Analysis of Public Comments on Draft Regulatory Guide DG-1404
Advanced Reactor Content of Application Project
"TICAP Reg. Guide"

Comments on draft regulatory guide DG-1404 are available electronically at http://www.nrc.gov/reading-rm/adams.html. From this page, the public can access the Agencywide Documents Access and Management System (ADAMS), which provides text and image files of the U. S. Nuclear Regulatory Commission (NRC) public documents. The following table lists the comments the NRC received on DG-1404.

Comment Number	ADAMS Accession Number	Commenter Affiliation	Commenter Name
NRC-2022-0073-DRAFT-0002	ML23167A020	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0074-DRAFT-0006	ML23234A039	Nuclear Energy Institute	B. Holtzman
NRC-2022-0075-DRAFT-0004	ML23234A052	X-energy	T. Chapman
NRC-2022-0073-DRAFT-0006	ML23278A033	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0073-DRAFT-0008	ML23278A067	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0073-DRAFT-0009	ML23278A036	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0073-DRAFT-0010	ML23284A384	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0073-DRAFT-0012	ML23284A388	Hybrid Power Technologies, LLC	M. Keller
NRC-2022-0073-DRAFT-0013	ML23284A389	Nuclear Energy Institute	B. Holtzman
NRC-2022-0073-DRAFT-0011	ML23284A386	NuScale	T. Griffith
NRC-2022-0073-DRAFT-0007	ML23278A034	Self	D. Henneke

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NRC-2022-0073 DRAFT 0002-1	Regulations.gov Site	Not Applicable	Include in regulations.gov, as downloadable files, all documents for which public comments are being solicited	The NRC staff responded to the request as documented in ML23174A004. The staff response states in part: "…the regulations.gov website identifies the documents (the ARCAP [advanced reactor content of

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				application project] ISGs [interim staff guidance] and the TICAP [technology inclusive content of application project] DG [draft guide]) for which the NRC staff is seeking public comment. While the Federal Register notices for the ARCAP ISGs reference NRC-issued, approved, or endorsed documents, the NRC staff is only requesting comment on the ARCAP ISG's proposed use of the referenced documents, and not the referenced documents themselves. As such, the NRC staff will not be providing documents referenced in the ARCAP ISGs on regulations.gov as this could imply that the NRC staff is seeking comments on these documents."
NRC-2022-0073 DRAFT 0002-2	Extension of Comment Period	Not Applicable	Alter the Federal Register notices to establish a reasonable, staggered schedule for document review and comment by the public.	The NRC staff responded to the request as documented in ML23174A004. As a result of this request and a request from the Nuclear Energy Institute (ML23171B098), the NRC staff extended the comment period for nine interim staff guidance documents and DG-1404, revision 0, from July 10, 2023, to August 10, 2023.
NRC-2022-0074-DRAFT-0006-1	LWR Applicability	General	There are statements in the draft regulatory guide that this guidance is applicable to non-Light Water Reactors (LWRs). However, the guidance is technology-inclusive and is equally applicable to both LWRs and non-LWRs. While NEI 18-04 and NEI 21-07 were developed specifically for advanced non-LWRs, applicants with LWR designs should also be able to use the Licensing Modernization Project (LMP) methodology if they elect to	The NRC staff disagrees with the comment. The stated applicability of the regulatory guide is limited to non-light-water reactors to reflect the limited scope of the guidance document that it is endorsing (NEI 21-07, "Technology Inclusive Guidance for Non-Light Water Reactor Safety Analysis Report: For Applicants Utilizing NEI 18-04 Methodology"). The staff acknowledges that the general approaches described in NEI 21-07 and NEI 18-04, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," are technology inclusive in footnote 2, which reads:

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			do so (e.g., NEI 18-04 and NEI 21-07). It would be up to the applicants to justify the use of the regulatory guide. Proposed Change Please rephrase to indicate the guidance is technology-inclusive and is equally applicable to both LWR and non-LWR designs.	The NRC encourages LWR applicants proposing to use the risk-informed, performance-based process described in NEI 21-07, Revision 1, to engage in pre-application discussions with the NRC to provide information to the staff on its intended implementation of the NEI 21-07, Revision 1 methodology for its design.
NRC-2022-0074-DRAFT-0006-2		General	The NRC states on page 6 that it "…endorses the methodology described in NEI 21-07, Revision 1 as one acceptable method for use in developing certain portions of the SAR for an application for a non-LWR CP or OL under 10 CFR Part 50, or COL, ML, SDA, or DC under 10 CFR Part 52, with clarifications and additions described below." However, NEI 21-07, Rev. 1 Section A.3 does not include an ML or an SDA in its scope. Also, the NRC provides no additional guidance for how an applicant would address an ML or an SDA. It is noted that industry expects ML or SDA guidance to be very similar to that of a DC. NRC should provide guidance on how the additional licensing pathways should be covered, i.e., the ML and SDA which are not explicitly addressed by NEI 21-07, Rev. 1.	The NRC staff partially agrees with the comment. The scope of license application types addressed by NEI 21-07 is a subset of the NEI 18-04 scope and is limited to the Combined License (COL), Construction Permit (CP), Operating License (OL), and Design Certification (DC) application processes. The Standard Design Approval (SDA) and Manufacturing License (ML) processes were not included in the scope of the NEI 21-07 approach being endorsed by this Regulatory Guide, even though they were included in the scope of NEI 18-04. On that basis, DG-1404 has been revised to more closely align with the scope of NEI 21-07. The affected portions of this guidance (Purpose and Applicable Regulations) have been revised to remove direct references to the SDA and ML processes. Footnote 1 in the document was revised to include the following sentence: "Applicants seeking to use the NEI 18-04 approach in the development of an application for an SDA or

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			Proposed Change Delete mention of ML and SDA as a covered approach in DG-1404 p. 1, paragraph 1; p. 6, paragraph 1; and p. 11, paragraph 1. In DG-1404 Section C on p. 11, add the following paragraph: NEI 21-07 explicitly addresses several licensing pathways: a combined license (COL) under 10 CFR Part 52 Subpart C; a design certification (DC) under 10 CFR Part 52 Subpart B; and a two-step license (CP/OL) under 10 CFR Part 50. Applicants using licensing pathways other than those explicitly covered in NEI 21-07 should base the SAR content on the licensing pathway covered by NEI 21-07 and most similar to the approach they are using. Applicants seeking a manufacturing license (ML) under 10 CFR Part 52 Subpart F or standard design approval (SDA) under 10 CFR Part 52 Subpart E should start with the guidance for a DC and make appropriate modifications. It will be up to the applicant to justify the guidance as applied.	ML should engage in pre-application dialogue with the NRC." In addition, the following has been added to the beginning of Section C, "Staff Regulatory Guidance": "NEI 21-07 explicitly addresses several licensing pathways: a combined license (COL) under 10 CFR Part 52 Subpart C; a design certification (DC) under 10 CFR Part 52 Subpart B; and a two-step license (CP/OL) under 10 CFR Part 50. An applicant using a licensing pathway other than one explicitly covered in NEI 21-07 may base the SAR content on the licensing pathway covered by NEI 21-07 and most similar to the approach it is using. For example, an applicant seeking a manufacturing license (ML) under 10 CFR Part 52 Subpart F or standard design approval (SDA) under 10 CFR Part 52 Subpart E may start with the guidance for a DC and make the necessary modifications to address its specific proposal and the applicable regulations. While such an approach reflects the similarity in the required contents of applications for the various licensing pathways in Parts 50 and 52, it will be up to the applicant to justify the guidance as applied and adjusted to address the scope of the application and to address the differences in the regulations for an ML or SDA application using the LMP methodology. As noted in Footnote 1, an ML or SDA applicant seeking to use RG 1.253 [Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications,

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				and Approvals for Non-Light-Water Reactors] guidance should engage in a pre-application dialogue with the NRC." It is also recognized that key considerations and attributes of the SDA and ML processes may closely align with the SAR content descriptions reflected in NEI 21-07 for other application types, with some variations associated with the details of the individual applicant's SDA or ML licensing strategy. Therefore, NRC has included guidance in selected portions of the ARCAP ISGs in response to industry comments in those areas to facilitate the development of SDA and ML application content, and to support the pre-application dialogue reflected in footnote 1.
NRC-2022-0074-DRAFT-0006-3	ML & SDA Applicability	Purpose and Applicable Regulations	As noted in NEI 21-07 and DG-1404, the application should address the site description. However, for an ML, this is not possible. Rather, site related information can only be provided in terms of postulated site parameters. Text should be added to this effect. <u>Proposed Change</u> Please add text similar to the following: For an ML application the site description should describe the site characteristics as they affect the design, e.g., a site parameter envelope. Other site characteristics	The NRC staff acknowledges the comment but notes that the scope of the RG has been clarified to exclude MLs. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.

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			are left to the COL applicant to provide as well the site-specific information necessary to demonstrate that site characteristics fit within the plant parameter envelope.	
NRC-2022-0074-DRAFT-0006-4	ML & SDA Applicability	2 – Plant and Site Description	For an ML application, only those items specified in C.2.e that would impact the design or its manufacture should be included. The other items should be included in the COLA. Proposed Change Please add text similar to the following: For an ML application, only those items identified in C.2.e (1) and (3) that are relevant to the design or manufacture of the reactor need to be included. However, the RGs applicable to the design as noted in (2) should be included in the ML application. All other information identified in (1) and (3) is left to the COL applicant to provide.	The NRC staff acknowledges the comment but notes that the scope of the RG has been clarified to exclude MLs. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.
NRC-2022-0074-DRAFT-0006-5	ML & SDA Applicability	3 – Methodologies, Analyses, and Site Evaluations	The site discussion in Section 3 is relevant to an OL or COL, but the ML applicant cannot address site-specific information. A caveat should be added that makes clear the ML applicant need only address information directly related to the design, leaving site-related	The NRC staff acknowledges the comment but notes that the scope of the RG has been clarified to exclude MLs. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.

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			information and analyses to the COL applicant. Proposed Change Please add text similar to the following: ML applicants should address methodologies and analyses specific to the design and manufacture of the reactor. All other information, including site evaluations that cannot reasonably be addressed through a plant parameter approach, are left to the COL applicant.	
NRC-2022-0074-DRAFT-0006-6	ML & SDA Applicability	4 – LBEs and Other Events	Although ML applicants may identify and provide relevant information on design features that may be useful to applicants to address the requirements for aircraft impact assessments or mitigation of beyond-design-basis events, ML applicants do not need to address these requirements. Instead, a COL or CP/OL applicant referencing an ML should address these topics. For an ML applicant, the additional material noted in C.4.c (1) Aircraft impact assessments and (2) Mitigation of beyond design-basis events should be left to the COLA. Proposed Change	The NRC staff disagrees with the comment. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2. In addition, because of this comment the NRC staff has identified a need to revise the ARCAP Roadmap Appendix B (applicability of regulations) to address the incorrect statement embedded in this comment related to the applicability of 10 CFR 50.150 as it applies to manufacturing licenses (MLs), design certifications (DCs), and standard design approvals (SDAs). Specifically, the NRC staff disagrees with the comment that ML applicants do not need to address aircraft impact assessment requirements found in 10 CFR 50.150. As stated in the applicability portion of 10 CFR 50.150 and as noted in RG 1.217, “Guidance for the Assessment of Beyond-Design-Basis Aircraft

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			Please add text similar to the following to C.4.c: ML applicants do not need to address aircraft impact assessments or mitigation of beyond-design-basis events. A COL applicant referencing an ML should address these topics.	Impacts," the aircraft impact rule applies to applicants for new construction permits (CPs); new operating licenses that reference a new CP, new DCs, new SDAs; MLs that do not reference a standard DC or SDA; and combined licenses that do not reference a DC, SDA, or manufactured reactor. As a result of this comment, the NRC staff is changing the applicability of regulations portion found in the ARCAP roadmap ISG appendix B for 10 CFR Part 150 from Yes (CP/OL/COLs) to simply "Yes" to reflect that the applicability of this regulation is broader than CPs/Ols/COLs that the draft version of the roadmap ISG implies.
NRC-2022-0074-DRAFT-0006-7	ML & SDA Applicability	5 – Integrated Evaluations	It is generally not possible for an ML applicant to perform the Integrated Evaluations. The evaluations of Chapter 5 should be left to the COL applicant. The exception is evaluation of defense-in-depth adequacy that is specific to design attributes for the manufactured reactor. Other aspects of the defense-in-depth (DID) adequacy should be left to the COL applicant. <u>Proposed Change</u> Please add text similar to the following to Chapter 5: An ML applicant need only address DID adequacy in terms of plant capability. All other information	The NRC staff disagrees with the comment. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.

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			required under Chapter 5 is left to the COL applicant.	
NRC-2022-0074-DRAFT-0006-8	ML & SDA Applicability	6 – Design Criteria	The PDC relevant to an ML do not include construction nor all aspects of testing since some of the testing is relevant to the installed manufactured reactor. Proposed Change Please add text to C.6.a (1), after the first sentence: ML applicants need only propose PDC to establish necessary design, fabrication, and performance requirements. PDC relevant to testing as part of the manufacturing process should also be included. However, a COL applicant should include all of the PDC in their SAR.	The NRC staff disagrees with the comment. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.
NRC-2022-0074-DRAFT-0006-9	ML & SDA Applicability	9- Plant Programs	ML applicants, similar to CP applicants, can only address Plant Programs to the extent that they are needed to implement special treatments and meet reliability and performance targets for safety related (SR) structures, systems, and components (SSCs) and non-safety related with special treatment (NSRST) SSCs. Proposed Change	The NRC staff acknowledges the comment but notes that the scope of the RG has been clarified to exclude MLs. Refer to the response to comment NRC-2022-0074-DRAFT-0006-2.

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			Please revise the penultimate sentence in the first paragraph under Section 9 to read: "Construction permit and Manufacturing License applications…."	
NRC-2022-0074-DRAFT-0006-10	TICAP Scope		The penultimate sentence of the first paragraph on p. 6 does not appropriately capture the scope of NEI 21-07. TICAP is much broader than "… describing the scope and level of detail for the fundamental safety functions of a design necessary for developing the safety analysis for the design." Similarly, the first sentence of the fifth full paragraph of p. 7 is too narrow in its description of TICAP; NEI 21-07 goes well beyond addressing "…the portions of the SAR that describe the fundamental safety functions of the design." It is important to explicitly tie NEI 21-07 back to NEI 18-04. <u>Proposed Change</u> On p. 6, change the penultimate sentence of the first paragraph to read "The technology inclusive methodology of NEI 21-07, Revision 1, provides a common approach to the development of those portions of the SAR that address the implementation of the	The NRC staff agrees with the comment, and made the following changes: The page 6 content is expanded to better align with the NEI 21-07 scope summary reflected in the Executive Summary of NEI 21-07, Rev. 1, and with the change proposed to resolve this comment, as follows: "The technology-inclusive methodology in NEI 21-07, Revision 1, provides a common approach to ~~identifying and describing the scope and level of detail for the fundamental safety functions of a design necessary for developing the safety analysis for the design~~ the development of those portions of the SAR that reflect the outcomes and insights from the implementation of the Licensing Modernization Project (LMP) methodology as described in NEI 18-04, Revision 1, and endorsed by the NRC in Regulatory Guide 1.233." This same change was applied to the similar text on page 7.

