussion in the SAR: “The information reflected in Table 5-2, which describes combinations of SSCs that are provided in the design to fulfill each RSF and identifying		

NEI 21-07 Section Number ID	Topic	Discussion		Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)	
				whether each set of SSCs is available or not on each of the DBEs, should be included in the application.”		
		6.1.1a	Design Basis Hazard Level discussion in the SAR	<p>Page 55 - The following text should be in regular font vice in italics since it provides guidance: “Note that this guidance document uses the nomenclature of DBHL instead of the DBEHL term from NEI 18-04. While not discussed comprehensively in NEI 18-04, there is a need to consider not only hazards external to the plant (traditional external events) but also hazards external to the SSCs performing PRA Safety Functions – i.e., internal plant hazards such as internal fires, floods, turbine missiles, and high energy line breaks. To clarify the original intent of NEI 18-04 to address both categories of hazards, this guidance document uses the DBHL term instead of DBEHL.”</p> <p>This appears to be a deviation from NEI 18-04 and if it is a deviation then it should be noted as such.</p>		
		6.1.2	Guidance regarding SRDC description should be regular font	<p>Page 57 - In the second paragraph, the following text should be regular font because it provides guidance: “For each of the RFDC, this section should identify a set of SRDC appropriate to the SR SSCs selected to perform the RSFs. These SRDC exclude Special Treatment Requirements, which are separately covered in Section 6.2. The RFDC, which are expressed in the form of functions and involve collections of SSCs and intrinsic capabilities of the plant, may be viewed as a bridge between the RSFs and the SRDC. The SRDC is more detailed requirements for specific SR SSCs in the performance of the RSF functions in specific DBAs. Examples of SRDC that were developed for the MHTGR are found in Appendix A of the LMP SSC report.”</p> <p>It would be more helpful to a user of this guidance document to include some SRDC examples rather than just provide a reference to an external document.</p>		

NEI 21-07 Section Number ID	Topic	Discussion			Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		7.1	Reliability and Capability Targets for NSRST SSCs	Page 63 – Text in first paragraph should be in regular text since it provides guidance		
B.5	Two-Step Licensing (CP/OL)	<p>Page 10 - Clarification of several items should be made: (1) the requirement under 50.34(a)(4) for demonstration of an affirmative safety case that includes normal operation reflecting that LMP does not address normal operation; (2) a licensing case also needs to be made by the applicant with respect to claims of compliance with or requests for exemption from regulations; and (3) the COL application scope includes ITAAC whereas the CP/OL scope does not.</p> <p>Clarification proposed that the LMP-based safety case shifts from compliance with prescriptive regulatory requirements to an approach that focuses on identification and performance of fundamental safety functions to address and satisfy associated regulatory requirements and provide reasonable assurance of adequate protection of public health and safety.</p>			Clarification and Addition	
B.6	Design Certification	<p>Page 11 – Further discussion is needed in either NEI 21-07, Revision 1, or in the TICAP draft RG white paper to clarify that the SAR content developed through use of LMP is similar in scope only to the Tier 2 information required for a DC application. Guidance for Tier 1 information, including ITAAC, required for a DC application is neither contemplated by NEI 18-04 nor discussed in the TICAP guidance document.</p> <p>Also included a proposed change to page 11 (last paragraph) to reference Tier 2 Information</p>			Clarification and Addition	
1b	Licensing Basis Information	Page 16 – Clarify what language in Chapter 1 of a SAR will be included and maintained as part of the licensing basis, and what parts of the regulation those parts seek to fulfill.			Clarification	
1.1.2	Intended Use of the Reactor	Page 17 – The NEI proposed text does not seem to fully address 10 CFR 50.34(a)(1)(ii)(A) regarding use of the reactor. Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to address the radioactive materials inventory portion of the regulation.			Addition	
1.3.3	Defense in Depth	Page 21 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that DID adequacy is based on 3-elements; plant capability DID, programmatic DID, and RIPB DID. Applicants should address risk-informed, performance-based DID also and cite key examples for this DID element			Clarification and Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
