Analysis of Public Comments on Draft DANU-ISG-2022-05

Advanced Reactor Content of Application Project

Chapter 11, "Organization and Human-System Considerations"

Comments on the draft interim staff guidance (ISG) 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 the draft ISG.

Comment Number	ADAMS Accession Number	Commenter Affiliation	Commenter Name
NRC-2022-0078-DRAFT-0003	ML23194A214	Hybrid Power Technologies LLC	Michael F. Keller
NRC-2022-0074-DRAFT-0006	ML23229A120	Nuclear Energy Institute	Ben Holtzman
NRC-2022-0075-DRAFT-0004	ML23234A052	X-energy	Travis Chapman
NRC-2022-0078-DRAFT-0002	ML23172A177	No Known Affiliation	Jamie Getchius

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NRC-2022-0078-DRAFT-0003 - 1	General	Background, p1	Industry standard NEI 18-04, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-light water Reactor Licensing Development" is a proper key driving consideration for the ISG, particularly in light of the Nuclear Modernization Act of 2019 whereby Congress has re-enforced the legality of the use of industry codes/standard. These codes/standards have higher precedence than NRC guidance documents. In our view, NEI 18-04 does not contain any material defects associated with risk-informed, graduated elements involving safety-related or safety significant considerations. Unclear why the staff considers it necessary to go "well beyond" the industry standard. Please provide an explanation as to why such a detailed ISG, "well beyond" NEI 18-04 is necessary.	The NRC staff disagrees with the comment. NEI 18-04 describes a modern, technology-inclusive, risk-informed, and performance-based (TI-RIPB) process for selection of licensing basis events (LBEs); safety classification of structures, systems, and components (SSCs) and associated risk-informed special treatments; and determination of defense-in-depth (DID) adequacy for non-LWRs. This NEI document, however, does not address all of the subjects that need to be addressed in a reactor application. As described in the Background section of this ISG, ARCAP is broader than NEI 18-04 and supplements its guidance. The Nuclear Energy Innovation and Modernization Act (NEIMA), in part, specifies that the NRC develop strategies for the increased use of risk-informed, performance-based licensing evaluation techniques and guidance for commercial advanced nuclear reactors within the existing regulatory framework. The

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				ARCAP and this ISG are part of the implementation of that strategy. Also refer to the response to the ARCAP Roadmap comment response NRC-2022-0074-DRAFT-0005-3. No change to the ISG.
NRC-2022-0078-DRAFT-0003 - 2	Backfitting	Back-fitting, p17	Delete all requirements in the ISG that rely on speculation of prospective elements in the proposed and unapproved 10CFR53. Appears the NRC staff is attempting to use the ISG for back fitting, considering that a number of new requirements are apparently being proposed that are outside the existing Code of Federal Regulations and industry codes/standards. Citing the unapproved 10CFR53 as a justification for new requirements, even on an interim basis, is of doubtful validity.	The NRC staff disagrees with the comment. The guidance in the ISG is based on the requirements in existing regulations (i.e., 10 CFR Parts 50 and 52). The references to "future" Part 53 are only for general background information. The ISG does not impose any preliminary proposed Part 53 provision as a requirement. No change to the ISG.
NRC-2022-0078-DRAFT-0003 - 3	General	General, pp 3 thru 16	Delete the entire ISG or modify as suggested by comments 3b and 4. The staff appears to be using portions of 10CFR50 and 52 as a basis for manufacturing new requirements that appear outside the current CFR and/or at odds with various industry codes and standards that technically govern these types of activities. Parts of the ISG involve safety-related items, some may involve safety significant areas while others have no significant bearing on nuclear safety. Risk-informed (graduation of in importance) considerations appear to be absent, thus running afoul of the Modernization Act. The ISG major sections have little in common while being rather disjointed: - 11.1.1 Design, Construction, and Operating Organization - Key Management Positions, (unclear why 10CFR50 Appendix B is not sufficient) - 11.1.2 Basis/number of Operating Shift Crews, their Staffing, and Responsibilities", (see comments 3b and 4) - 11.1.3 Human Factors Engineering (appears to create open-ended, nebulous requirements not previously seen) The proposed ISG is overly complicated, confusing and a likely springboard for open-ended, (and unproductive) never-ending staff requests for information. Comments 3b and 4 suggest an alternative	The NRC staff disagrees with the comment. The guidance in the ISG is based on the requirements in existing regulations (i.e., 10 CFR Parts 50, 52, and 55). For example: • 10 CFR 50.34(a)(6) and (b)(6)(i) require that an application provide a plan for the applicant's organization, training of personnel, and conduct of operations. • 10 CFR 50.34(b)(6)(ii) requires that applications describe managerial and administrative controls to be used to assure safe operation. • 10 CFR 50.34(f)(2) requires that applications provide information regarding various human factors topics. The references to "future" Part 53 are only for general background information. The ISG does not impose any preliminary proposed Part 53 provision as a requirement. Regarding the NEIMA, refer to the response to comment NRC-2022-0078-DRAFT-0003 – 1.