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			Licensing Modernization Plan (LMP) methodology as described in NEI 18-04, Revision 1, and endorsed by the NRC in Regulatory Guide 1.233 ["Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors"]." On p. 7, change the first two sentences of the fifth full paragraph to the following single sentence: "TICAP is an industry-led guidance activity focused on the scope and depth of information to include in the portions of the SAR that address the implementation of the LMP methodology as described in NEI 18- 04, Revision 1, and endorsed by the NRC in Regulatory Guide 1.233."	
NRC-2022-0074-DRAFT-0006-11	Editorial		Typo in 4th full paragraph. "...an SAR that includes..." should be "… a SAR that included..." Proposed Change Please change as noted.	The NRC staff disagrees with the comment and has revised to "an SAR" throughout the RG.
NRC-2022-0074-	Application Scope	B - Background	The last sentence in the 4th full paragraph is confusing. It mentions "… a SAR that includes technical specifications, an emergency plan,	The NRC staff agrees in part with the comment, and has updated the sentence to be consistent with the description associated with Figure 1, and the

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DRAFT-0006-12			and other information such as physical security plans." Technical specifications are technically part of the license, not the SAR. The other documents are typically submitted separately, not as part of the SAR. Proposed Change Please change to "… a complete non-LWR application should include, among other things, a SAR, proposed technical specifications, an emergency plan, and other information such as physical security plans."	discussion in the ARCAP roadmap ISG, to include a footnote as follows: "Requirements for the contents of a final safety analysis report (FSAR) are provided in 10 CFR 50.34(b) and include items such as proposed technical specifications and emergency plans, as well as other technical and programmatic contents listed there. It should be noted that items such as technical specifications and emergency plans may be incorporated by reference in the FSAR and subsequently controlled by change processes other than 10 CFR 50.59 for OLs. For example, changes to the technical specifications, which are part of the license, require a license amendment, and emergency plan changes are controlled by 10 CFR 50.54(q).
NRC-2022-0074-DRAFT-0006-13	Normal Operation	2 – General Plant and Site Description	Addition C.2.b is unnecessary. NEI 21-07, Sections A.1 and A.3, make it amply clear that the information addressed in NEI 21- 07, Rev 1, is not the totality of the information required of the applicant. Moreover, the ARCAP Roadmap ISG reinforces the point. It is simply not credible that an applicant would be unclear on this point. Proposed Change Please delete Addition C.2.b.	The NRC staff agrees with the comment in part. The staff disagrees that NEI 21-07 Section A.1 is sufficient to address this topic. NEI 21-07 Section A.3 makes mention of the exclusion of normal operations in its discussion of the affirmative safety case concept, while also acknowledging that "…*this TICAP guidance pertains to most of the content in Chapters 1 through 8*…" The existing DG-1404 text will be retained as a clarification as opposed to an addition, to promote a thorough understanding of the expected SAR content, including descriptions related to normal operations, where applicable.
NRC-2022-0074-	LMP Alternatives	2 – General Plant and Site Description	Addition C.2.c is unnecessary. It provides guidance to "… non- LWR applicants pursuing a CP under 10	The NRC staff agrees with the comment. The guidance is focused on applications based on NEI 18-04 and NEI 21-07 and therefore the addition

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DRAFT-0006-14			CFR Part 50 using a risk-informed, performance-based approach other than the LMP …" Such an applicant is clearly beyond the scope of NEI 21-07, which was developed for applicants using LMP (see NEI 21-07 Section A). It does not make sense for a regulatory guide endorsing NEI 21-07 to also attempt to address all possible deviations from NEI 21-07. NEI 21-07 Section C.1.3.1 places the onus on the applicant which deviates from NEI 18- 04 to address and justify those deviations. Proposed Change Please delete Addition C.2.c.	for other approaches is not needed. Based on this the NRC staff has removed Addition C.2.c.
NRC-2022-0074-DRAFT-0006-15	Inventory of Radioactive Materials	2 – General Plant and Site Description	Addition C.2.d is unnecessarily prescriptive. Industry does not contest the requirement for providing the information, but would like the flexibility of putting it in Chapter 2 if more appropriate for a particular applicant. Proposed Change Please add the following to C.2.d: "… radioactive materials either along with the intended use of the reactor in Chapter 1 or in Chapter 2."	The NRC staff agrees in part with the comment. This addition is revised as follows: "In addition to the information identified in NEI 21-07, Revision 1, Section C.1.1.2, on intended use of the reactor, applicants should also provide the nature (e.g., physical form) and inventory of contained radioactive materials in Chapter 1 or other appropriate sections of the SAR." This would allow the inventories for normal operational issues (e.g., normal effluents from waste systems) to be in SAR Chapters 9 or 10 and core inventories or other licensing basis event (LBE) issues to be in Chapter 2 (or others) and hopefully

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				align the content with the licensing reviews. If it is deemed important to keep this in Chapter 1, pointers to other sections to minimize duplication would be acceptable to the NRC staff.
NRC-2022-0074-DRAFT-0006-16	Applicability of Generic Issues	2 – General Plant and Site Description	Industry has concerns with both the letter and the spirit of Addition C.2.e, which would levy substantial documentation requirements that are largely not applicable to non-LWRs, thereby complicating the development of an application and the subsequent staff review. With respect to Item (1), generic safety issues, unresolved safety issues, and TMI action items are largely LWR-centric and not applicable to advanced non- LWRs; there should be no presumption to the contrary. There is no regulatory requirement that applicants address LWR GSIs and USIs in the SAR. The regulatory requirement to address TMI requirements in 10 CFR 50.34(f) is applicable only to LWRs. 10 CFR 52.47(a)(8) invokes most of the TMI requirements in 10 CFR 50.34(f) to the extent they are “technically relevant.” This term, as well as the terms "technically applicable to the design" and “directly applicable to the design” used in DG-1404 Addition C.2.3, are undefined and subjective, and will be fertile ground for interpretation disagreements	The NRC staff partially agrees. As a result of the comment the NRC staff has removed addition C.2.e from RG 1.253 and added this guidance to the ARCAP roadmap ISG. The NRC staff finds the information provided in this addition is appropriate to include in summary form in the SAR. The NRC notes that in accordance with the concepts in NEI 21-07, Revision 1, RGs and consensus codes and standards that are applicable to the outcomes derived from the LMP process should be discussed in the applicable portions of the SAR that are derived from the LMP process. Regarding the applicability of 10 CFR 50.34(f) to non-LWRs, the ARCAP roadmap guidance will continue to include a reference to ARCAP Roadmap ISG Appendix B on applicability of regulations. Appendix B, Table 1, notes that 10 CFR 50.34(f) does not apply to applications under 10 CFR Part 50 but includes a footnote that provides a clarification regarding the need for the staff to ensure that an applicant addresses the technically relevant TMI-related items during the review process and propose license conditions requiring the appropriate items in the interim while the Commission is considering rulemaking on this issue. Regarding the discussion of providing a listing of consensus codes and standards in summary form, the

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			between applicant and regulator. At most, the TMI requirements should be applied only to Part 52 applicants. NRC expectations from LWR licensing experience should not be applied blindly to advanced reactors following NEI 18-04 guidance. In fact, applying LWR GSIs, USIs, and TMI action requirements to non-LWR advanced reactors stands the concept of risk-informed, performance-based regulation on its head. It adds an unnecessary backward-looking deterministic framework on top of the systematic evaluation of safety provided by NEI 18-04. With respect to Item (2), regulatory guides are not regulatory requirements and most were developed for light water reactors. There should be no presumption that regulatory guides are to be applied to non- LWRs, and the NRC should be clear on that point in its guidance. The NEI 18-04 approach to demonstrating safety is not centered around a deterministic checklist approach of following prescriptive guidance. If the NRC insists on including a requirement that the applicant catalog items like reg guides in Chapter 1 of the SAR, that guidance should make it clear	NRC staff notes that this guidance is consistent with the guidance found in the ARCAP roadmap ISG Appendix A for preapplication activities that a prospective applicant should identify any consensus codes and standards or code cases that have not been endorsed or previously accepted by the staff.

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			that the Chapter 1 material is simply a list of items included by the applicant in subsequent sections of the SAR. The discussion relative to Item 3 (codes and standards) is similar. Codes and standards will be addressed in appropriate sections of the SAR. If the NRC insists on including lists of codes and standards in Chapter 1 of the SAR, it should be with the understanding that any substantive information is reserved for later chapters. <u>Proposed Change</u> Please delete Addition C.2.e. However, if the addition is retained, to the extent the NRC uses terms like "technically relevant" and "directly applicable to the design," clarify that the NRC does not presume applicability of LWR regulatory guidance to non-LWRs following the NEI 18-04 methodology. Furthermore, if the NRC insists that applicants provide lists of documents in Chapter 1 (e.g., regulatory guides and/or codes and standards), make it clear that those lists are simply catalogs of material addressed elsewhere in the SAR.	
NRC-2022-0074-	PRA Guidance	3 - Methodologies	Paragraph 5 states "The NRC staff notes that additional guidance is being considered for development	The response to this comment relates to the comment response for NRC-2022-0074-DRAFT-0006-38, and NRC-2022-0074-DRAFT-0006-39.

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DRAFT-0006-17			that would supplement the guidance in RG 1.247 ["Acceptability of Probabilistic Risk Assessment Results for Non-Light Water Reactor Risk-Informed Activities"]. Appendix A of this document identifies guidance that is being considered for development that could result in a revision of this Draft RG." These sentences are speculative and do not provide useful guidance to an applicant. Appendix A stands on its own and does not need specific mention with respect to the PRA. In the interest of removing superfluous and unnecessary material, these sentences should be deleted. If additional guidance is promulgated and deserves mention in a particular reg guide, that reg guide may be revised at the appropriate time. <u>Proposed Change</u> Please delete sentences 2 and 3 of paragraph 5.	The NRC staff agrees and has removed these sentences from RG 1.253 because the information does not directly relate to NRC's endorsement of NEI 21-07. However, the material in these two sentences has been included in the ARCAP Roadmap ISG for applicant awareness.
NRC-2022-0074-DRAFT-0006-18	Documents Incorporated by Reference	3 - Methodologies	Clarification C.3.a is not necessary. It addresses separate licensing documents that are incorporated by reference in the SAR, and states that NEI 21-07, Rev. 1, does not address them. In fact, NEI 21-07 does address them thoroughly in Section B.3, which includes a reference to	The NRC staff agrees with the comment. Clarification C.3.a is deleted. Items C.3.b through C.3.h will be renumbered.

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			NEI 98-03, Rev. 1, for additional information. Moreover, this "clarification" should not be specific to Section C.2 of NEI 21-07. If the clarification was actually needed, it should be applied generically to the entire SAR. However, as noted above, it is not needed because NEI 21-07 Section B.3 already addresses the issue generically for the entire SAR. Proposed Change Please delete Clarification C.3.a.	
NRC-2022-0074-DRAFT-0006-19	Non-LMP Option	3 - Methodologies	Clarification C.3.c(2) (i.e., Option 2) uses undefined terms "bounding DBA" and "bounding BDBE." It also refers to "the bounding DBA" (presumably there is one bounding DBA) and "a bounding BDBE," which implies there are more than one bounding BDBE. Proposed Change Please provide additional clarity on the meaning and use of the terms.	The NRC staff disagrees with the comment. The term bounding in the context of this option refers to the estimated doses at the boundary of the exclusion area/low population zone or in the control room. This is clear from the context of the discussions being related to dose consequences for use in assessing related regulatory requirements. The distinction between "the bounding design basis accident (DBA)" and "a bounding beyond-design basis event (BDBE)" was intentional to address the potential that BDBEs may include event sequences more severe than a major accident as defined in 10 CFR 50.34 and 10 CFR 52.79. As described in the existing text, Option 2 would only call for consideration of BDBE event sequences meeting the description of a major accident. No change has been made to DG-1404.

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NRC-2022-0074-DRAFT-0006-20	Non-LMP Option	3 - Methodologies	In Addition C.3.c the staff provides two options for demonstrating the facility meets the requirements of 10 CFR 50.34(a)(1)(ii)(D) or 10 CFR 52.79(a)(1)(vi) and the PDC for the control room (if applicable); however, it does not appear that these two options are the totality of options with respect to the staff's expectations for an assumed "major accident." Given the design of the plant and its safety features, when using the NEI 18-04 approach there may be no DBA or BDBE that would be considered a "major accident" due to lack of fuel damage or release. In this case, is it the NRC's expectation that the applicant must request an exemption in accordance with Option 1? Could an alternate approach (Option 3) be pursued by postulating a specific event only for the purposes of satisfying the "major accident" definition? It would appear this approach would satisfy regulations, but this is not provided as an option in DG-1404. There may be other alternatives as well, and the guidance should not foreclose them. The current wording ("… the applicant has two options …") seems to indicate the applicant must choose either Option 1 or Option 2.	The NRC staff agrees with the comment. Applicants could possibly develop other options, including the assessment of a stylized event meeting the description of a major accident. The guidance has been revised to read: ~~To confirm to this guidance, the applicant has two~~ Although an applicant is free to propose different approaches, two possible options for addressing these assessments based on the outcome of the LMP approach include:

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			Proposed Change Please revise the text to allow for Option 3 and clarify that applicants are free to propose approaches other than the stated options.	
NRC-2022-0074-DRAFT-0006-21	Radionuclide Sources	3 - Methodologies	There is a nuance associated with Addition C.3.d. Industry agrees with the addition of "Identification of the sources of radionuclides addressed and the sources of radionuclides that were screened out" to the items from the Section C.2.1.1 list that should be addressed in a CP application. The nuance is that excluding items from the scope of the CP PRA is not the same as screening them out. Some sources may be excluded at the CP stage but included later. Proposed Change Please insert the new penultimate sentence in the addition as shown below. "It is noted that sources outside the scope of the CP PRA and therefore not listed in the PSAR [preliminary safety analysis report] may then become part of the PRA scope, and at that point they may or may not be screened out for the purposes of the OL PRA description. As noted above..."	The NRC staff disagrees with the comment. Addressing identified radionuclide sources via implementation of guidance in NEI 18-04, Revision 1, and NEI 21-07, Revision 1, may involve a combination of PRA logic modeling, screening methods, risk-informed supplemental evaluations, and crediting design-basis hazard levels. As such, a radionuclide source that is either not modeled or screened out of the CP probabilistic risk assessment (PRA) (i.e., not included in the scope of the PRA) may be addressed via such other methods. Although design information at the time of the construction permit application is preliminary, all sources of radionuclides need to be addressed in the CP application as per 10 CFR 50.34(a)(1)(ii)(A), unless a radionuclide source can otherwise be justified to meet item (2) of 10 CFR 50.35(a) that further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report. No change has been made to DG-1404.
NRC-2022-	PRA Maturity at CP Stage	3 - Methodologies	Clarification C.3.e is unnecessary. The NEI 21-07 guidance makes it	The NRC staff does not agree that Clarification C.3.e found in DG-1404 revision 1 should be deleted. Note

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0074-DRAFT-0006-22			clear that the description of the PRA in the PSAR goes beyond the "simple statement." NEI 21-07 states the "simple statement" applies only to the eventual qualification of the PRA at the OL stage, and not to the totality of PRA-related documentation for the PSAR. NEI 21-07 goes on to address clearly what documentation is needed (beyond the "simple statement") for the CP. The NEI 21-07 guidance states "In either case, the applicant should ..." so there is no ambiguity. In fact, the NRC states in its clarification "As noted in NEI 21-07..." The existing guidance in NEI 21-07 already addresses peer review and CP documentation - no further clarification is needed related to the "simple statement." Proposed Change Please delete Clarification C.3.e.	that as a result of comments, DG-1404, Revision 1, items C.3.a and C.3.f were deleted and the section was renumbered accordingly. The text below notes the changes based on the numbering in DG-1404, Revision 1, in order to better address the comment that was based on the DG numbering scheme. However, the NRC staff agrees that some of the text is redundant to the content of NEI 21-07 and the statement at the end of DG-1404 Clarification C.3.d should be moved to the end of DG-1404 Clarification C.3.e because it is more pertinent to the context of the latter clarification. As such, the last sentence was moved and DG-1404 Clarification C.3.e has been revised as follows: "C.3.e ~~Clarification~~: ~~Section C.2.1.1 of NEI 21-07 states that "At the CP stage, neither the plant design nor the PRA is expected to have the level of maturity that will be necessary to support an OL application. At the CP application stage, the applicant should describe its ultimate intended approach for qualifying the PRA. If conformance to ASME/ANS RA-S-1.4-2021 is planned, a simple statement to that effect should be sufficient." The "simple statement" is only regarding the commitment to conform to ASME/ANS RA-S-1.4-2021 at the OL stage. The description or a summary of PRA in a CP application, however, is broader than a simple commitment to the standard.~~ As noted in Section C.2.1.1 of NEI 21-07, a CP applicant should describe the attributes of the PRA in the application. In addition to these attributes, as amended by position C.3.d above, the CP application should also discuss

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				topics such as the PRA's conformance to RG 1.247 for trial use, and NEI 20-09, if a peer review is performed at the CP stage. Appendix A of this RG 1.253, Revision 0, provides additional guidance on demonstrating the acceptability of the PRA supporting the CP application."
NRC-2022-0074-DRAFT-0006-23	PRA Guidance	3 - Methodologies	Clarification C.3.f is unnecessary. The "Note" is clearly part of, and applies to, the main section of NEI 21-07 C.2.1.1, which is the baseline guidance for a Part 50 operating license and a Part 52 combined license. Obviously, the note does not apply to the section below it, which addresses CP content. Proposed Change Please delete Clarification C.3.f.	The NRC staff agrees that Clarification C.3.f is not necessary, and it has been deleted. Subsequent items (g-h) were renumbered. "C.3.f ~~Clarification: Section C.2.1.1 of NEI 21-07 states that "Note: This guidance document does not address SAR content for a PRA that has not been peer reviewed using the non-LWR PRA standard. In such an instance, the information to be provided on the PRA, either in the SAR or other documentation, may be more extensive than the guidance provided herein." NEI 21-07, Revision 1, however, addresses the SAR content for a CP application for which no peer review has been performed; accordingly, this Note should be applied only to SAR content for applications other than a CP application.~~" It's recognized that the "Note" referred to in this comment is generally applicable to applicants utilizing either the Two-Step Licensing or the Design Certification approaches. In addition, the Two-Step Licensing portion of Section 2.1.1 from NEI 21-07, Rev. 1 provides additional guidance regarding the need for PRA peer review if an applicant is requesting design finality for any design feature or specification within the CP application.
NRC-2022-	DBHL and DID Clarifications	3 - Methodologies	The information in numbered items (1), (2), and (3) under Addition	The NRC staff partially agrees with the comment.