2a	Pre-licensing engagement	Page 21 – The highlighted sentence gives the incorrect perception that pre-licensing interactions affect the level of detail that should be provided within the docketed license application and related submittals (e.g., topical reports)	Clarification	
2.1	PRA discussion to be included in the SAR	Page 22– The fourth and fifth sentences in the first paragraph of Section 2.1 provide guidance and should therefore be in regular text. In order to reflect the Commission’s affirmation in SRM-SECY-2015-002 regarding the need for PRA information for CP/OL applications for new reactors, they should be modified to read, “The PRA information included in the SAR should be at a summary level only as described below. It should include a description of the design-specific or plant-specific PRA, as appropriate, and its results.”	Clarification	
2.1.1a	Conformance (with any deviations) with the advanced non-LWR PRA standard, ASME/ANS RA-S-1.4-2021 NEI 20-09, Rev. 0 PRA peer review	Page 22 and 23 - Trial-use RG 1.247 to endorse the std is under development. NRC staff positions in RG 1.247, once issued, should be addressed along with the Std. NEI 20-09, Revision 1, has been submitted to the NRC for endorsement. Revision 1 should be cited instead of Revision 0.	Clarification	
2.1.1b	Discussion of PRA information to be included in the SAR	Page 23 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to cover the level of detail for the PRA information to be included in the SAR as follows: “This section should describe PRA assumptions, the identification of PRA-based insights, and an overview of the results and insights from importance, sensitivity, and uncertainty analyses. A pointer should be provided if the information is described in other Chapters (e.g., Chapter 3). Detailed information used in the PRA will not be included in the SAR but will be available for NRC audit.”	Clarification and Addition	
2.1.1c	Discussion of PRA info in SAR – Two-step licensing (CP application)	Page 24 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG with paper to clarify the basis for omitting peer review for PRA for a CP application as follows (italics are used to set off the clarification – final text should be in regular font): To be clear, consistent with the baseline for this guidance, to the extent that an applicant does not request any design finality as part of its CP application, no PRA peer review should be required at the CP application stage.	Clarification and Addition	
2.1.2	Summary of Key PRA Results	Page 24 – The last bullet in this section states that SAR Chapters 6 and 7 are to address reliability and capability targets for SR and NSRST SSCs. Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to address SR and NSRST human actions.	Clarification and Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
3.3	Anticipated operational occurrences (AOOs) – clarification of discussion of AOOs in the SAR	Page 31 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that non-DBA LBE as analyzed in the PRA should be summarized in the SAR.	Clarification	
3.3.1	AOOs – key information regarding AOOs should be captured in the SAR	<p>Page 31 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences (to the extent such information is not provided in Section 2.2) should be included in the discussion of AOOs with a release in Section 3.3.1 of the SAR. The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word “additional” is suggested as a modifier to the “information that should be provided for any AOO with a release” in the sentence preceding the bulleted list to clarify that it is in addition to the narrative that should be provided for each AOO as listed in the same section.</p> <p>The exception to the statement regarding omission of the information and retention in plant records is appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events, including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.</p>	Clarification and Exception	
3.4.1	Design Basis Events (DBEs) - key information regarding DBEs should be captured in the SAR	<p>Page 32 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences for DBEs with a release (to the extent such information is not provided in Section 2.2). The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word “additional” is suggested as a modifier to the information that should be provided for the most limiting DBE that was used to map into each DBA to clarify that it is in addition to the narrative that should be provided for each DBE as listed in the same section.</p> <p>The exception to the statement regarding omission of the information and retention in plant records appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events,</p>	Clarification and Exception	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
		including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.		