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			approach. In passing, the ISG appears to be an attempt to justify the creation of a new staff "Human Factors" organization. Unclear why the creation of such complexity is necessary.	The staff acknowledges that human factors engineering (HFE) considerations relate to a wide variety of topics, some of which may appear unrelated to one another. The NRC staff, however, evaluates each of these topics by applying fundamental underlying HFE principles. The staff has included individuals with HFE expertise since before the Three Mile Island accident in 1979. A staff organization dedicated to evaluating HFE considerations has existed for many years. No change to the ISG.
NRC-2022-0078-DRAFT-0003 - 4	General	pp 3 -16 References, p18	Highlight key considerations clearly derived from 10CFR50 using the topic associated with the referenced CFR50.34xx entries. The simple reference to just 50.34xx numbering is too difficult to follow and inevitably creates confusion if only an alpha/numeric designation is used. Just say what topic is meant. Might be easier to use some form of table in the main body of the SRP, with clear linkage to CFR50.34xx topic. Also, minimizes "mission creep". See comment #4 below for a more efficient and less confusing approach.	The NRC staff disagrees with the comment. The ISG references various paragraphs within 10 CFR 50.34 that specify individual requirements. The staff believes that by first listing the applicable regulations followed by a description of the application content guidance presents the clearest approach for applicants. No change to the ISG.
NRC-2022-0078-DRAFT-0003 - 5	References	PP 3-16 References, p18	Incomplete list of references. We note various industry standards are applicable. As examples, ANS 3.1-2014 "Selection, Qualification and Training of Personnel for Nuclear Power Plants"; ANS 3.2-2012 "Managerial, Administrative, and Quality Assurance for Operational Phase of Nuclear Plants". There are undoubtedly more potentially applicable industry codes/standards associated with a particular topic area. The point of this comment lies with a simpler method to construct the ISG. Namely, 1. Identify the key topic area, as suggested in comment 3b (clearly linked back to 10CFR50.xx source topic). 2. Require the applicant to identify the industry code/standard intended for use with the key topic area and require the applicant summarize their general approach for conformance with the part of the referenced code/standard linked to the subject topic area. The reviewer can then assess whether or not compliance with the key topic area is being achieved relative to the industry code/standard, recognizing that reviewer efforts must be commiserate with the risk involved, as tied to the applicant's identification of the safety significance (importance to	The NRC staff disagrees with the comment. The standards identified in the ISG are listed in the References section, including ANS 3.1-2014 and ANS 3.2-2012. The staff does not agree that the proposed methodology would provide a simpler review because the structure of this ISG already provides an efficient method for reviewing these topics during licensing; the topics addressed in this ISG are arranged in logical groups under the section headings "organization," "basis/number of operating shift crews, their staffing, and responsibilities," and "human factors engineering." Various standards and regulatory guides are listed under the applicable topic as acceptable approaches to developing application content. The ISG suggests that applicants refer to these documents but does not mandate that applicants follow them. No change to this ISG.