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0074-DRAFT-0006-24			C.3.g is a restatement of material in NEI 18-04 and NEI 21-07 and it is not clear why it needs to be restated in the regulatory guide. Similarly, the first sentence of the last paragraph is a restatement of NEI 18-04 information and is not needed in the regulatory guide. Moreover, the statement in the sentence that special treatments will be determined by an integrated design process panel (IDPP) is not an accurate depiction of the NEI 18-04 and NEI 21-07 text. NEI 18-04 allows for IDPPs but does not mandate them. <u>Proposed Change</u> Please address the issues raised in the comment as noted, i.e., remove the numbered items and delete the first sentence of the last paragraph.	Item (1) of Addition C.3.g is adequately addressed in NEI 21-07 and, thus, does not need to be repeated. However, items (2) and (3) are not clearly described in NEI 21-07 and, therefore, these items will remain in the ISG. Addition C.3.g, item (1) below was deleted and items (2) and (3) were renumbered and changed from an addition to a clarification. "~~(1) SR SSCs must be protected from or designed to withstand the corresponding DBHL with no adverse impact on their ability to perform their required safety functions (RSFs),~~" Additionally, to improve alignment with NEI 18-04, the last paragraph in Addition C.3.g is revised to read: "~~Determination of these special treatments for NSRST SSC will be made by the integrated design process panel (IDPP) in accordance with NEI 18-04 and RG 1.233.~~ The draft ARCAP ISG. DANU-ISG-2022-02, "Site Information," (Ref. 26), contains additional guidance on one acceptable approach to determining the scope and level of detail of the site information to be provided."
NRC-2022-0074-DRAFT-0006-25	Licensing Basis Change Control	3 - Methodologies	Addition C.3.h is unnecessary and overreaching. First, the term "analysis and calculation methodologies" is not clearly defined. It could refer to anything that involves a calculation. The SAR is not the compendium of all	The NRC staff partially agrees with the comment. The addition is intended to capture methodologies that would typically be used in establishing the design bases of SSCs as needed to fulfill the required contents of application in 10 CFR 50.34(a)(3), 10 CFR 52.47(a)(3), and 10 CFR 52.79(a)(4). Appendix

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			analyses and calculations related to a nuclear power plant, but this additional guidance in DG- 1404 could be interpreted that way. It should be noted that NEI 21-07 already contemplates SAR Chapter 2 as a home for analyses such as site related information and analyses used to develop the design basis hazards levels (DBHLs) (see last paragraph of C.2 introduction on NEI 21-07). Moreover, the NRC addition was not discussed during the extensive interactions preceding the submittal of NEI 21-07. It defeats the purpose of SAR Chapter 2 as intended in NEI 21-07. SAR Chapter 2 was never intended to be the mandatory home of all analyses and calculation methodologies. Industry intended Chapter 2 primarily as a repository of convenience for cross-cutting information or evaluations (see first paragraph of the C.2 introduction on NEI 21-07). This concept was clearly communicated to the NRC, and the NRC raised no objection at the time. If retained and followed, Addition C.3.h would prevent applicants from describing analyses for a particular design basis accident (not repeated elsewhere) where it most logically belongs - i.e., in SAR	B to NEI 97-04, *Guidance and Examples for Identifying 10 CFR 50.2 Design Bases*, provides examples of design basis information for SSCs and topics. For clarity, addition C.3.h is revised to read: "In addition to the information that NEI 21-07, Revision 1, states applicants should include in SAR Chapter 2, applicants should identify and describe the cross-cutting ~~non PRA~~ engineering analyses ~~analysis~~ and ~~calculation~~ methodologies used to establish their ~~licensing~~ design bases or to confirm that intended safety functions will be fulfilled. ~~A change to any of the evaluation methodologies used in the licensing basis is one of the criteria in the existing facility change process (e.g., 10 CFR 50.59); therefore, for the facility change process to be effective, the licensing basis needs to describe these evaluation methodologies."~~

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			Chapter 3, with the DBA description. <u>Proposed Change</u> Please delete Addition C.3.h.	
NRC-2022-0074-DRAFT-0006-26	LBE Selection	4- Licensing Basis Events	The introductory section of addition and clarification C.4.a is confusing and does not provide clear guidance. It is counter to the discussions in 2021 and 2022 about documenting dose calculations performed in the PRA. NEI 21-07 contained modifications to Section C.2.1.1 intended to address the NRC's desire to see documentation of the PRA methodology for calculating doses associated with anticipated operational occurrences (AOOs), design basis events (DBEs), and beyond design basis events (BDBEs). In fact, Clarification C.4.b states that the guidance in C.2.1.1 is adequate for the purpose – so why is Clarification C.4.a needed at all? If the applicant's information provided in SAR Chapter 2 on this aspect of the PRA is not adequate, it should be addressed in the review of that applicant's application, not in this guidance. <u>Proposed Change</u> Please delete Addition and Clarification C.4.a.	The NRC staff partially agrees with the comment. This addition and clarification C.4.a were intended to address the need for a description of models, site characteristics, and supporting data as associated with the calculation of the mechanistic source terms and radiological consequences. For a description of models, NEI 21-07 Section 2.1.1 already states that "Discussion of the software and analytical tools that were used to perform the event sequence modeling and quantification, determine the mechanistic source terms, and perform radiological consequence evaluations… The discussion should include identification of the methods and a high-level description of how they are applied to the radiological consequence evaluation." For a description of site characteristics, NEI 21-07 Section 2.1.1 already states that "Description of the site characteristics modeled or assumed in the radiological consequence evaluations covered by the previous bullet." For a description of supporting data, the NRC staff has determined that a clarification is needed as discussed below for C.4.a(1).

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				As a result, the introductory section of addition and clarification C.4.a and C.4.a(1) are revised as follows: a. Addition and Clarification: The discussion of AOOs, DBEs, ~~DBAs,~~and BDBEs in Chapter 3 of the SAR should include 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 that such information does not appear in the discussions of methodologies and analyses in Chapter 2, the descriptions of systems and functions in Chapters 5–7, or other sections of the SAR). ~~Other additions/clarifications related to this topic include:~~ ~~(1) The supporting data should include the data that is significant to determining whether the frequency-consequence targets and quantitative health objectives (QHOs) are met and the development of the analysis conclusions on risk significance, SSC classification, or DID adequacy.~~
NRC-2022-0074-DRAFT-0006-27	LBE Guidance	4- Licensing Basis Events	C.4.a(1) is not clear. What "supporting data" is desired here? It's not clear what information is being requested and whether that information would already be reviewed during a PRA audit. Can the NRC provide any specific examples of what is sought or provide the analogous information for a LWR SAR? The intent of the modifications provided in NEI 21-07, Rev. 1 to C.2.1.1 was to spell out	The NRC staff partially agrees with the comment. Regarding a description of supporting data, NEI 21-07 Section 2.4, "Other Methodologies and Analyses," states that "The applicant should address the applicability of the analytical methodology to the specific analysis, including *a discussion of supporting data*." NEI 21-07 Sections 3.3.1, 3.4.1, and 3.5.1 states that "Details on the models, site characteristics, and supporting data associated with the calculation of

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			the necessary and sufficient information. Clarification C.4.b indicates that NEI 21-07 subsection C.2.1.1 is adequate which conflicts with this Addition and Clarification C.4.a(1). Moreover, SAR Chapter 3 is not the appropriate place to address quantitative health objectives (QHOs). They are covered in SAR Chapter 4. <u>Proposed Change</u> Please delete Addition and Clarification C.4.a(1).	probabilities, mechanistic source terms, and radiological consequences are part of the PRA documentation that is included in the plant records." NEI 21-07 Section 3.5.1 states that "For each DBA, the following information should be provided: • For DBAs that involve a release of radionuclides, *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)" For consistency, a description, not details, of supporting data should be discussed for AOOs, DBEs, and BDBEs. See the revision discussed in the previous item (NRC-2022-0074-DRAFT-0006-26), which included the deletion of the details of C.4.a(1) while keeping the general clarification that the application should include a description of supporting data.
NRC-2022-0074-DRAFT-0006-28	LBE Clarifications	4- Licensing Basis Events	Clarifications C.4.a(2), C.4.a(3), and C.4.a(4) are all unnecessary. With respect to AOOs, the guidance in Section C.3.3.1 states "The following information should be provided for any AOO with a release." A bulleted list follows. There is no possible interpretation that the information is not required. However, the NRC clarification is that all of the information be provided. The clarification is	The NRC staff agrees that the "all of the information" text is not necessary to clearly describe the expected SAR content resulting from the application of the associated guidance in NEI 21-07. The guidance was revised to delete Clarifications C.4.a(2), C.4.a(3), and C.4.a(4) as follows to address this comment: "~~(2) For Section C.3.3.1 of NEI 21-07, Revision 1, the staff clarifies that for any AOO with a release, all of the information in the second bulleted list on NEI~~

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			completely unnecessary. With respect to DBEs and BDBEs, the same logic applies. The words in Section C.3.4.1 states for DBEs: "For the most limiting DBE that was used to map into each DBA ... the following information should be provided." The NRC clarification that "... all of the information ... should be provided" is superfluous and unnecessary. Similarly, the words in Section C.3.5.1 for BDBEs are "The information below should be provided for any high consequence BDBEs ..." The NRC's admonishment that "all of the information ... should be provided" is again unnecessary. <u>Proposed Change</u> Delete Clarifications C.4.a(2), C.4.a(3), and C.4.a(4).	~~21-07 page 33 should be provided in addition to the information in the first paragraph on that page.~~ ~~(3) For Section C.3.4.1 of NEI 21-07, Revision 1, the staff clarifies that for the most limiting DBE used to map into each DBA, all of the information in the second bulleted list beginning on NEI 21-07 page 34 should be provided in addition to the information in the first bulleted list on page 34.~~ ~~(4) For Section C.3.5.1 of NEI 21-07, Revision 1, the staff clarifies that for any high consequence BDBEs and other BDBEs that bound the risks~~ "
NRC-2022-0074-DRAFT-0006-29	LBE Level of Detail	4- Licensing Basis Events	Regarding Clarification C.4.b, industry does not agree that the second-to-last paragraph in each of NEI 21-07 Sections C.3.3.1, C.3.4.1, and C.3.5.1 conflicts with the guidance in NEI 21-07 Section C.2.1.1 on the level of detail in the SAR for AOOs, DBEs, and BDBEs respectively. Industry agrees with the NRC statement in Clarification C.4.b "Section C.2.1.1 … contains adequate guidance on the level of	The NRC staff agrees and has deleted Clarification C.4.b. b. ~~Clarification: The second-to-last paragraph in each of Sections C.3.3.1, C.3.4.1, and C.3.5.1 of NEI 21-07, Revision 1, appears to conflict with guidance in Section C.2.1.1 on the level of detail in the SAR for non-DBA LBEs. Therefore, the staff provides the following clarification: Section C.2.1.1 of NEI 21-07, Revision 1, contains adequate guidance on the level of detail in the SAR to describe non-DBA LBEs. If there is~~

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			detail in the SAR to describe non-DBA LBEs." However, industry does not agree that the statement is needed as a clarification in the reg guide. By definition, the guidance is adequate and there is no need to add such statements on the validity of NEI 21-07 SAR Chapter 2 guidance, particularly in NEI 21-07 guidance for SAR Chapter 3. Regarding the remainder of the clarification, it is essentially equivalent to the guidance that is already in NEI 21-07 Section C.3.3.1 paragraph 3 on event-specific information, so it is not needed. Note: The industry assumes that the NRC's reference to the second-to-last paragraph in NEI 21-07 Section C.3.1.1 was actually intended to be to the 4th from last paragraph which begins "For AOOs that involve a 30-day EAB dose …" <u>Proposed Change</u> Please delete Clarification C.4.b.	~~event-specific information associated with the radiological consequence evaluation, the applicant may elect to provide that information in Chapter 3 of the SAR instead of in Section 2.1.1. Further details on the models, site characteristics, and supporting data associated with the calculation of probabilities, mechanistic source terms, and radiological consequences, beyond the content specified for Section 2.1.1 of the SAR (or Chapter 3 for event-specific information), are part of the PRA documentation and can be included in the plant records.~~
NRC-2022-0074-DRAFT-0006-30	Special Event Analysis	4- Licensing Basis Events	Industry understands that NRC wishes to include certain information related to deterministic events and requirements in SAR Chapter 3. Industry is amenable to that approach but would like to ensure the events are clearly delineated as separate from licensing basis events (AOO, DBEs, BDBEs,	The NRC staff agrees, and has updated DG-1404 to reflect the proposed change: "C.4.c: Addition: In addition to the material identified in NEI 21-07, Revision 1, Section C.3, ~~Chapter 3 of the SAR should also discuss the following:~~ that is derived by following the methodology of NEI 18-04, the applicant should address certain specified events

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			and DBAs) as defined in NEI 18-04. Therefore, it would be most appropriate to put that information in a new Section 3.7, Special Event Analyses, in SAR Chapter 3. Proposed Change Modify C.4.c to read: Addition: In addition to the material identified in NEI 21-07, Revision 1, Section C.3 ~~Chapter 3 of the SAR should also discuss the following~~ that is derived by following the methodology of NEI 18-04, the applicant should address certain deterministic events and requirements in a new SAR Section 3.7, Special Event Analyses, as described below:	and requirements in a new SAR Section 3.7, Special Event Analyses, as described below:"
NRC-2022-0074-DRAFT-0006-31	Special Event Analysis	4- Licensing Basis Events	The guidance provided for aircraft impact assessments [C.4.c(1)] is somewhat redundant to guidance provided in the draft ARCAP Roadmap DANU-ISG-2022-01 (p. 39 of 56). The ARCAP Roadmap guidance is more thorough and should be used, but DG-1404 may be the more appropriate location. Guidance should be provided in one document, not in multiple documents with different content in each. Proposed Change	The NRC staff agrees with the comment. Addition C.4.c(1) will be replaced with the following text: "10 CFR 50.150(b) requires that the PSAR or FSAR include a description of (1) the design features and functional capabilities identified in 10 CFR 50.150(a)(1) (i.e., through the applicant's assessment required by section 50.150(a)(1)), and (2) how the design features and functional capabilities identified in 10 CFR 50.150(a)(1) meet the assessment requirements in 10 CFR 50.150(a)(1). The ARCAP Roadmap ISG contains guidance regarding aircraft impact assessments."

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			Please place the aircraft impact assessment guidance from the ARCAP Roadmap into one location – either the ARCAP Roadmap or DG-1404. Delete the aircraft impact assessment guidance from the other location so the guidance is not spread among multiple documents.	
NRC-2022-0074-DRAFT-0006-32	BDBE Content at CP Stage	4- Licensing Basis Events	Addition C.4.c(2) addresses mitigation of specific beyond design basis events per 10 CFR 50.155. Industry requests NRC include in this addition a note that the information is not required at the CP stage unless the applicant is requesting design finality. Proposed Change After the last bullet, please add words to the effect of "Applicants that are not requesting design finality for mitigation of beyond design basis events are not required to provide any information on the topic at the CP stage."	The NRC staff agrees with this comment because the subject requirements reflected in 10 CFR 50.155(a) apply at the Operating License or the Combined License stages. DG-1404 has been revised to include this note after the last bullet: "Note: Applicants for a CP that are not requesting design finality for mitigation of specific beyond design basis events reflected in 10 CFR 50.155(a) and applicants for a DC are not required to provide information on the topic."
NRC-2022-0074-DRAFT-0006-33	DID at CP Stage	5 – Integrated Evaluations	NRC Addition C.5.a pertaining to defense-in-depth (DID) is not clear and it does not appear to be necessary, as discussed below. (1) The first two sentences are essentially quotes from NEI 21-07 and are therefore not needed. (2) The next two sentences state "The CP application should provide a	The NRC staff agrees with the comment that the third sentence should be revised to improve clarity. While the staff agrees that the first two sentences are addressed in NEI 21-07, they are being retained for context. The third sentence has been revised to: "The CP application should provide a discussion in the SAR of the approach to establish DID adequacy."