3.5.1	Beyond Design Basis Events (BDBEs) – key information regarding BDBEs should be captured in the SAR	<p>Page 33 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a description of the models, site characteristics, and supporting data associated with the calculation of the mechanistic source terms and radiological consequences for BDBEs with a release (to the extent such information is not provided in Section 2.2). The text stating that this information is only in plant records should be removed from NEI 21-07, Revision 1 or addressed by an exception in the TICAP draft RG white paper. The word “additional” is suggested as a modifier to the information that should be provided for information provided for BDBEs with a release to clarify that it is in addition to the narrative that should be provided for each BDBE.</p> <p>The exception to the statement regarding omission of the information and retention in plant records appropriate because the safety case for the reactor is tied to appropriately identifying licensing basis events, including Anticipated Operational Occurrences (AOOs), Design Basis Events (DBEs), Design Basis Accidents (DBAs), and Beyond Design Basis Events (BDBEs). This type of information should be captured in the SAR to ensure that changes to the plant are appropriately assessed under the applicable change process (e.g., 10 CFR 50.59) reflecting their status as methods of evaluation used in establishing the design bases or in safety analyses.</p>	Clarification and Exception	
4.1	Discussion of overall plant risk information found in the SAR	<p>Page 37 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document the need for a discussion of the following items where different from the analysis performed under Chapter 3:</p> <ul style="list-style-type: none"> • The site parameters (e.g. meteorology, off-site population distribution, EAB size) used in the analysis, • Assumptions on location of individual members of the public, • Source of dose (cloud shine, inhalation, ground shine) • The analysis method used, • Key assumptions (e.g., emergency preparedness measures, source terms, timing and duration of release, credit for medical treatment, early and latent fatality risk coefficients) used in the analysis, • Modes of operation (full power, low power & shutdown, refueling) considered in the analysis. • How multiple units on the site were considered, • Uncertainty/sensitivity analysis performed. 	Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
4.2.1	Guidance for DID evaluation	Page 40– Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that “For SSCs that are relied upon to perform DID prevention and mitigation functions for risk-significant LBEs, and where not described elsewhere in the SAR, this section should describe the set of requirements related to the performance, reliability, and availability of the SSC functions that are relied upon to ensure the accomplishment of their tasks, as defined by the PRA or deterministic analysis. This description should include how that capability is ensured through testing, maintenance, inspection and performance monitoring.”	Clarification	
4.2.1.4	Prevention-Mitigation Balance	Page 43 – ADAMS ML numbers or hyperlinks to referenced documents and reports should be added to promote efficient user interface with this guidance document.	Clarification	
4.2.2b	Guidance for programmatic DID added	Page 44 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that “The applicant should provide the justification for where the design does not incorporate the programmatic capability attributes provided in NEI 18-04 Table 5-6.” This text should be regular font.	Clarification	
4.2.2.2	Human Factors Considerations – SR SSC performance Monitoring	Page 44, Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to state that an applicant should include the description of programs to assure human performance for risk-significant functions should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, procedures, training and V&V, human performance monitoring (where not described in Chapter 6).	Addition	
4.2.2.3	Human Factors Considerations – NSRST SSC performance monitoring	Page 45, Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to state that an applicant should include the description of programs to assure human performance for safety-significant functions should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, procedures, training and V&V, human performance monitoring (where not described in Chapter 7).	Addition	
4.2.3b	Integrated defense in depth discussion in the SAR	Page 45 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that an applicant should address the following to describe how the integrated DID analysis meets the standards in NEI 18-04: “The applicant should summarize how the integrated DID process was applied in evaluating the overall adequacy of DID. The description should address how each of the decision guidelines listed in NEI 18-04, Section 5.9.3, was evaluated and the basis for an affirmative response. The criteria used in making the decisions (e.g., risk margins are sufficient, prevention/mitigation balance is sufficient, etc.) should be provided. If quantitative measures were used as part of the criteria, they should be provided. A description of how the results of the integrated DID process are documented and available for future DID decision-making and operations support should also be provided.”	Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
4.2.3c	Added guidance to include a description of the change process to defense in depth discussion found in the SAR	Page 46 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that an applicant should include a discussion of the change process associated with defense in depth analysis described in Section 4.2.3 of the NEI guidance document: "The change control process should be described addressing how the baseline DID evaluation will be re-evaluated, based on proposed changes, to determine which programmatic or plant capability attributes have been affected for each layer of defense. Changes that impact the definition and evaluation of LBEs, safety classification of SSCs, or risk significance of LBEs or SSCs should be assessed.	Clarification and Addition	