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			safety) being employed by the applicant for the items in question. This approach greatly lessens the burden on all parties while placing the fundamental onus on the applicant. Further, the exceptionally prescriptive methods of the past are avoided	
NRC-2022-0074-DRAFT-0006-1	LWR applicability	General	Please rephrase to indicate the guidance is technology-inclusive and is equally applicable to both LWR and non-LWR designs. Throughout all the documents of the package, there are statements that this guidance is applicable to non-Light Water Reactors (LWRs). However, all the guidance is technology-inclusive and is equally applicable to LWRs. ARCAP is supposed to be applicable for any technology (non-LWR and LWR), any licensing approach (LMP, classical, etc.), and any licensing path (CP, COL, DC etc.). For the ARCAP guidance, industry specifically requested the NRC develop guidance applicable to both non-LWRs and LWR SMRs, and we were informed in various meetings that this would be the NRC's approach. 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 do so (e.g., NEI 18-04 and NEI 21-07). It would be up to the applicants to justify the use of the guidance documents and associated regulatory guides.	The NRC staff disagrees with the comment. The NRC staff is considering expanding the applicability of ARCAP guidance documents beyond non-light water reactors (non-LWRs). However, expansion of the guidance beyond non-LWRs at this time is considered premature. The final ISG continues to note that the NRC is developing an optional performance-based, technology-inclusive regulatory framework for licensing nuclear power plants designated as 10 CFR Part 53, "Licensing and Regulation of Advanced Nuclear Reactors," (RIN 3150-AK31). If the NRC promulgates a final 10 CFR Part 53 rule, the NRC staff plans to apply the 10 CFR Part 53 guidance to both LWRs and non-LWRs. Should the 10 CFR Part 53 rulemaking include requirements for both LWR and non-LWRs, the NRC staff envisions that the guidance documents supporting that rulemaking would provide a basis to expand the concepts found in the ARCAP ISGs guidance beyond non-LWRs. In the interim, the NRC staff notes that the applicability section of the ISG notes that applicants desiring to use the ISG for a light water reactor application should contact the NRC staff to hold pre-application discussions on their proposed approach. No change to this ISG.
NRC-2022-0074-DRAFT-0006-2	Staffing at CP stage	p. 4	Please add clarification on the level of detail expected as noted. The ISG denotes that NRC staff expects to see general staffing plans for the construction pre-op testing, fuel load, and startup and power ascension testing. There is also text denoting CPAs include preliminary plans for the operating organization. What Reg Guide or NUREG will NRC staff use to verify staffing methodology for new reactor designs with advanced safety features and technologies that vendors believe will warrant fewer staff than current LWRs?	The NRC staff partially agrees with the comment. ISG-05, Chapter 11, "Organization and Human-System Considerations," pages 3 and 4 provide guidance for CP/OL and COL applications focusing on the pre-operation/construction period. ISG page 5 describes addition guidance for OL and COL applications focusing on the operational period. The ISG references American National Standards Institute (ANSI)/American Nuclear Society (ANS)-3.2-2012, "Managerial, Administrative, and Quality Assurance Controls for

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			Additional information on the level of detail expected in the CP and OL applications would be helpful to remove subjectivity from applicant reviews. For example, does the technical basis need to be provided in the CPA? Does the NRC just want a list of proposed staff, or does the eligibility requirements with justification need to be provided?	the Operational Phase of Nuclear Power Plants." Currently, the NRC staff does not have a separate set of review guides for non-LWRs regarding organizational staffing. To provide additional guidance, references to the guidance in Section III, "Acceptance Criteria," of applicable SRP Sections as described below are added to Section 11.1.1 of the ISG as follows: "NUREG-0800 sections 13.1.1, "Management and Technical Support Organization" and 13.1.2 - 13.1.3, "Operating Organization" provide further guidance to the staff on the review of the construction, testing, and operating organizations. Additionally, NUREG-0800 sections 13.5.1.1, "Administrative Procedures - General" and 13.5.2.1, "Emergency and Operating Procedures" provide further guidance to the staff on the review of operating plans. The staff should consider whether portions of these guidance documents are relevant within the context of a given application and apply the applicable guidance in conjunction with this ISG. Relevant guidance should be applied to the extent reasonable for a given application type during the review of CP, ML, DC, SDA, OL, and COL applications (e.g., a CP application may not contain the fully developed information in certain areas that an OL application would include)." Additional guidance was also added to Section 11.2 of the ISG as follows: e. "Plans for the construction, testing, and operating organizations are consistent with the relevant portions of NUREG-0800 sections 13.1.1, "Management and Technical Support Organization" and 13.1.2 - 13.1.3, "Operating Organization." f. Plans for conduct of operations are consistent with the relevant portions of NUREG-0800 sections 13.5.1.1, "Administrative Procedures - General" and 13.5.2.1, "Emergency and Operating Procedures."""