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			discussion in the SAR to establish DID adequacy. A discussion in the SAR to implement the DID adequacy assessment processes in RG 1.233 is considered acceptable for this purpose." Regarding the first of the two sentences, a discussion cannot establish DID adequacy, so industry believes the NRC may have intended to say "should provide a discussion of the approach to establishing DID adequacy." Moreover, the approach to establishing DID adequacy is already documented in NEI 18-04 and does not need to be repeated. Regarding the second of the two sentences, it appears the NRC is soliciting a commitment on the part of the applicant to follow the guidance in Regulatory Guide 1.233 for DID. This is not necessary, because NEI 21-07 subsection C.1.3.1 already requires the applicant to identify departures from NEI 18-04 and RG 1.233, and describe them in more detail in the appropriate section, which for DID is SAR Section 4.2.c) The remaining sentences address the situation in which the applicant does not intend to follow RG 1.233, and would then require an explanation of how the applicant intends to address DID. As	The NRC staff also agrees that a discussion of alternate approaches and expectations regarding their justification is nominally outside the scope of this Regulatory Guide. Therefore, the last two sentences of the paragraph have been deleted: "~~Alternatively, the applicant should ensure that its DID process involves incorporating DID into design features, operating and emergency procedures, and other programmatic elements to ensure that performance requirements are maintained throughout the life of the plant. An applicant that chooses not to use the approach endorsed in RG 1.233 will need to explain its approach to DID and describe how it addresses DID in the application.~~"

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			noted above, this is already a requirement of NEI 21-07, and it does not need restatement in the regulatory guide. Proposed Change Please delete Addition C.5.a.	
NRC-2022-0074-DRAFT-0006-34	PRA Methods	5 – Integrated Evaluations	Addition C.5.b requests detailed information underpinning the PRA calculations addressing QHOs in SAR Section 4.1. Industry believes the guidance goes well beyond what is needed for a SAR. The PRA methods would be addressed in the PRA peer review, and the detailed information would be available for NRC to inspect in an audit. Furthermore, it is not clear NRC appreciates the scope of this requirement. The requests are quite broad – e.g., "(5) key modeling assumptions." Because these are integrated analyses, the requirements pertain to each and every PRA realization that involves an offsite dose. Another specific concern is "(8) uncertainty/sensitivity analysis performed." No definition is provided as to what is intended. Depending on the interpretation, the amount of information required to satisfy this desire for each and every part of the integrated analyses could be huge. The approach prescribed in	The NRC staff partially agrees with the comment and has revised the addition as follows: In addition to the results and margins, the SAR Chapter 4 should include a summary of departures taken from or unique inputs to the methodologies described in other chapters, if any, related to the analyses of cumulative risk measures. Examples that could arise due to factors such as the different time periods used in the assessments of licensing basis events and cumulative risk metrics could include sources of dose (cloud shine, inhalation, ground shine), additional inputs for dose conversion factors, and modeling assumptions (e.g., offsite protective actions). The summary can be provided via references to other documents or guidance related to the assessment of cumulative risk metrics.

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			NEI 18-04 and NEI 21-07 is to rely on conformance with the non-LWR PRA Standard, provide general descriptive PRA information in the SAR, and encourage regulatory audits to address details of the analyses if necessary. Literal compliance with the expectations laid out by the NRC in Addition C.5.b could result in levels of detail on the order of those seen in SAR Chapter 19 of advanced light water reactors licensed under Part 52 – a level of detail which, it was thought, all parties agreed was excessive and inappropriate. <u>Proposed Change</u> Please delete Addition C.5.b.	
NRC-2022-0074-DRAFT-0006-35	Human Factors Considerations	5 – Integrated Evaluations	Addition C.5.c is unnecessary and, at the very least, inappropriate for SAR Chapter 4. Per discussions between industry and the NRC, human factors are to be addressed in SAR Chapters 6 and 7, in conjunction with the associated SSCs, and in SAR Chapter 11 per ARCAP. Appropriate guidance is already provided for HFE in other SAR chapters. Moreover, this proposed addition does not provide clear and actionable guidance for an applicant. It is more of a "kitchen sink" approach of "tell me	The NRC staff partially agrees with the comment and has changed the addition to a clarification as follows: C.5.c Clarification: Human factors considerations for SSCs should be included in SAR Chapter 6 or 7 as appropriate. The human factors information in these SAR chapters should be consistent with the human factors information provided in SAR Chapter 11 in accordance with ARCAP DANU-ISG-2022-05, "Organization and Human Systems Considerations. (Ref. 34)"

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			everything about human factors." Such guidance is not consistent with the goal of focused, transparent, risk-informed guidance; it is more in line with a "business as usual" LWR approach. <u>Proposed Change</u> Please delete Addition C.5.c.	
NRC-2022-0074-DRAFT-0006-36	DID Change Control	5 – Integrated Evaluations	Addition C.5.d would require that the applicant provide a change control process for DID in the SAR. This requirement is inappropriate for a SAR, and there is no precedent for it. Change control is an operational issue. Moreover, industry is working with the NRC on change control for licensees who followed NEI 18-04. Specifically, the Technology Inclusive Risk Informed Change Evaluation (TIRICE) Project and draft NEI Guidance Document NEI 22-05 should address the issue. <u>Proposed Change</u> Please delete Addition C.5.d. Additionally, consider adding NEI 22-05 to the list of guidance being developed in Appendix A of the NRC Reg Guide.	The NRC staff agrees with the comment in part and is making the changes described below. NEI 18-04, section 5.9.7, Evaluation of Changes to Defense-in-Depth, specifies a process for evaluating the impact of plant changes on DID. It states, in part, "*Changes that impact the definition and evaluation of LBEs, safety classification of SSCs, or risk significance of LBEs or SSCs will need to have the DID adequacy re-evaluated and the baseline updated as appropriate.*" However, NEI 21-07 did not address this section of NEI 18-04. Therefore, the staff believes that an application should address this section of NEI 18-04, so DG-1404 addressed it via this addition. The NRC staff also recognizes that future interactions regarding the Technology Inclusive Risk-Informed Change Evaluation (TIRICE) approach may further inform this topic. Based on the above, C.5.d was changed from an addition to a clarification and reworded as follows:

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				Guidance for the change control process for the SAR including ensuring defense-in-depth (i.e., up to issuance of an operating license), is addressed in NEI 18-04, revision 1 as endorsed by RG 1.233. Additional guidance related to change control for the FSAR following issuance of the operating license is under development and the NRC is not taking a position on this topic at this time. The staff may address such change control processes in future regulatory actions, including possible rulemakings, license conditions, and development of guidance documents.
NRC-2022-0074-DRAFT-0006-37	Principal Design Criteria	6 – Safety Functions, Design Criteria, and SSCs	Addition C.6.a(1) provides a discussion of PDC. However, it is not clear that the discussion includes any new guidance that is not already provided in NEI 21-07. Proposed Change Please delete Addition C.6.a(1) or clarify what is actually new guidance.	The NRC staff partially agrees with this comment in that a portion of this text is redundant to NEI 21-07, and that the discussion regarding the applicability of the exemption process is well understood generically and is not needed here. This text has been deleted as indicated below. The NRC staff has retained the portion of the addition that summarizes its position regarding the concept of the quality assurance principal design criteria (PDC), including considerations regarding their interface with other PDCs. "(1) Clarification: ~~Addition: The requirements in 10 CFR 50.34(a)(3), 52.79, 52.137, and 52.157 to propose PDC includes a requirement, for both LWRs and non-LWRs, to establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety (as described in paragraph C.6.a.(2) of this staff position below). As provided in Appendix A to Part 50, the GDC are intended to provide guidance in~~

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				~~establishing the PDC for nuclear power plants such as non-LWRs. Applicants addressing less than the full scope of PDC must request an exemption from the applicable requirements for providing proposed PDCs and provide suitable justification for the exemption. For example, the justification may be that, to address specific elements of PDC scope, the applicant has complied with other regulatory requirements that compel the applicant to provide the relevant information in other portions of the application.~~ The inclusion of a proposed quality assurance PDC as described in Chapter 5 of NEI 21-07, Revision 1, is an acceptable method for implementing a graded approach to quality assurance for SSCs; it can also contribute to the basis for not addressing quality assurance in the scope of PDC in the more system- and component-specific PDC proposed."
NRC-2022-0074-DRAFT-0006-38	Principal Design Criteria	6 – Safety Functions, Design Criteria, and SSCs	Clarification C.6.a(2) discusses the "two-tiered" approach to PDC provided in NEI 21-07. However, it is not clear what part of the discussion is actually clarifying; it seems instead to be an endorsement of the approach. <u>Proposed Change</u> Please delete Clarification C.6.a(2) or clarify what is actually being clarified.	The NRC staff does not agree with the comment recommending deletion of this Clarification [C.6.a(2)]. Although this section of DG-1404 does not provide new guidance, it does provide a clarification through an expanded background discussion to aid in a common and consistent understanding of the relationship between this NEI 21-07 approach and the scope of the associated regulatory requirement for developing a proposed set of PDC. However, the last two sentences of Clarification C.6.a(2) have been deleted, since they repeat the NRC staff's endorsement of the proposed PDC development approach that NRC provides in C.6.a.

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				"~~The NRC staff considers the proposed PDC-RFDC and PDC-CDC to be equivalent in establishing the necessary requirements for SSCs that provide reasonable assurance that the facility can be operated without undue risk to public health and safety. The staff therefore considers the two-tiered approach to be an acceptable method for proposing PDC for non-LWRs using the LMP methodology.~~"
NRC-2022-0074-DRAFT-0006-39	Principal Design Criteria	6 – Safety Functions, Design Criteria, and SSCs	Addition C.6.a(3) addresses alternative approaches to PDC and potential exemption requests. The material seems largely to be covered by NEI 21-07 Section C.5.3. <u>Proposed Change</u> Please delete Addition C.6.a(3) or clarify what is actually new guidance.	The NRC staff disagrees with the comment. The new guidance in DG-1404, Section C.6.a(3) is associated with risk-informed, performance-based methodologies that are similar to, but different from the NEI 21-07 approach, so is not covered by NEI 21-07 Section C.5.3. In addition, the DG-1404 provides an example justification for an exemption from the regulations addressing contents of applications. Nevertheless, item C.6.a(3) is revised from an Addition to a Clarification, and the second sentence was revised to make it clear that the exemptions are from the regulations addressing contents of applications.
NRC-2022-0074-DRAFT-0006-40	Fuel Qualification	6 – Safety Functions, Design Criteria, and SSCs	Addition C.6.b addresses fuel qualification. Industry considers this additional guidance to be unnecessary and, as proposed, inappropriate, and counter-productive. Industry also notes that this addition raises an issue that was never discussed at any significant level of detail during industry-NRC	The NRC staff agrees in part and disagrees in part. The NRC staff agrees that fuel qualification should be essentially complete at the license application stage, and that additional context on fuel qualification in particular is not required here. However, the staff disagrees with the characterization of the statement "The reactor core

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			interactions prior to submittal for endorsement. The issue was essentially absent from the NRC's draft additions, clarifications, and exceptions that formed the basis for detailed interactions during the fall and winter of 2021, prior to submittal of NEI 21-07, Rev. 1 for endorsement. First, fuel qualification should essentially be done at the time of a license application, with the possible exception of some confirmatory items. The emphasis for fuel qualification should be during pre-application interactions as is discussed in DANU-ISG-2022-01, Appendix A. The NRC proposal to address fuel qualification expectations in the SAR, as reflected in this proposed addition, is wholly out of sequence and unnecessary, and it detracts from the guidance overall. Second, the document states "The reactor core and its fuel are generally classified as SR" as if that point justifies this special deterministic carve out of SAR documentation requirements for fuel. It does not. NEI 18-04 provides a systematic means of identifying	and its fuel are generally classified as SR" as being a "deterministic carve out." The NRC staff is not aware of a design where fuel is not safety-related, and the safety demonstration of the fuel is generally unique to the reactor and/or fuel type. The NRC staff views additional context in this area regarding the adequacy of the fuel as important in demonstrating the safety functions and design criteria associated with the fuel specific to the given reactor design can be satisfied. The statement does not prescribe the specific uses of probabilistic or deterministic methods to analyze the fuel. The NRC staff also disagrees that the last two paragraphs of the addition are guidance for the staff review. Rather, these paragraphs are indicative of information that NRC staff requires to make its safety finding i.e., that the fuel will perform as presumed in the analysis associated with its safety functions, and that the basis for this demonstration is adequately justified. An application lacking this information (whether directly or as a referenced report completed prior to the application) would be unlikely to contain adequate information for the staff to arrive at the necessary findings. Based on the above, the NRC staff has made the following changes to C.6.b: Additional information on the role of fuel ~~qualification~~: In addition to the material identified in NEI 21-07, Revision 1, Section C.5, Chapter 5 of an SAR following NEI 21-07, Revision 1, should also address fuel qualification. The reactor core and its

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			safety related structures, systems, and components, based on the approach taken to satisfy Required Safety Functions. Provisions are already in place to address safety-related SSCs in SAR Chapter 6. It is certainly expected that fuel performance will be particularly important to some advanced reactor designs, and if so the SAR documentation related to fuel will be more extensive than other SSCs, but there is no need to arbitrarily address fuel in a special way as proposed in the text. Third, there is no rationale for addressing fuel qualification in SAR Chapter 5, as proposed herein. SAR Chapter 5 covers safety functions, design criteria, and SSC classification, but the document proposes to use it as a repository for additional information on one particular SSC (fuel). Fourth, the last two paragraphs of the "addition" are written like guidance for the staff, not for an applicant. If such staff guidance were needed, NRC should place such guidance in an ISG, not in a regulatory guide with the stated primary purpose of providing	fuel are generally classified as SR because they are directly involved in performing fundamental safety functions. The application should provide the information for SR SSCs identified in NEI 21-07, Revision 1, Chapter 6, "Safety Related SSC Criteria and Capabilities." However, the adequacy of fuel performance also depends on other information such as fuel design limits and fuel qualification, which the application should describe... ~~In particular, fuel cannot be qualified without irradiation data collected over certain time frames. Accordingly, non-LWR applicants may use existing data (e.g., Advanced Gas-Cooled Reactor program data, legacy metal fuel data), to some degree, to support regulatory licensing. Two documents provide additional background on non-LWR fuel qualification: (1) NRC guidance in NUREG-2246, "Fuel Qualification for Advanced Reactors," issued March 2022 (Ref.), and (2) an example of a generic fuel qualification topical report and associated safety evaluation applicable to multiple non-LWR designs, "Uranium Oxycarbide (UCO) Tristructural Isotropic (TRISO) Coated Particle Fuel Performance," issued December 2020 (Ref.).~~ The applicant's discussion ~~of fuel qualification~~ should focus on the role of the fuel in the safety analysis for the reactor and on the adequacy of the plan to provide the basis for fuel performance as credited in the safety analysis. If not included elsewhere in the application or in referenced reports, this section of the SAR should include information sufficient to establish that: [the items in the bulleted list in the RG have been met].:

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			guidance to applicants. In summary, the approach taken by the NRC to fuel qualification is quite troubling to industry. Placing unnecessary special emphasis on certain SSCs is not technology-inclusive, and it detracts from the logical and systematic sequencing of NEI 18-04 and NEI 21-07 to do so. SAR Chapter 5 progresses in a step-wise, logical manner until it hits the rock of unnecessary and inappropriate fuel qualification guidance. This approach should be reconsidered. Proposed Change Please delete Addition C.6.b.	
NRC-2022-0074-DRAFT-0006-41	Reliability and Capability Targets	7 – Safety-Related structures, systems, and components (SSCs)	The last two sentences of the first paragraph of DG-1404 Section 7 are confusing and do not convey appropriate guidance to the applicant. The penultimate sentence requests a discussion of how the applicant intends to confirm, at the OL stage, that the reliability and capability performance targets assumed in the PRA have been met. NEI 21-07, Section C.6.2 already addresses reliability and capability targets, including plant programs used to maintain them. Moreover, Section C.6.2 makes it clear that reliability and capability targets are not "assumed in the PRA" as stated	The NRC staff partially agrees with the comment. Reliability and capability targets should be included in the SAR. PSARs contain preliminary design information and, therefore, reliability and capability targets may not be confirmed at this stage. Therefore, information should be provided in the PSAR that explains how the applicant will confirm that the reliability and capability targets informed by the final PRA will be met. For clarification, the DG is revised as follows: "For those SR SSCs whose reliability and capabilities have not been confirmed at the CP stage, the PSAR ~~application~~ should include ~~a~~ sufficient information (e.g., commitments for testing or R&D) ~~discussion in the SAR on how the applicant intends~~

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			by DG-1404, but instead informed by PRA information. The last sentence of the first paragraph in DG-1404 Section 7 is confusing because it convolves inappropriately special treatments with testing and validation. Testing and validation are types of special treatments. Proposed Change Please delete the last two sentences of the first paragraph of DG-1404 Section 7.	~~to confirm, at the OL stage that the~~ to confirm that the reliability and capability performance targets informed by ~~assumed in~~ the final PRA will be ~~have been~~ met. ~~The application should describe any testing and validation planned to confirm SR SSC performance capabilities and availability, including any special treatment to be applied to the SR SSCs.~~"
NRC-2022-0074-DRAFT-0006-42	Required Safety Functions	7 – Safety-Related SSCs	The second paragraph of DG-1404 Section 7 is not necessary and it conveys inaccurate information. The LBE selection process is addressed in SAR Chapter 3, not SAR Chapter 2. The LBE selection process does not determine the Required Safety Functions. Footnote 10 also contains the inaccuracy "determined in the LBE selection process" and it is mostly a rehash of some elements of the NEI 18-04 methodology. In total, the paragraph and the footnote provide no useful guidance to an applicant. Proposed Change Please delete the second paragraph of DG- 1404 Section 7 and the associated footnote 10.	The NRC staff agrees with the comment. Subject paragraph and footnote were removed from the DG. "~~The safety-related design criteria10 are derived from the RFDC, which are developed from the RSFs determined in the LBE selection process described in Chapters 2 and 3 of NEI 21-07, Revision 1.~~"