5.3	Principal Design Criteria (PDC)	<p>Page 47 and 48- considering whether following proposed addition is appropriate related to PDC guidance: "These LMP derived requirements may be considered together with generic applicable Advanced Reactor Design Criteria (ARDC) in formulating the principal design criteria for the license application. When considering the use of generic ARDC for this purpose, the LMP methodology does not include the application of the Single Failure Criterion (SFC) that is included in the ARDC language. In the LMP approach to formulating design requirements for SSCs, reliability and capability targets are used to inform the selection of special treatment requirements. This obviates the need to applying the SFC. Hence when ARDCs are considered in developing the principal design criteria, the SFC language should be removed."</p> <p>Last sentence, third paragraph proposed edits to be more consistent with stated NRC positions: However, the General Design Criteria and Advanced Reactor Design Criteria are intended to provide guidance in establishing the principal design criteria for non-LWR designs.</p> <p>Fourth paragraph proposed edits to be more consistent with stated NRC positions. Proposed revised paragraph</p>	Note – staff still developing position and path forward regarding PDC guidance. It is unclear at this point as to whether an exception, clarification or addition (or a combination of these) will be included in the staff TICAP RG	
5.5.1	Non Safety Related SSCs performing risk significant functions discussion in the SAR	Page 51 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to document that information similar to that found in Tables 5-1 and 5-2 for safety related SSCs should be provided for non-safety related SSCs performing a risk-significant function.	Addition	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
5.6a	Complimentary Design Criteria (CDC) discussion in the SAR	<p>Page 53 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper regarding CDC information that should be provided in the SAR, similar to the comments provided in an August 13, 2021, email that was discussed during an August 17, 2021, public meeting (see: https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML21225A565)</p> <p>This could include (a) the CDC are considered part of the affirmative safety case, since they specify safety criteria, (b) when they are defined at the functional level, they are considered equivalent to PDCs and (c) when they are defined at the PRA Safety Function level, they are considered subparts of a higher level PDC. In addition, the TICAP Guidance Document text should provide examples of both types of defined CDCs.</p> <p>The staff notes that the expectations regarding discussion of the CDC information in the SAR could be influenced by the outcome of the staff’s position regarding PDC.</p>	Clarification and Addition	
5.6b	CDC discussion in the SAR	Page 53 - Language should be added to clarify that NSRST SSCs may be included within the PDC rather than being limited to inclusion in the CDCs.	Clarification	
5.6c	CDC discussion in SAR	Page 53 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the importance and contribution of engineering criteria for the design will be considered under 10 CFR 50.35(a), as necessary, in the finding of reasonable assurance regardless of whether the NSRST SSCs are addressed by CDCs. The focus is on the engineering criteria for the design rather than inclusion of SSCs as part of CDCs or PDCs. It is clear from the LMP process that NSRST SSCs are necessary for either PRA Safety Functions or DID. Inclusion of CDCs may also bridge the gap between the NRC's expectation for an affirmative safety case and an LMP-based affirmative safety case which does not include normal operations (see comment in earlier Section A.3)	Clarification	
6.1.1b	Design Basis Hazard Level discussion in the SAR	<p>Page 56 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the SAR Should include discussion regarding the calculation methodology for DBHLS loads on the SSCs</p> <p>Calculation methodology has traditionally been part of the licensing basis. For example, where the methodology for combining loads is either ABSUM (absolute summation) or SRSS (square root of sum of the squares) can make a big difference for the design loads on SSCs. Also, there is a 50.59 question that specifically focuses on evaluation methodology. Not sure if this question will carry over to Part 53 but Part 50 and Part 52 applicants will need to consider it.</p>	Clarification	

NEI 21-07 Section Number ID	Topic	Discussion	Type	Disposition (i.e., addressed in NEI 21-07, Revision 1 or included in this RG)
6.1.1c	Design Basis Hazard Level discussion in the SAR	Page 56 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG white paper to clarify that an applicant should summarize the basis for the DBHLs in the SAR.	Clarification and Addition	
6.1.1d	Editorial correction to Table 6-1	Page 56 – verify that the table title and the second column heading should exclude the term “external.”	Clarification	
6.3/7.2	FOAK SR SSCs and NSRST SSCs	Page 60 and 63 – Text suggests incomplete Validation and Verification tests can be covered under special treatment at the submittal of a license application. Staff suggests an addition / revision to the text to include the timing of the NRC SER and the possibility of license conditions, consistent with 50.43(e).	Clarification and Addition	
6.4.1a	Human Factors Considerations – SR SSCs	Page 62 – Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that where human actions perform required safety functions, the description of controls and displays should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, and V&V.	Addition	
7.3.1a	Human Factors Considerations – NSRST SSCs	Page 65 - Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that where human actions perform PRA safety functions, the description of controls and displays should address human factors considerations such as operating experience review, safety function review, human action task analysis, human system interface design, and V&V.	Addition	
6.4.1b and 7.3.1b	Human Reliability and Capability	Pages 61 and 65 - These sections list the design aspects of the various SR and NSRST SSCs, including human actions. Further discussion is needed in either NEI 21-07, Revision 1, or the TICAP draft RG white paper to clarify that the applicant should describe the measures to be taken to ensure that the human actions meet their reliability and capability targets assumed in the PRA. For the reliability and capability of equipment, these measures are called Special Treatment.	Addition	
Appendix B	Example LBE Descriptions	The staff does not plan to endorse Appendix B “Example Descriptions” of NEI 21-07 because the agency does not endorse examples provided in guidance documents due to the need for technical review and approval.	Clarification	