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NRC-2022-0074-DRAFT-0006-43	Special Treatments and DBHLs	7 – Safety-Related SSCs	Paragraphs 3-5 of DG-1404 Section 7 repeat information from NEI 21-07 and NEI 18-04. It is not clear what purpose the information serves in DG-1404.	The subject text is italicized in NEI 21-07, Rev. 1, indicating that it is being provided by NEI as background information for context and perspective, but not as guidance for application content development. The NRC staff concludes that this text is useful for context, so has also included it in DG-1404. No change to DG-1404.
NRC-2022-0074-DRAFT-0006-44	DBHLs	7 – Safety-Related SSCs	The first sentence of the sixth (last) paragraph of DG-1404 Section 7 states "Chapter 6 also establishes the DBHLs associated with NSRST SSCs and SSCs that are non-safety related with no special treatment (NST)." The sentence could be taken to imply there are different DBHLs associated with safety-related SSCs, which is not the case. A DBHL is a DBHL. The second sentence states "The design requirements for NSRST and NST SSCs are determined by the need to protect SR SSCs in the performance of their RSFs from adverse effects from the failure of NSRST or NST SSCs during and after DBEs." In fact, that is only one source of design requirements for NSRST and NST SSCs. Moreover, NSRST SSCs could have special treatments associated with DBHLs but not connected with a need to protect SR SSCs. The discussion in NEI 21-07	The NRC staff agrees with the comment. Section 6.1.3 of NEI 21-07 addresses the topic of DBHLs related to non-safety related SSCs. Therefore, the referenced paragraph (sixth (i.e., last) paragraph of DG-1404 Section 7) is not necessary and is deleted. "~~Chapter 6 also establishes the DBHLs associated with NSRST SSCs and SSCs that are non-safety related with no special treatment (NST). The design requirements for NSRST and NST SSCs are determined by the need to protect SR SSCs in the performance of their RSFs from adverse effects from the failure of NSRST or NST SSCs during and after DBEs.~~"

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			is already adequate in this area, and the additions in this paragraph in DG-1404 are confusing. Proposed Change Please delete the sixth (i.e., last) paragraph of DG-1404 Section 7.	
NRC-2022-0074-DRAFT-0006-45	DBHLs	7 – Safety-Related SSCs	Clarification and Addition C.7.a is unnecessary. The guidance is already provided in NEI 21-07 Section C.6.1.1. Proposed Change Please delete Clarification and Addition C.7.a.	The NRC staff partially agrees with the comment. There is some duplication between DG-1404, Item C.7.a, and NEI 21-07, Section C.6.1.1. DG-1404, Item C.7.a, has been revised to eliminate the duplication and now reads as follows: "Addition: In addition to describing the DBHLs as stated in NEI 21-07, Revision 1, Section C.6, the applicant may also use the guidance in section C.I.3 of RG 1.206, Revision 0, ["Applications for Nuclear Power Plants,"] to determine the information that should be included in Chapters 5 and 6 of the SAR regarding the translation of DBHLs to loads on SSCs, evaluation of those loads, and related design analysis. Pre-application interactions with the staff may be appropriate to determine the necessary level of information to be included in the SAR." Footnote # 11 has been deleted since it duplicates what is in Section C.6.1.1 of NEI 21-07.
NRC-2022-0074-DRAFT-0006-46	DBHLs	7 – Safety-Related SSCs	Related to Clarification and Addition C.7.a, there appears to be an inconsistency between the guidance in NEI 21-07 and DG-1404, compared to DANU-ISG-2022-01 (ARCAP Roadmap). Pages 12-13 of the ARCAP roadmap	The NRC staff partially agrees with the comment. Refer to the response to comment NRC-2022-0074-DRAFT-0006-45 for the revised Clarification C.7.a. The convention of discussing the DBHLs and the related challenges to specific SR SSCs in Chapter 6 is consistent among the listed documents.

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			indicate that the information related to translation of DBHLs to loads (and evaluation of those loads) would be placed in SAR Chapters 5 and 6, while NEI 21-07 and DG-1404 would put that information in Chapter 2 or in external reports referenced in the SAR. <u>Proposed Change</u> Please review and resolve the discrepancy.	
NRC-2022-0074-DRAFT-0006-47	Editorial	7 – Safety-Related SSCs	There is an inconsistency between Footnote 12 in C.7.b(1) and the actual footnote at the bottom of the page, which is labeled Footnote 11. <u>Proposed Change</u> Please fix the footnote numbering.	The NRC staff agrees with the comment. This footnote is deleted per the response to comment NRC-2022-0074-DRAFT-0006-48.
NRC-2022-0074-DRAFT-0006-48	NRC-DRG on Instrumentation & Controls	7 – Safety-Related SSCs	Addition C.7.b(1) is unnecessary and inappropriate. The addition would put special requirements on certain safety-related SSCs based on what is apparently an arbitrary factor - they are safety-related instrumentation and control (I&C) systems. The additional requirements are not appropriate as the NEI 21-07 guidance already requires that special treatments be listed for all safety-related SSCs. The proposed text would include a special requirement to "describe the	The NRC staff partially agrees with the comment. The Design Review Guide (DRG) addressing I&C that is reflected in Addition C.7.b(1) provides review guidance for the NRC staff regarding I&C systems. While the DRG sets forth review guidance for the staff and is not application guidance, it indicates that it "… *factors in the principles*…" of Reg. Guide 1.233 and NEI 18-04. NRC provided a reference to the information within DG-1404 as additional background that may be useful to license applicants. However, the DRG is not directly related to NRC's endorsement of NEI 21-07.

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			special treatments" and "analyze their capability to perform their credited safety functions" (presumably "their" refers to the I&C systems, not the special treatments). No justification is provided for this additional and burdensome SAR documentation requirement, nor why it is being applied to I&C. This type of information would be available in the design records and available for audit, if needed. This requirement is entirely new and was never discussed as part of the extensive discussions that took place between industry and NRC prior to the submittal of NEI 21-07 Revision 1 for endorsement. <u>Proposed Change</u> Please delete Addition C.7.b(1)	On that basis, this addition is deleted. However, a reference to the DRG has been included in the Roadmap ISG.
NRC-2022-0074-DRAFT-0006-49	Codes and Standards	7 – Safety-Related SSCs	Addition C.7.b(2) is unnecessary and inappropriate. The addition imposes an additional SAR documentation requirement to justify the use of codes and standards. This requirement goes beyond standard practice for light water reactors. Moreover, it was never proposed by the NRC during the extensive discussions that took place between industry and NRC concerning NEI 21-07.	Note: This comment relates to item NRC-2022-0074-DRAFT-0006-48 and NRC-2022-0074-DRAFT-0006-16. The NRC staff partially agrees with the comment. The NRC staff notes that the information provided in C.7.b(2) including the reference to RG 1.87, revision 2, “Acceptability of ASME [American Society of Mechanical Engineers] Code Section III, Division 5, 'High Temperature Reactors,'” and the reference to materials compatibility guidance being developed

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			Proposed Change Please delete Addition C.7.b(2)	was provided as additional background that may be useful to license applicants. However, this guidance is not directly related to NRC's endorsement of NEI 21-07. On this basis C.7.b(2) has been deleted. However, the background information in C.7.b(2) has been included in the ARCAP Roadmap ISG. Regarding the use of codes and standards, the NRC staff made changes as discussed in response to comment NRC-2022-0074-DRAFT-0006-16. In addition, while an applicant need not justify the use of an NRC-endorsed code or standard in accordance with the regulatory guide in which it is endorsed, the NRC staff notes that the use of codes and standards or editions of the ASME Code that the NRC has not endorsed for SR SSCs should be justified.
NRC-2022-0074-DRAFT-0006-50	Reliability and Capability Targets	8 – NSRST SSCs	The last two sentences of the first paragraph of DG-1404 Section 8 are confusing and do not convey appropriate guidance to the applicant. The penultimate sentence requests a discussion of how the applicant intends to confirm, at the OL stage, that the reliability and capability performance targets have been met. NEI 21-07 Section C.6.2 already addresses reliability and capability targets, including plant programs used to maintain them. It is not envisioned that all targets be fully confirmed at the CP stage, or even provided on a preliminary	The NRC staff agrees that this text would benefit from clarification and confirms that it is not the intention or expectation that all targets be established and verified at the CP stage. The NRC staff disagrees with the recommendation to delete the last two sentences. The text has instead been revised as follows: "NSRST reliability and capability targets can be provided at the CP or the OL stage. For those NSRST SSCs whose reliability and capabilities have not been provided and confirmed at the CP stage, the application should include a discussion in the PSAR on how the applicant intends to confirm, at the OL stage, that reasonable reliability and capability

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			basis. The penultimate sentence could be interpreted as meaning that the applicant must provide an SSC by SSC discussion of each target at the CP stage, which we hope was not the intention. The last sentence of the first paragraph in DG-1404 Section 8 is confusing because it convolves inappropriately special treatments with testing and validation. Testing and validation are types of special treatments. Proposed Change Please delete the last two sentences of the first paragraph of DG-1404 Section 8.	performance targets have been ~~met~~ established, align with the supporting analyses, and have special treatments defined to ensure the performance of SSCs meet the targets. The OL application should describe any testing and validation ~~planned to~~ confirming NSRST SSC performance capabilities and availability, including any additional special treatments to be applied to the NSRST SSCs as compensatory measures to address a lack of operating experience."
NRC-2022-0074-DRAFT-0006-51	DBHLs	8 – NSRST SSCs	The second paragraph of DG-1404 Section 8 is not necessary and does not relate to the rest of Section 8. Proposed Change Please delete the second paragraph of DG- 1404 Section 8.	The NRC staff agrees with the comment. This text has been deleted from Section 8: "~~As discussed earlier, Chapter 6 of the SAR establishes DBHL requirements and identifies design parameters for NSRST and NST SSCs.~~"
NRC-2022-0074-DRAFT-0006-52	NRC-DRG on Instrumentation and Controls	8 – NSRST SSCs	Addition C.8.a(1) is unnecessary and inappropriate. The addition would put special requirements on certain NSRST SSCs based on what is apparently an arbitrary factor – they are I&C systems. The additional requirements are not appropriate as the NEI 21-07 guidance already requires that special treatments be identified for all NSRST SSCs. The	The NRC staff partially agrees with the comment. The Design Review Guide (DRG) addressing I&C that is reflected in Addition C.8.a(1) provides review guidance for the NRC staff regarding I&C systems. While the DRG sets forth review guidance for the staff and is not application guidance, it indicates that it "… *factors in the principles*…" of Reg. Guide 1.233 and NEI 18-04. "NRC provided a reference to the information within DG-1404 as additional

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			text would include a special requirement to "describe the special treatments" and "analyze their capability to perform their credited safety functions" (presumably "their" refers to the I&C systems, not the special treatments). No justification is provided for this additional SAR documentation requirement, nor why it is being applied to I&C. This NRC requirement is entirely new and was never discussed as part of the extensive discussions that took place between industry and NRC prior to the submittal of NEI 21-07 Revision 1 for endorsement. <u>Proposed Change</u> Please delete Addition C.8.a(1)	background that may be useful to license applicants. However, the DRG is not directly related to NRC's endorsement of NEI 21-07. On that basis, this addition is deleted. However, a reference to the DRG has been included in the Roadmap ISG.
NRC-2022-0074-DRAFT-0006-53	Plant Programs at CP Stage	9 – Plant Programs	The last two sentences of paragraph 1 of DG-1404 Section 9 are not necessary. Guidance for CP applications for Plant Programs is provided on NEI 21-07 and is adequate for the purpose. The penultimate sentence of the DG-1404 Section 9 paragraph 1 is unclear. Is the NRC seeking some kind of commitment at the CP stage to develop certain programs? If so, it should state that point directly, not ask for a "discussion." There seems to be no basis for the need for a	The NRC staff does not agree with the comment to delete the last two sentences. However, the content has been revised as follows to improve clarity and consistency with NEI 21-07: "Construction permit applications should include general descriptions ~~a discussion~~ in the SAR regarding ~~to develop~~ any programs needed to implement special treatments and meet reliability and performance targets for SR SSCs and NSRST SSCs. These may include programs for inservice inspection/testing, maintenance, human factors, training, and reliability assurance."

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			commitment of that type. NEI 21-07 Section C.8 already provides ample guidance on what is needed in the SAR associated with the operating license application. If the NRC considers that an addition to the guidance is necessary (a position with which industry does not agree), NRC should call it out specifically as an addition and justify it. Proposed Change Please delete the last two sentences of paragraph 1 of DG-1404 Section 9 or clarify the intent.	
NRC-2022-0074-DRAFT-0006-54	Editorial	References	The ADAMS accession number for Reference 14 should be ML102510405 not ML1025210405. Proposed Change Please correct the ADAMS accession number.	The NRC staff agrees with the comment and has corrected the Accession No. associated with Reference 14 to "ML102510405".

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NRC-2022-0075-DRAFT-0004-1	LWR Generic Issues	2 – General Plant and Site Description	X-energy has concerns with both the letter and the spirit of Addition C.2.e, which would levy substantial documentation requirements that are largely not applicable to non-LWRs, thereby complicating the development of an application and the subsequent staff review. With respect to Item (1), generic safety issues, unresolved safety issues, and TMI action items are largely LWR-centric and not applicable to advanced non-LWRs; there should be no presumption to the contrary. There is no regulatory requirement that applicants address LWR GSIs and USIs in the SAR. The regulatory requirement to address TMI requirements in 10 CFR 50.34(f) is applicable only to LWRs. 10 CFR 52.47(a)(8) invokes most of the TMI requirements in 10 CFR 50.34(f) to the extent they are "technically relevant." This term, as well as the terms "technically applicable to the design" and "directly applicable to the design" used in DG-1404 Addition C.2.3, are undefined and subjective, and will be fertile ground for	See response to NRC-2022-0074-DRAFT-0006-16

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			interpretation disagreements between applicant and regulator. At most, the TMI requirements should be applied only to Part 52 applicants. NRC expectations from LWR licensing experience should not be applied blindly to advanced reactors following NEI 18-04 guidance. In fact, applying LWR GSIs, USIs, and TMI action requirements to non-LWR advanced reactors stands the concept of risk-informed, performance-based regulation on its head. It adds an unnecessary backward-looking deterministic framework on top of the systematic evaluation of safety provided by NEI 18-04. With respect to Item (2), regulatory guides are not regulatory requirements and most were developed for light water reactors. There should be no presumption that regulatory guides are to be applied to non-LWRs, and the NRC should be clear on that point in its guidance. The NEI 18-04 approach to demonstrating safety is not centered around a deterministic checklist approach of following prescriptive guidance. If the NRC	

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			insists on including a requirement that the applicant catalog items like Reg Guides in Chapter 1 of the SAR, that guidance should make it clear that the Chapter 1 material is simply a list of items included by the applicant in subsequent sections of the SAR. The discussion relative to Item 3 (codes and standards) is similar. Codes and standards will be addressed in appropriate sections of the SAR. If the NRC insists on including lists of codes and standards in Chapter 1 of the SAR, it should be with the understanding that any substantive information is reserved for later chapters. <u>Proposed Change</u> Please delete Addition C.2.e. However, if the addition is retained, to the extent the NRC uses terms like "technically relevant" and "directly applicable to the design," clarify that the NRC does not presume applicability of LWR regulatory guidance to non-LWRs following the NEI 18-04 methodology.	

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			Furthermore, if the NRC insists that applicants provide lists of documents in Chapter 1 (e.g., regulatory guides and/or codes and standards), make it clear that those lists are simply catalogs of material addressed elsewhere in the SAR.	
NRC-2022-0075-DRAFT-0004-2	Human Factors Engineering	9 – Plant Programs	Chapter 8 of a SAR that uses the guidance in NEI 21-07 addresses plant programs, including Human Factors Engineering. The NRC Staff's position (Staff Position C.9) states this an acceptable method for developing information related to Plant Programs. However, DANU-ISG-2022-05 provides guidance for Human Factors and Human-System Considerations to be included in Chapter 11 of a SAR. Which chapter would the NRC prefer to have the HFE program addressed? <u>Proposed Change</u> Where there is duplicate guidance, such as HFE in Chapter 8 and HFE in Chapter 11, provide clarification on where the NRC staff prefers to	The NRC staff disagrees with the comment (insofar as it is not possible to avoid discussions of major topics, such as HFE, in multiple places within an application). HFE program content should be provided in Chapter 11 of an SAR as described in DANU-ISG-2022-05. This is consistent with the summary of NRC interactions that was included with the NEI letter transmitting NEI 21-07 Rev. 1, which summarized that: *"The TICAP presumption is that ARCAP Chapter 11 will contain the guidance for describing Human Factors Engineering (HFE) program components. Therefore, specific guidance in NEI 21-07 on HFE programs is not needed in Chapter 6. Programs are invoked by special treatments (Chapters 6 and 7) and addressed in Chapter 8. HFE is addressed in Chapter 11 by ARCAP guidance."* Having said that, to the extent FSAR Chapter 11 describes the HFE

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			see certain plant programs in the SAR.	program, that description need not be repeated in FSAR Chapter 8. No change to DG-1404.
NRC-2022-0075-DRAFT-0004-3	Reliability and Capability Targets	8 – NSRST SSCs	The last two sentences of the first paragraph of DG-Section 8 are confusing and do not convey appropriate guidance to the applicant. The 1404 penultimate sentence requests a discussion of how the applicant intends to confirm, at the OL stage, that the reliability and capability performance targets have been met. NEI 21-07 Section C.6.2 already addresses reliability and capability targets, including plant programs used to maintain them. It is not envisioned that all targets be fully confirmed at the CP stage, or even provided on a preliminary basis. The penultimate sentence could be interpreted as meaning that the applicant must provide an SSC by SSC discussion of each target at the CP stage, which we hope was not the intention. The last sentence of the first paragraph in DG-1404 Section 8 is confusing because it convolves inappropriately special treatments with testing and validation. Testing	Refer to the response to comment NRC-2022-0074-DRAFT-0006-50.

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			and validation are types of special treatments <u>Proposed Change</u> Please delete the last two sentences of the first paragraph of DG-1404 Section 8.	
NRC-2022-0075-DRAFT-0004-4	PRA Methods	5 – Integrated Evaluations	Addition C.5.b requests detailed information underpinning the PRA calculations addressing QHOs in Section 4.1. X-energy believes the guidance goes well beyond what is needed for a SAR. The PRA methods would be addressed in the PRA peer review, and the detailed information would be available for NRC to inspect in an audit. Furthermore, it is not clear NRC appreciates the scope of this requirement. The requests are quite broad – e.g., "(5) key modelling assumptions." Because these are integrated analyses, the requirements pertain to each and every PRA realization that involves an offsite dose. Another specific concern is "(8) uncertainty/sensitivity analysis performed." No definition is provided as to what is intended. Depending on the interpretation, the amount of information required to satisfy this desire for each and every part of the integrated analyses could	Refer to the response to comment NRC-2022-0074-DRAFT-0006-34.

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			be huge. The approach prescribed in NEI 18-04 and NEI 21-07 is to rely on conformance with the non-LWR PRA Standard, provide general descriptive PRA information in the SAR, and encourage regulatory audits to address details of the analyses if necessary. Literal compliance with the expectations laid out by the NRC in Addition C.5.b could result in levels of detail on the order of those seen in SAR Chapter 19 of advanced light water reactors licensed under Part 52 – a level of detail which, it was thought, all parties agreed was excessive and inappropriate. <u>Proposed Change</u> Please delete Addition C.5.b.	
NRC-2022-0075-DRAFT-0004-5	DID Change Control	5 – Integrated Evaluations	Addition C.5.d would require that the applicant provide a change control process for DID in the SAR. This requirement is inappropriate for a SAR, and there is no precedent for it. Change control is an operational issue. Moreover, industry is working with the NRC on change control for licensees who followed NEI 18-04. Specifically, the Technology Inclusive Risk Informed Change Evaluation (TIRICE) Project and draft NEI Guidance Document NEI 22-05 should address the issue.	Refer to the response to comment NRC-2022-0074-DRAFT-0006-36

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			Proposed Change Please delete Addition C.5.d. Additionally, consider adding NEI 22-05 to the list of guidance being developed in Appendix A of the NRC Reg Guide	
NRC-2022-0075-DRAFT-0004-6	Affirmative Safety Case	Background	"The applicant is also responsible for demonstrating compliance with all applicable regulations and may request exemptions, as appropriate, to establish the licensing basis for the design." Is NRC making a determination on the acceptability of the "affirmative safety case" concept? Proposed Change None	The answer to the question in the comment is no – the quoted statement is not a determination on the acceptability of the "affirmative safety case" concept as defined in NEI 21-07. In fact, Section C.2.a of DG-1404 clarifies that this term is not used and applicants should instead continue to use the established terminology in the current regulatory framework, including "safety analysis" and "licensing basis." The subject statement is meant to remind applicants that there are other regulations outside the scope of NEI 21-07 that need to be complied with. No change made to DG-1404.
NRC-2022-0075-DRAFT-0004-7	Fuel Qualification	6- Safety Functions, Design Criteria, and SSC Classifications	Addition C.6.b addresses fuel qualification. X-energy considers this additional guidance to be unnecessary and, as proposed, inappropriate, and counter-productive. The issue was essentially absent from the NRC's draft additions, clarifications, and exceptions that formed the basis for detailed interactions during the fall and winter of 2021, prior to	Refer to the response to comment NRC-2022-0074-DRAFT-0006-40.

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			submittal of NEI 21-07 Rev. 1 for endorsement. First, fuel qualification should essentially be done at the time of a license application, with the possible exception of some confirmatory items. The emphasis for fuel qualification should be during pre-application interactions as is discussed in DANU-ISG-2022-01, Appendix A. The NRC proposal to address fuel qualification expectations in the SAR, as reflected in this proposed addition, is wholly out of sequence and unnecessary, and it detracts from the guidance overall. Second, the document states "The reactor core and its fuel are generally classified as SR" as if that point justifies this special deterministic carve out of SAR documentation requirements for fuel. It does not. NEI 18-04 provides a systematic means of identifying safety related structures, systems, and components, based on the approach taken to satisfy Required Safety Functions. Provisions are already in place to address safety-related SSCs in Chapter 6. It is certainly expected that fuel	

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			performance will be particularly important to some advanced reactor designs, and if so the SAR documentation related to fuel will be more extensive than other SSCs, but there is no need to arbitrarily address fuel in a special way as proposed in the text. Third, there is no rationale for addressing fuel qualification in SAR Chapter 5, as proposed herein. Chapter 5 covers safety functions, design criteria, and SSC classification, but the document proposes to use it as a repository for additional information on one particular SSC (fuel). In summary, the fuel qualification guidance for SAR Chapter 5 should be reconsidered. <u>Proposed Change</u> Please delete Addition C.6.b.	
NRC-2022-0075-DRAFT-0004-8	Radionuclide Inventories	2-General Plant and Site Description	Chapter 1 should not list radionuclide inventories, it is more appropriately covered in Chapter 3 as alluded to in C.3 d. <u>Proposed Change</u> Please clarify if the requested information should be included in Chapter 1 or Chapter 3.	The NRC staff disagrees with the comment. The inclusion of radionuclide inventories in Chapter 1 follows NEI 21-07, Section 1.3.2.1, "Retaining Radionuclides," which states that Chapter 1 should "include a high-level discussion of location and types of radiological inventory." Item C.3.d in DG-1404 only applies to identification of the "sources of radionuclides," not their inventories.

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				No change made to DG-1404.
NRC-2022-0075-DRAFT-0004-9	Codes and Standards	7- Safety-Related SSCs	Addition C.7.b(2) is unnecessary and inappropriate. The addition imposes an additional SAR documentation requirement to justify the use of codes and standards. This requirement goes beyond standard practice for light water reactors. <u>Proposed Change</u> Please delete Addition C.7.b(2)	Refer to the response to comment NRC-2022-0074-DRAFT-0006-49.
NRC-2022-0075-DRAFT-0004-10	CP Content	Various	Some guidance should include clarification that it is not required for Construction Permit applicants: NSRST SSC performance (C.8.a), NSRST I&C Special treatments, MBDBE (C.4.c.(2)), uncertainties and sensitivities for cumulative risk metrics (C.5.b.(8)), change evaluation process (C.5.d). <u>Proposed Change</u> Please include clarification of which information is necessary for those requesting design finality versus those 10 CFR 50 Construction Permit applicants who are not requesting design finality.	The NRC staff does not agree that additional guidance is needed within DG-1404 regarding Construction Permit (CP) content because the guidance provided in NEI 21-07 is adequately clear on this point, with some of the proposed clarifications in DG-1404. For example, the topic of CP application content associated with integrated evaluations is reflected in Section 4.1 of NEI 21-07, Rev. 1 as follows: *For a CP application, Section 4.1 should provide a preliminary description of the integrated plant performance for the three cumulative plant performance metrics contained in NEI 18-04 Section 3.2.2, Task 7b for risk to the public from radiation. The PRA methodology described in Chapter 2 should be used in the dose and risk estimates addressed in Section 4.1. The applicant should identify limitations in the scope and level of detail of the CP-stage PRA that are to be addressed in the OL application.*

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				In general, applicants seeking design finality for a particular topic or portion of the facility reflected in the PSAR should provide the same level of information needed for the FSAR in support of the Operating License application. Applicants are encouraged to discuss any particular questions associated with pending CP application content with NRC during pre-application interactions. No change to DG-1404 resulting from this comment. Additional PRA-related guidance for CP applications was addressed via Revision 1 to DG-1404.
NRC-2022-0075-DRAFT-0004-11	DBHLs	7- Safety-Related SSCs	Related to Clarification and Addition C.7.a, there appears to be an inconsistency between the guidance in NEI 21-07 and DG-1404, compared to DANU-ISG-2022-01 (ARCAP Roadmap). Pages 12-13 of the ARCAP roadmap indicates that the information related to translation of DBHLs to loads (and evaluation of those loads) would be placed in SAR Chapters 5 and 6, while NEI 21-07 and DG-1404 would put that information in Chapter 2 or in external reports referenced in the SAR. <u>Proposed Change</u> Please review and resolve the discrepancy.	The NRC staff agrees with the comment. This detailed design information should be described in Chapters 5 and 6 as indicated in the Roadmap ISG. DG-1404, Section C.7.a has been changed as described in the response to comment NRC-2022-0074-DRAFT-0006-45.

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NRC-2022-0075-DRAFT-0004-12	PRA Consequence Uncertainty	Appendix A	X-energy is interested in the draft ISG on consequence uncertainty referenced in Appendix A. <u>Proposed Change</u> None	The NRC staff intends to make the subject ISG publicly available when completed. No change to DG-1404.
NRC-2022-0075-DRAFT-0004-13	NRC-DRG on Instrumentation and Controls	7 – Safety-Related SSCs 8- NSRST SSCs	Sections C.7.b(1) and C.8.a(1) are identified as additions to the associated Sections C.6 and C.7 of NEI 21-07, Rev. 1. What is the purpose of the focus on I&C SSCs? And, what is the addition? The DG-1404 guidance reiterates what is required by NEI 21-07, namely descriptions of special treatments for SR and NSRST I&C SSCs and analyses of capabilities of SR and NSRST I&C SSCs. If the intent is simply to identify the Design Review Guide (DRG), "Instrumentation and Controls for Non-Light-Water Reactor (non-LWR) Reviews," as providing additional guidance for content and review of this material, the addition should state this and cite the DRG; as written, it suggests the NRC is imposing additional requirements beyond what is required by NEI 21-07. <u>Proposed Change</u> Please provide additional clarification.	Refer to the response to comment NRC-2022-0074-DRAFT-0006-48.

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NRC-2022-0075-DRAFT-0004-14	Editorial	7- Safety-Related SSCs	Footnote 11 on Page 26 should be Footnote 12. <u>Proposed Change</u> Please update the footnote.	This footnote is deleted. Refer to the response to comment NRC-2022-0074-DRAFT-0006-48.
NRC-2022-0075-DRAFT-0004-15	Human Factors	9- Plant Programs	Chapter 8 of a SAR following NEI 21-07 addresses plant programs, including Human Factors Engineering. The NRC Staff's position (Staff Position C.9) states this an acceptable method for developing information related to Plant Programs. However, DANU-ISG-2022-05 provides guidance for Human Factors and Human-System Considerations to be included in Chapter 11 of a SAR. Would the NRC prefer to have the HFE program addressed in a specific chapter, or left to the applicant to decide? <u>Proposed Change</u> Please provide specific guidance.	The answer to the question in the comment is that HFE program content should be provided in Chapter 11 of an SAR as described in DANU-ISG-2022-05. This is consistent with the summary of NRC interactions that was included with the NEI letter transmitting NEI 21-07 Rev. 1, which summarized that: *"The TICAP presumption is that ARCAP Chapter 11 will contain the guidance for describing Human Factors Engineering (HFE) program components. Therefore, specific guidance in NEI 21-07 on HFE programs is not needed in Chapter 6. Programs are invoked by special treatments (Chapters 6 and 7) and addressed in Chapter 8. HFE is addressed in Chapter 11 by ARCAP guidance."* Having said that, to the extent FSAR Chapter 11 describes the HFE program, that description need not be repeated in FSAR Chapter 8. Also refer to the response to comment NRC-2022-0075-DRAFT-0004-2. No change to DG-1404.
NRC-2022-			DANU-ISG-2022-07 acknowledges the development of the ASME OM-	The NRC staff agrees with the comment.[1]

[1] The NRC staff does not agree with the comment's usage of "requirements" with respect to the ISG, which includes guidance on one acceptable approach to meeting NRC regulatory requirements (in NRC regulations and orders) but does not require any particular approach.

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0075-DRAFT-0004-16			2 code and states that the ISG assumes that applicants following the ISG will implement IST programs utilizing previously endorsed codes. The ISG later requires that construction permit applications include what standards are going to be followed at the operating license stage. Proposed Change Please clarify the requirements for applicants who expect to follow an endorsed OM-2 code at the point of Operating License issuance who will be requesting Construction Permits prior to OM-2 code endorsement.	Appendix A of DANU-ISG-2022-07 has been updated to provide the following discussion regarding the status of ASME OM-2 code: "The new ASME OM-2 Code may be available when non-LWR applicants are preparing to develop their plant-specific IST programs. If a CP applicant seeks to use codes and standards the NRC staff has not endorsed, the applicant is encouraged to engage the staff on that topic during pre-application interactions. Nonetheless, a subsequent OL application must reference NRC staff-approved codes and standards or justify the use of codes and standards the NRC staff has not previously approved. Further, the NRC staff will consider granting design finality requested for unendorsed codes or standards in a CP application only if the application includes information sufficient for the NRC staff to approve the use of the code or standard for the purpose requested in the application. Any portion of the design affected by a draft code (if not approved on an application-specific basis) is not eligible for a design finality determination."
NRC-2022-0075-DRAFT-0004-17	Editorial	References	Reference 14 cites ML1025210405, which should be ML102510405. Proposed Change Please update the reference.	The NRC staff agrees with the comment and has updated the text to reflect "ML102510405."
NRC-2022-0073-DRAFT-0006-1	Extension of Comment Period	Not Applicable	Make NEI 21-07, Revision 1, publicly available, and provide this document and NEI 18-04, Revision 1, on regulations.gov docket ID NRC-2022-0073. Because these documents are not publicly available	The NRC staff provided a response to the commenter in ML23283A013. As documented in this response, the comment period extension request for DG-1404 Revision 1 was not granted on the basis of the unavailability of key documents given that NEI 21-07, Revision 1, and NEI 18-04, Revision 1 are

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			a comment period extension was requested.	publicly available, and provided in the list of references in DG-1404, Revision 1. The NRC staff did extend the comment period on DG-1404 Revision 0 as noted in response to NRC-2022-0073-DRAFT-0002-2.
NRC-2022-0073-DRAFT-0012-1			Our Ref. [3] letter (Comment NRC-2022-0073-DRAFT-0006-1) advised that the key NEI document was apparently not publicly available as the document was not an available download in regulations.gov under docket NRC-2022-0073. Subsequently during the Ref. [4] meeting, the NRC staff advised that the subject document was available on the NRC website. We were able to obtain the document, although just using regulations.gov would have likely proved problematic.	Refer to the response to comment NRC-2022-0073-DRAFT-0006-1.
NRC-2022-0073-DRAFT-0008 -1 NRC-2022-0073-DRAFT-0009-1	Use of Codes and Standards	Cover letter	The comment is similar to previous comments provided for the ARCAP ISG (Comment NRC-2022-0074 DRAFT 0005-CL-1).	The NRC staff notes that the comment is largely outside the limited scope of Revision 1 to DG-1404 and duplicative of comments on the ARCAP ISG (see Comment NRC-2022-0074 DRAFT 0005-CL-1). Refer to the NRC staff response to comment NRC-2022-0074 DRAFT 0005-CL-1 on the ARCAP ISG (ML23277A148). That response is duplicated below for convenience. It is the NRC's policy to (i) involve all interested stakeholders in the NRC's regulatory development processes, (ii) participate in the development of

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				consensus standards that support the NRC's mission, and (iii) use consensus standards developed by voluntary consensus standards bodies consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Public Law 104-113). However, the NRC has not adopted an automatic endorsement of consensus standards as suggested by the comment because (i) such an action could constitute an unlawful delegation of power to a private entity and (ii) possible efficiency gains of such a process would be limited compared to existing practice of review and endorsement (with appropriate exceptions and clarifications) of consensus codes and standards for use by applicants and licensees to address specific topics important to the safety of a nuclear power plant. NRC review is required in both the current process of reviews performed at the request of standards development organizations and the proposed case-by-case reviews to determine if changes or limitations on the use of a standard is needed to ensure compliance with regulations, or to be technically correct. (See SECY-99-029, "NRC Participation in the Development and Use of Consensus Standards," January 28, 1999, available at http://www.nrc.gov/reading-rm/doccollections/commission/secys/1999/secy1999-029/1999-029scy.pdf, and the related Staff Requirements Memorandum dated February 17, 1999 (ML003751820).
NRC-2022-0073-DRAFT-0010-1			Please provide the specific law(s) and the specific section(s) of the law(s) that verify the claim that NRC endorsement of all codes and standards is a requirement. We can	The NRC staff notes that the comment is largely outside the limited scope of Revision 1 to DG-1404 and is similar to other comments (e.g., Comment NRC-2022-0074 DRAFT 0005-CL-1 on the ARCAP ISG). The guidance nonetheless does not state that

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			find no such law(s). Rather, the NRC claim is customary. Further, a simple inspection reveals that not all codes/standards used in nuclear applications have been endorsed by the NRC. Claims of the illegality of using unendorsed codes/standards are not supported by actual law and practice. As we advised in our Ref. [3] letter, we suggest the use of the following simple statement. "The Applicant must identify and justify the use of all major consensus industry codes and standards used in conjunction with the design, manufacture, construction, and operation of systems, major structures and major components involving Safety-Related functions, as defined by the Code of Federal Regulations. Citing clearly germane regulatory documents/guides constitutes an acceptable justification method."	the NRC staff needs to endorse all codes and standards that might be used by an applicant. However, to the degree that an application relies on an unendorsed consensus code or standard as a vehicle to comply with NRC regulations, the NRC staff will need to verify such claims within the review of an application. Refer to the response for comment NRC-2022-0073-DRAFT-0008-1.
NRC-2022-0073-DRAFT-0013-1	PRA Guidance	General	Most of the information provided in Appendix B provides guidance on NRC's expectations regarding how an applicant should do an acceptable probabilistic risk assessment (PRA) in support of a construction permit (CP) application for a non-light water reactor (non-LWR) following NEI 18-04. That introduces confusion because DG-1404 is a	The NRC staff partially agrees with the comment. Regarding the first proposed change in this comment, the NRC staff declines to re-issue the guidance in Appendix B to DG-1404, Revision 1, in a separate document as doing so would not meet the near-term needs of applicants currently developing applications. NEI 21-07, Revision 1, states in Section A.1 that it, "…provides one acceptable approach for the

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			draft regulatory guide addressing NEI 21-07 which addresses the content for the safety analysis report (SAR), not how to perform analyses (including PRAs). In fact, the first page of DG-1404 clearly states the guidance should be focused on SAR content, not how to do the analyses. The fundamental concern is that Appendix B does not clearly delineate between 1) what is guidance for how to document the CP PRA and 2) what is guidance for how to do the CP PRA. One interpretation of this is that, NEI 21-07, Rev 1, plus the additions and clarifications in the body of DG-1404 is the totality of information to describe the preliminary SAR (PSAR) scope and level of detail (see B.7.1). Based on discussions at the September 26, 2023, NRC public meeting on DG-1404 Appendix B, both industry and the NRC staff currently share this interpretation. However, it is also possible to interpret Appendix B as indicating that everything discussed in Appendix B must be described in the PSAR as the guidance is located in an NRC document addressing	development of those portions of the Safety Analysis Report required for…a reactor construction permit followed by an operating license…that employs the LMP methodology endorsed by Regulatory Guide 1.233." It also references the use of the non-LWR PRA standard and staff guidance that serves as the endorsement vehicle for that standard that was under development at the time and was subsequently issued as RG 1.247. In addition to endorsing the non-LWR PRA standard with exceptions, RG 1.247 provides guidance on the information that should be included in an application. Consistent with staff position C.3.d of DG-1404, Revision 1, RG 1.247 provides an acceptable approach for documenting the acceptability of the PRA in an application. Position C.4.2 of RG 1.247 indicates that PRA documentation for the application has generic characteristics and attributes that are fundamental to the staff's assessment of PRA acceptability for a given application. RG 1.247 also indicates this PRA documentation should justify that the application PRA has been performed such that its results are acceptable and commensurate with the design maturity of the proposed facility. The PRA documentation should include any commitments for updating the PRA to ensure that it reflects the plant design and is consistent with the PRA's intended use in the application. In keeping with the stated purpose of these documents, Appendix B to DG-1404, Revision 1,

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			expectations for SAR and PSAR content. There are also specific instances in Appendix B that could be construed as adding on to the documentation requirements in NEI 21-07 (see for example B.3.6). [Additionally,] the material in DG-1404 Appendix B has no relation to the stated purposes of NEI 21-07, Revision 1, or DG-1404. Because Appendix B goes beyond simply guidance on PSAR content, it is imperative that there be a clear delineation between CP PRA guidance and PRA PSAR content guidance. <u>Proposed Change:</u> NEI suggests two approaches to address the problem. 1. NRC can reissue the material in Appendix B in a separate and more appropriate document, such as an Interim Staff Guidance (ISG) document. As the guidance in Appendix B exceeds the scope of NEI 21-07 and the purpose of DG-1404 (expectations for SAR and PSAR content), we believe that	provides guidance on what is needed to achieve an acceptable PRA and the documentation necessary to demonstrate the acceptability of the PRA for a construction permit application. As it relates to the latter, the documentation needed to demonstrate the acceptability of the PRA supporting the application will relate to what is needed for the content of the application in the SAR. The applicant may maintain detailed supporting or confirmatory information in archival documentation (i.e., referred to in NEI 21-07, Revision 1, as plant records) that is available to the NRC staff for audit. As such, because the NRC staff positions in Appendix B to DG-1404, Revision 1, effectively address three areas of guidance, the NRC staff agrees that additional clarity is warranted to identify which NRC staff positions relate to each area. The NRC staff has revised the guidance in Appendix B to DG-1404, Revision 1 (relabeled in RG 1.253 as Appendix A), to more clearly distinguish which NRC staff positions relate to 1) achieving an acceptable CP PRA supporting an LMP-based, non-LWR, construction permit application; 2) additional description of documentation in the PSAR sufficient to demonstrate the acceptability of the CP PRA; and 3) guidance on documentation that provides additional background and support for the information in the application that confirms the acceptability of the CP PRA but is not included in the PSAR. The documentation in category (3) is also referred to as “archival documentation.” Regarding the second proposed change in this comment, based on the above response to the

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			creating a separate guidance document is the best solution. 2. NRC can make a global statement in the front of Appendix B acknowledging that the guidance provides staff expectations for the development of the CP PRA, not staff expectations for the documentation of the CP PRA in the PSAR. Such a statement should go on to state that the combination of the guidance on PSAR content in NEI 21-07, Rev 1, and the body of the regulatory guide are adequate. If the NRC chooses this approach, please add the following paragraph after the three bullets on page 1 of Appendix B. *Unlike the body of the regulatory guide, this Appendix B provides no guidance for the documentation of information in the safety analysis report (SAR) associated with a reactor license application. NEI 21-07, Revision 1, as endorsed with additions and clarifications in the main body of this Regulatory Guide, already provides an acceptable approach and format for providing SAR documentation, including information associated with the CP PRA.*	comment, the NRC staff declines to provide "a global statement in the front of Appendix B [to DG-1404, Revision 1,] acknowledging that the guidance provides NRC staff expectations for the development of the CP PRA and not [NRC] staff expectations for the documentation of the CP PRA in the PSAR." However, the NRC staff has revised the guidance as stated above.

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NRC-2022-0073-DRAFT-0013-2	PRA Guidance		The text in sections noted below applies to how to perform a CP PRA, not how to document the PRA in the PSAR. B.2.3, B.3.4, B.3.5, B.3.7, B.4.1, B.4.2, B.5.1, B.5.2, B.6.1, B.6.2, B.6.3, B.8.4, B.8.5, B.8.6 <u>Proposed Change:</u> Action required as noted in Comment NRC-2022-0073-DRAFT-0013-1 to differentiate in the guidance between 1) information on how to perform the CP PRA and 2) what information regarding the CP PRA is needed for inclusion in the PSAR.	The NRC staff partially agrees with the comment. Staff positions B.2.3, B.3.4, B.3.5, B.4.1, B.5.2, B.6.2, B.6.3, B.8.4, B.8.5, and B.8.6 relate to PRA acceptability and not documentation of the PRA in the PSAR. Refer to the NRC staff response to comment NRC-2022-0073-DRAFT-0013-1.
NRC-2022-0073-DRAFT-0013-3	PRA Guidance	B.2.2	The text begins by stating "Consistent with NEI 21-07, Revision 1, Section 2.1.1" but the PSAR guidance seems to go far beyond NEI 21-07. There are technical requirements for each technical element in the PRA standard to document assumptions made in addressing the supporting requirements, including those made to address the lack of design, site, and operational information available to support the PRA. Hence this information is more appropriately placed in the PRA	The NRC staff partially agrees with the comment. Although the ASME/American Nuclear Society (ANS) non-LWR PRA standard (ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants") includes technical elements related to the identification and documentation of assumptions in the PRA model, as noted in the comment, NEI 21-07, Revision 1, indicates that assumptions made in performing the PRA that are essential to the LMP-based safety analysis will be identified in the sections of the SAR to which they apply. The footnote related to NRC staff position B.2.2 defines a key assumption in NUREG-2122, "Glossary of Risk-Related Terms in Support of Risk-

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			documentation so it is presented in the context of the other supporting requirements selected to support the PRA which would be available to audit by the NRC. This level of detail of PRA information is too voluminous for inclusion in the CP application and is inconsistent with the concept in NEI 21-07 Section 2.1.1 for a two-step licensing submittal. The expectation that all key assumptions be documented in the SAR is substantially different from the guidance provided in NEI 21-07. The Appendix B guidance is not well-bounded and is inappropriate for incorporation in the SAR, particularly at the CP stage. NEI 21-07, Rev 1, Section 2.1.1 explicitly calls for documentation of "*site characteristics modeled or assumed in the radiological consequence evaluations*." That is narrow and limited guidance related to assumptions. Furthermore, NEI 21-07 Section 2.1.1 specifies that assumptions will be addressed in the appropriate SAR section. The NEI 21-07 text states "*Assumptions made in performing the PRA that are essential to the LMP-based affirmative safety case will be*	Informed Decision," as one that "…could affect the PRA results that are being used in a decision and, consequently, may influence the decision being made." Comparing this definition to the guidance in NEI 21-07, Revision 1, it is reasonable to conclude that the essential assumptions made in performing the PRA would necessarily affect the results of the PRA, which is in turn being used in and influences the decisions under consideration related to the implementation of LMP and development of the design bases. As such, the assumptions made in performing the PRA that are essential to establishing the LMP-based design are the same as key assumptions, as defined by the NRC. The NRC staff has revised NRC staff position B.2.2 and the related footnote to explicitly acknowledge the relationship between the meaning of key assumptions and essential assumptions described in NEI 21-07, Revision 1. However, while such assumptions need to be documented in their respective sections of the SAR, doing so should not imply the need for a greater level of detail in the SAR documentation. The guidance in NRC staff position B.2.2 provides additional detail on types of assumptions made in performing the PRA that are essential to the LMP-based design but is not intended to imply that additional documentation should be included in the SAR beyond that identified by NE1 21-07, Revision 1. No changes were made to DG-1404 as a result of this comment.

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			identified in the sections of the SAR to which they apply. For example, such assumptions that impact the selection and evaluation of LBEs will be noted in Chapter 3. PRA assumptions that are not essential to the safety case will not be included in the SAR but will be available in the plant records for NRC audit." The intent of this guidance was to avoid a compendium of assumptions in the front of the SAR which may or may not be pertinent to the safety case. <u>Proposed Change:</u> The guidance of B.2.2 is not needed and should be deleted. Alternatively, revise B.2.2 to state, "*The CP applicant should clearly document internally in its records the key assumptions made in developing the PRA, including those that are relevant to the probability and consequence models, and the selection of elements for models to incorporate*."	
NRC-2022-0073-DRAFT-0013-4	PRA Guidance	B.3.1	The information described in B.3.1.1 and B.3.1.2 are essentially covered in PSAR Chapters 3 and 4, respectively. It is not clear what the purpose of B.3.1 is, because it	The NRC staff disagrees with the comment. The guidance in Chapter 4 of NEI 21-07, Revision 1, on page 39 under the heading "Two-Step Licensing (CP Content)" states that a preliminary description of the three cumulative plant performance metrics in

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			basically duplicates information already in NEI 21-07, Revision 1. As discussed in Comment 1, it is essential to delineate between actual PSAR content guidance and other information. <u>Proposed Change:</u> Action required as noted in Comment NRC-2022-0073-DRAFT-0013-1 to differentiate in the guidance between the information regarding the CP PRA that is needed for inclusion in the PSAR, and other information.	NEI 18-04 should be provided. However, "providing a description" could be interpreted as only providing a narrative description of the risk metrics themselves without also providing a preliminary quantitative or qualitative determination of the values of those risk metrics and an explanation of how the Commission's quantitative health objectives (QHOs) from the Commission policy statement on safety goals will be met in support of the OL application. Specifically, RG 1.247 for trial use provides definitions for the individual early fatality risk and individual latent cancer fatality risk metrics, which can be directly compared to the QHOs. As such, the purpose of NRC staff position B.3.1.2 is to ensure a CP applicant estimates the identified metrics, on either a quantitative or qualitative basis, given the information available when the CP application is prepared. The staff has revised staff position B.3.1 accordingly.
NRC-2022-0073-DRAFT-0013-5	PRA Guidance	B.3.2 and B.3.3	The second sentence of section B.3.3. states: "*The staff notes that a minimally acceptable PRA would not support full implementation of the LMP methodology at the CP stage because it may not address non-core radiological sources, low power and shutdown POSs, and all internal and external hazards groups*." First, this text provides guidance on performing the PRA analysis, not what information from the PRA	The NRC staff partially agrees with the comment. Regarding the portion of the comment about NRC staff positions B.3.2 and B.3.3 providing guidance on performing the PRA analysis, not what information from the PRA should be documented in the SAR, refer to the NRC staff response to comment NRC-2022-0073-DRAFT-0013-1. Regarding the portion of the comment stating that NRC staff position B.3.3 conflicts with NRC staff position B.3.2, the NRC staff acknowledges the need for additional clarity regarding the use of the term PRA in these two NRC staff positions. The use of the term "PRA" in NRC staff position B.3.3 refers to the PRA logic models and related analyses that

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			analysis should be documented in the SAR. Second, this language is in conflict with B.3.2 whose text states: "…*the CP PRA scope should address all radiological sources, all hazards, and all POSs*." Third, the idea that a PRA would address or include all these items is incorrect. Things may be screened out or addressed deterministically and not necessarily included in the PRA. LMP is a risk-informed and not risk based methodology. In addition, the phrase "*full implementation of LMP*" is not appropriate because there are no criteria to decide which are deemed "full". A CP application either applies the methodology in NEI 18-04 or does not. If the CP application deviates from the methodology that must be documented. Finally, B.3.2 states "1. *Identify all radiological sources, POSs, and hazards by performing a comprehensive and systematic search*." And "2. *Disposition the search results by a combination of PRA logic modeling, acceptable screening methods, risk-informed supplemental evaluations, and*	would be used to directly inform the development of LBEs, support SSC classification, and inform evaluations of defense-in-depth adequacy. The NRC staff has revised the guidance accordingly. The NRC staff disagrees with the portion of the comment asserting it is incorrect that a PRA would address or include all sources, hazards, and POSs. The NRC staff has revised Position B.3.2 to clarify that the applicant should identify all radiological sources, all hazards, and all POSs and disposition them by either representing them in the PRA logic model, justifying their exclusion from the PRA logic model through screening analyses, representing them through a risk-informed supplementary evaluation, or using a DBHL as a way of bounding the expected risk contribution. The NRC staff also notes that the LMP methodology is risk-informed by design, even when supported by a full-scope PRA logic model, because the LMP methodology is informed by input from analyses other than risk. No changes were made to DG-1404 as a result of this comment. The NRC staff agrees with the portion of the comment stating that the phrase "full implementation of LMP" is not appropriate. The NRC staff acknowledges that this phrase and the related statement is primarily associated with an applicant's management of project risk for its application. However, the focus of the staff's review of an application is on compliance with regulatory

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			crediting design-basis hazard levels (DBHLs).” This text also provides guidance on performing the PRA analysis, not what information from the PRA analysis should be documented in the SAR. <u>Proposed Change:</u> Please delete or rewrite B.3.2 and B.3.3 to address the points raised in the comment. Action required as noted in Comment NRC-2022-0073-DRAFT-0013-1 to differentiate in the guidance between 1) information on how to perform the CP PRA and 2) what information regarding the CP PRA is needed for inclusion in the PSAR.	requirements and determining whether the findings related to the issuance of a CP can be made.
NRC-2022-0073-DRAFT-0013-6	Editorial	B.3.4	The acronym “SR” is defined as “Supporting Requirements.” However, this acronym is defined as “safety-related” throughout DG-1404 including elsewhere in Appendix B (example: Item B.3.7) and in other ARCAP documents. <u>Proposed Change:</u> It is an error-likely situation to define SR as two different terms. Industry would prefer to keep SR as “safety-related” and not use an	The NRC staff agrees with the comment and will revise the guidance to spell out the use of the term “supporting requirement.”

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			acronym for "supporting requirements."	
NRC-2022-0073-DRAFT-0013-7	PRA Guidance	B.3.6	It is unclear if B.3.6 is intended to apply to the PSAR or to internal documentation (plant records). If it is the former (PSAR), the guidance goes beyond current documentation requirements and is a level of detail that is inappropriate for the PSAR. If it is the latter (plant records), the information should be sufficiently differentiated to ensure regulatory predictability and certainty. <u>Proposed Change:</u> Action required as noted in Comment NRC-2022-0073-DRAFT-0013-1 to differentiate in the guidance between the information regarding the CP PRA that is needed for inclusion in the PSAR, and other information.	The NRC staff partially agrees with the comment. Refer to the NRC staff response to comment NRC-2022-0073-DRAFT-0013-1.
NRC-2022-0073-DRAFT-0013-8	PRA Guidance	B.4.2	The last sentence of the guidance text states: "*Consistent with Staff Position C.2.1 in RG 1.247, all HLRs for a given PRA element should be met.*" This statement is inappropriate because self-assessments and peer reviews under the NEI guidance generally do not include meeting HLR requirements.	The NRC staff disagrees with the characterization that the cited language is inappropriate. The guidance on PRA elements in RG 1.247 relates to meeting the NRC staff positions in Section C.1.3 of RG 1.247. One way to meet those NRC staff positions is to meet the high-level requirements from ASME/ANS RA-S-1.4-2021, as endorsed by RG 1.247. As discussed in Section 1.4.2 of ASME/ANS RA-S-1.4-2021, a high-level

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			Self-assessments and peer reviews only involve meeting the supporting requirements. This is the case for both non-LWRs and LWR applications of the NEI PRA peer review guidelines. <u>Proposed Change:</u> Please remove this statement and limit the expectations to meet technical requirements to supporting requirements.	requirement is met by virtue of meeting the applicable supporting requirements. As such, while a self-assessment or peer review using NEI 20-09, Revision 1, assesses how applicable supporting requirements were met for a given PRA, the purpose is ultimately to determine whether a high-level requirement to which those supporting requirements relate is met. No changes were made to DG-1404 as a result of this comment.
NRC-2022-0073-DRAFT-0013-9	PRA Guidance	B.5.2	The guidance text states: "*The staff has applied the process provided in Section 3 of the ASME/ANS non-LWR PRA standard and the results are presented in Tables B-2 and B-3, which follow the main body of this appendix. The CP applicant may use Tables B-2 and B-3 to establish the acceptability of the PRA level of detail.* *Alternatively, the CP applicant may perform a separate analysis using the process provided in Section 3 of the ASME/ANS non-LWR PRA standard and justify any deviations from or alternatives to Tables B-2 and B-3*."	The NRC staff partially agrees with the comment. The NRC staff understands and appreciates that some applicants may not have sufficient information on the design and operational features of the plant to support a PRA scope and level of detail that would be capable of addressing all of what ASME/ANS RA-S-1.4-2021 identifies as supporting requirements designated in Tables B-2 and B-3. However, because the NRC staff must consider the full range of potential design maturity represented by the information submitted to the NRC staff in a CP application, including designs that may be sufficiently complete to account for all aspects of a PRA addressed in Tables B-2 and B-3, the NRC staff applied the risk assessment application process in Section 3 of ASME/ANS RA-S-1.4-2021 to all supporting requirements in that standard. This effort does not and should not be understood to call for conformance with the substance of every item in Tables B-2 and B-3. The NRC staff has revised the

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			Table B-2 covers all the technical requirements for an internal event at power PRA and suggests that all the requirements should be met for a minimally acceptable PRA for CP application. Table B-3 addresses the remaining requirements for PRAs with an expanded scope. The expectation raised in these tables about standard compliance is unreasonable because it is unlikely that there would be sufficient design and operational information included in the CP application to support the PRA scope that would be required to meet all these requirements. It is made clear in Section 1.3 of the non-LWR standard that the selection of the scope and the technical requirements to support PRAs in different life cycle stages is dependent on the level of design and site information that is available at that life cycle stage. As stated in Section 3.1(a) of the standard: *The scope and level of detail of the PRA is then selected based on the design and site characteristics and the state of design and site information available to support the PRA.*	guidance to more clearly explain the purpose of the tables. The NRC staff agrees that the risk assessment application process in Section 3 of ASME/ANS RA-S-1.4-2021 explicitly considers varying degrees of design maturity in determining the applicability of what it identifies as supporting requirements for a given application. The NRC staff has revised the guidance to clarify this point.

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			It is expected that most CP applications will not have sufficient information on the design and operational features of the plant to be able to support a PRA scope and level of detail that would be capable of addressing all these requirements. Although the second paragraph provides a means of proposing an alternative scope of requirements and capability categories, the overall impression is that NRC is expecting a scope and level of detail that is likely to exceed that which can be supported by the level of design and operational information that will be included in the CP application. The problem is this issue should not be viewed as a case-by-case exception, but rather a generic problem with PRAs to support CP applications. <u>Proposed Change:</u> In presenting the expectations for meeting the technical requirements in Table B-2 and in Table B-3, the NRC should note that the selection of requirements for inclusion in the CP PRA are dependent on the level of detail of design and operational information included in the CP application. The requested self-assessments should be limited to	

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			those technical requirements that can be addressed with the design and operational information included in the CP application.	
NRC-2022-0073-DRAFT-0013-10	PRA Guidance	B.7	The text in sections noted below applies to how to document PRA archival information (not in the PSAR) rather than how to document the PRA in the PSAR. B.7.2, B.7.3 Proposed Change: Action required as noted in Comment NRC-2022-0073-DRAFT-0013-1 to differentiate in the guidance between the information regarding the CP PRA that is needed for inclusion in the PSAR, and other information.	The NRC staff partially agrees with the comment. Refer to the NRC staff response to comment NRC-2022-0073-DRAFT-0013-1.
NRC-2022-0073-DRAFT-0013-11	PRA Guidance	B.7.1	The text states "NEI 21-07, Revision 1, as endorsed with additions and clarifications in the main body of this RG, provides an acceptable approach and format for providing CP PRA submittal information." NEI emphatically agrees with the comment. Proposed Change: Given this point, NRC needs to clarify that none of the other guidance in Appendix B applies to	The NRC staff disagrees with the comment. Although the NRC staff stated in DG-1404 that NEI 21-07 provides an acceptable approach and format for providing CP PRA information in a CP application, DG-1404 also refers to the provisions in RG 1.247, which gives more detailed guidance on the information that should be included in an application. Accordingly, the staff disagrees with and has not adopted the proposed change because the staff position in RG 1.247 on PRA documentation for the application includes providing documentation justifying that the application PRA has been performed such that its results are acceptable and

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			documentation of the CP PRA in the PSAR, and that the guidance in NEI 21-07, Revision 1, is sufficient to cover all of PRA documentation requirements. See Comment NRC-2022-0073-DRAFT-0013-1	commensurate with the design maturity of the proposed facility. As such, the staff has revised the guidance in position B.7.1 of DG-1404, Revision 1, to reflect that this documentation should be provided as part of the PSAR. The staff also revised the guidance in position B.7.2 to emphasize that detailed documentation that provides additional background and support for (or confirmation of) the information in the application that demonstrates the acceptability of the CP PRA should be maintained in archival documentation (i.e., plant records), which would be available for NRC audit.
NRC-2022-0073-DRAFT-0013-12	PRA Guidance	B.8.3	The guidance text states, "*Consistent with NEI 21-07, Revision 1, Section 2.1.1, page 24, the CP applicant should describe its ultimate intended approach for qualifying the PRA*." This guidance is completely unnecessary. As Appendix B makes clear, the point is completely covered in NEI 21-07 on p. 24; there is no need to repeat it. Moreover, it is already covered by the general statement in B.7.1. <u>Proposed Change:</u> Delete B.8.3	The NRC staff agrees that staff position B.8.3 repeats guidance from NEI 21-07, Revision 1. The staff has deleted staff position B.8.3 from the guidance and renumbered the subsequent staff positions accordingly.
NRC-2022-0073-DRAFT-0011-1	LWR Applicability	Applicability, p. 2	Regulatory guide only applicable for non-LWRs. <u>Proposed Change:</u>	The NRC staff notes that the comment is largely outside the limited scope of Revision 1 to DG-1404 and similar to comment NRC-2022-0074-DRAFT-0006-1.

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			Please remove the "non-LWR" language to the extent that it could be read to exclude LWRs. Because the regulatory guide is technology neutral, it should also cover LWRs. If LWRs are not included, please clarify why this regulatory guide is not applicable to LWRs if it is technology-inclusive.	Refer to response to comment NRC-2022-0074-DRAFT-0006-1.
NRC-2022-0073-DRAFT-0011-2	Reliability and Capability Targets	Section 7, p. 24	The first paragraph implies reliability testing is required to confirm performance-based targets for all SR SSCs before the plant starts up. For first-of-a-kind technologies this seems cost prohibitive. Proposed Change: Clarify that reliability testing of all SR SSCs is not necessarily required before plant startup.	The NRC staff disagrees with the statement in the comment that the first paragraph of Section 7 of DG-1404, Revision 1, implies reliability testing is required to confirm performance-based targets for all SR SSCs before the plant starts up. Consistent with the staff's response to comment NRC-2022-0074-DRAFT-0006-41, information should be provided in the PSAR that explains how the applicant will confirm that the reliability and capability targets informed by the final PRA will be met, which may indicate when the confirmation would be performed.
NRC-2022-0073-DRAFT-0011-3	Reliability and Capability Targets	Section 8, p. 26	The first paragraph implies reliability testing is required to confirm performance-based targets for all NSRST SSCs before the plant starts up. For first-of-a-kind technologies this seems cost prohibitive. Proposed Change:	The NRC staff agrees the cited text would benefit from clarification and confirms that the staff does not intend that all targets be established and verified at the CP stage. The text has been revised as follows: "NSRST reliability and capability targets can be provided at the CP or the OL stage. For those NSRST SSCs whose reliability and capabilities have not been provided and confirmed at the CP stage, the application should include a discussion in the PSAR on how the applicant intends to confirm, at the OL stage, that reasonable reliability and capability

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			Clarify that reliability testing of all NSRST SSCs is not necessarily required before plant startup.	performance targets have been ~~met~~ established, align with the supporting analyses, and have special treatments defined to ensure the performance of SSCs meet the targets. The OL application should describe any testing and validation ~~planned to~~ confirming NSRST SSC performance capabilities and availability, including any additional special treatments to be applied to the NSRST SSCs as compensatory measures to address a lack of operating experience."
NRC-2022-0073-DRAFT-0011-4		Multiple	It is unclear how a high-level conceptual PRA at the CP stage can provide Level 3 dose consequences to support SSC classification and DID adequacy evaluations. There seems to be a disconnect between the level of detail in the PRA for the CP stage and other activities that use the PRA results. <u>Proposed Change:</u> The conclusions drawn from the preliminary PRA should not be expected to have more precision than the underlying PRA.	The NRC staff agrees with the statement that the conclusions drawn from the preliminary PRA should not be expected to have more precision than the underlying PRA. Regarding the use of the PRA to support SSC classification and DID adequacy evaluations, the staff notes that, as provided for in NEI 18-04, Revision 1, the incorporation of PRA insights into the design and licensing of a nuclear power plant is an iterative process. Accordingly, the NRC staff understands that the information available at the time of the CP application is preliminary in nature and that the acceptability and usefulness of the PRA will be commensurate with the detail and maturity of the available preliminary design information. A key aspect of establishing the acceptability of the PRA at this stage of the licensing process is understanding whether the foundational elements of a PRA have been performed acceptably given the design maturity and how the PRA is used to support the design decisions and LMP implementation at the CP stage of licensing. No changes were made to DG-1404 as a result of this comment.

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NRC-2022-0073-DRAFT-0011-5	Reliability and Capability Targets	Section 7 and 8	No reliability or availability targets for SSC classes. Proposed Change: Please allow the possibility of establishing performance-based targets (e.g., reliability) for different classes of SSCs similar to UK ONR and Canada CNCS guidance.	The NRC staff partially agrees with the comment in that an applicant is free to establish common performance-based targets for groups or classes of SSCs. However, the NRC staff does not see a need for a change to the guidance to support an applicant proposing to establish common performance-based targets for groups or classes of SSCs because the guidance does not prohibit doing so. No changes were made to DG-1404 as a result of this comment.
NRC-2022-0073-DRAFT-0011-6	PRA Guidance	B.3.1	The document states an applicant should determine the "…average individual risk of latent cancer fatalities within 10 miles of the EAB…" The Safety Goal Policy Statement uses the phrase "average individual risk" for early fatality risk and "risk to the population" for cancer fatality risk Proposed Change: Please clarify the type of risk to be calculated for cancer fatality risk to be consistent with the Safety Goal Policy Statement.	The NRC staff acknowledges the comment and recognizes that different terminology and points of reference have been used in various NRC documents. The guidance documents most directly related to this question are RG 1.233 and trial use RG 1.247. These documents refer to the exclusion area boundary (EAB) as the reference point for the evaluation of radiological consequences and refers to the risk of latent cancer fatality to a biologically average individual who resides within 10 miles of the site, which means within 10 miles of the EAB. No changes were made to DG-1404 as a result of this comment.
NRC-2022-0073-DRAFT-0011-7		B.3.1	The document states an applicant should determine the "…average individual risk of latent cancer fatalities within 10 miles of the EAB…" The Safety Goal Policy Statement uses the phrase "plant site boundary" for early fatality risk and "plant site" or "plant" for cancer	The NRC staff acknowledges the comment and clarifies that the distance to calculate cancer fatality risk is within 10 miles of the EAB.

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			fatality risk. The use of plant may refer to the release point. Proposed Change: Please clarify if the distance to calculate cancer fatality risk is from the release point or the site boundary.	
NRC-2022-0073-DRAFT-0011-8	LWR Applicability	Tables B-2 and B-3	Minimally acceptable and more than minimally acceptable PRA for LWRs at CP stage. Proposed Change: Please provide a similar set of tables to Table B- 2 and B-3 for LWRs.	Refer to response to comment NRC-2022-0074-DRAFT-0006-1.
NRC-2022-0073-DRAFT-0007-1		Table B-2	Since a CP application will not yet have developed procedures, the standard requirements that should be met at CP stage should not require any procedures. Generally, this is considered in Table B-2 of the DG. However, several of the SRs listed appear to require procedures to be met. These include HR-G8, HR-H2 and DA-C9. Recommend these be listed in the Table as required to be met at capability category (CC)-I.	The NRC staff agrees with the comment and performed a review of all CC-I and CC-II entries in Tables B-2 and B-3 of Appendix B to DG-1404, Revision 1, to confirm the designations. This review resulted changes to the designations for some of the entries in the table to address the comment.
NRC-2022-0073-DRAFT-0007-2		Table B-2	Prior to operation, plant specific data is not developed. The SRs under DA requirements of the standard include the required treatment for the plant specific data analysis using Bayesian	The NRC staff agrees with the comment and revised the capability category designations for supporting requirement DA-D1 from CC-II to CC-I.

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			analysis. Generally, these are not required in Table B-2 for the CP stage. However, DA-D1 CC-II requires a Bayesian update of the generic data. It is recommended that this SR be met at CC-I.	
NRC-2022-0073-DRAFT-0007-3		Table B-3	At the CP stage, the benefit of performing detailed health effects is minimal, especially given the limited scope of the PRA and the completeness of the PRA given we are conservatively estimating failure rates such as HEPs (given no procedures), system failures, etc. It is recommended that RCHE-A2 and A3, related to estimating the health effects on organs, be required to be CC-I at the CP stage.	The NRC staff agrees with the comment and revised the capability category designations for supporting requirements RCHE-A2 and RCHE-A3 from CC-II to CC-I.
NRC-2022-0073-DRAFT-0007-4		Table B-3	Table B-3 is listed in a note in the appendix. However, it is not clear from the note what the purpose of the table is. Please specific this in a paragraph and be clearer as to the purpose of the table.	The NRC staff agrees the note related to DG-1404, Appendix B, Table B-3 can be revised to more clearly explain the purpose of that table. The staff has revised the guidance to include a narrative description that precedes Tables B-2 and B-3 (Tables A-2 and A-3 in RG 1.253) to clearly explain their purpose and how they should be used.
NRC-2022-0073-DRAFT-0007-5		Table B-3	Since Table B-3 is developed as additional scope that is possible at the CP stage, it is recommended that the listed capability categories be removed. If an applicant is, for example, performing a LPSD PRA, then it is not necessary that the SRs be met at CC-II at the CP stage. As an alternate, it may be useful to	The NRC staff disagrees with removing the capability category designations for the supporting requirements (as defined in ASME/ANS-RA-S-1.4-2021) in DG-1404, App. B, Table B-3. The staff acknowledges that not all applicants may be able to achieve the capability category designation for supporting requirements in Table B-3. However, the staff determined those designations in Table B-3 are needed for the purpose of accommodating a wide

Comment Identifier	Topic	Section of Document	Specific Comments	NRC Staff Response
			provide guidance that the CCs are not required at CP stage, but more of a goal or provided for guidance.	range of potential maturities of design information that may be submitted to the NRC in a CP application. Additionally, the provisions in Table B-3 are guidance and need not be used if an applicant justifies a different combination of applicable supporting requirements from ASME/ANS RA-S-1.4-2021 for its application.