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NRC-2022-0074-DRAFT-0006-3	Acceptance criteria	P. 15 and 16	Please add clarifying basis for the criteria similar to 11.2.g "… adequate number of licensed operators will be available at all required times to satisfy the minimum staffing requirements of 10 CFR 50.54(m), or the applicant has provided justification for an exemption. (10 CFR 50.54(i)–(m)..." This provides clear criteria with a basis that both applicant and reviewer can agree on. Alternatively, the criteria could be removed from the ISG if no clear acceptance criteria and basis can be identified. The ISG acceptance criteria in sections 11.2 c, d, i, l, and m lack clear criteria with a basis to ensure both the reviewer and applicant will reach the same conclusion on whether the criteria is met. This could lead to rework by both applicant and reviewer. If no clear criteria can be identified, then these should not be part of the acceptance review.	The NRC staff partially agrees with the comment. The following clarifications are provided. The following footnote was added to Section 11.2 "It should be noted that while certain Part 50 requirements are specifically cited within the acceptance criteria for the purposes of providing clarification, the acceptance criteria themselves are broadly applicable to the review of CP, ML, DC, SDA, OL, and COL applications. However, it may be necessary for the reviewer to adjust the review depth associated with individual criteria in light of the specific type of application under consideration (e.g., the information in a CP may be less detailed than that of an OL)." Item 11.2.c, is revised to read: "To address 10 CFR 50.34(b)(6)(i), (ii), (iv), and (v), the key positions for ensuring the safe operation of the plant are in the operating organization, consistent with the quality assurance program and ANS 3.2…" Item 11.2.d, is revised to read: "To address 10 CFR 50.34(b)(6)(iii), the applicant has adequately described the groups and key positions responsible for implementing the initial test program, consistent with the quality assurance program and ANS 3.2…." Item 11.2.k, is revised to read: "To address 10 CFR 50.34(f)(3)(vii), the applicant has described the role and function of the architect-engineer and the nuclear steam supply system vendors during design and construction, consistent with NUREG-800, Section 13.1.1…." Item 11.2.n, is revised to read: "To address 10 CFR 50.34(b)(6)(v), sufficient managerial depth is available to provide qualified backup, consistent with the quality assurance program and ANS 3.2…."

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				Section 11.2, 0, is revised to read: "To address 10 CFR 26.205(c), the numbers of licensed and non-licensed personnel subject to § 26.205 are sufficient to allow shift schedules that prevent personnel impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. ~~The number of licensed and non-licensed personnel for onsite shift operating crews is sufficient to prevent the routine use of overtime.~~" Also refer to the response to comment NRC-2022-0074-DRAFT-0006-2.
NRC-2022-0074-DRAFT-0006-4	Engineering expertise onshift	P. 16	Please add clarification on technology neutral approaches for a site can meet the requirement for engineering expertise. Additionally, please provide clarification on what information and features would need to be demonstrated to enable engineering expertise to be on-call, part of the Emergency Response Organization (ERO), or remote. The requirement for engineering expertise on shift based on LWR operating experience from TMI comes from a Commission Policy statement rather than regulation, and may not be relevant to advanced reactor technologies. More relevant engineering expertise will be from the technology specific training programs that will teach engineering fundamentals and principles required to operate that specific technology. Information should be provided regarding how applicants can credit the technology-specific training program and design features that reduce the need for traditional engineering expertise (LWR technology scope not applicable to all designs) while identifying other activities more relevant to the applicant's design.	The NRC staff disagrees with the comment. As described in this ISG, Section 11.2, engineering expertise on shift should be consistent with the Commission's Policy Statement on Engineering Expertise on Shift (Volume 50 of the Federal Register, page 43621; October 28, 1985) and within the guidelines of Three Mile Island Action Plan Item I.A.1.1, "Shift Technical Advisor," of NUREG-0737, "Clarification of TMI Action Plan Requirements," issued November 1980. Furthermore, 10 CFR 50.120 requires that the applicant provide a training program derived from a systems approach to training as defined in 10 CFR 55.4 and must provide for the training and qualification of the shift technical advisor. If an applicant chooses to depart from these requirements and policy statements, it should provide justification for an alternative approach or an exemption request, as applicable. SECY-21-0039 (ML21060A823) discusses how the NRC staff addressed a past request regarding elimination of the STA position from an operating crew complement. Thus, the staff has demonstrated flexibility with regard to the need for the STA role when warranted by, in part, the implications of new reactor technologies. The staff plans to consider, on a case-by-case basis, proposals from Part 50 and 52 applicants and licensees with regard to the STA role and, if warranted, will engage the

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				Commission on any related matters of policy. With specific regard to the training-related aspect of the comment, it should also be noted that the 1989 Commission policy statement provided in 54 FR 33639 highlights, more generally, the importance of maintaining a balance of education and experience amongst the control room staff. No change to this ISG.
NRC-2022-0075-DRAFT-0004- 27	Staffing at CP stage	Page 4	Please clarify the level of detail expected for the CPA. For example, would the NRC like a list of proposed staff or do the eligibility requirements with justification need to be provided? The NRC staff expects to see staffing plans for the construction pre-op testing, fuel load, and startup and power ascension testing. The NRC staff also expects to see the preliminary plans for the operating organization, including a staffing plan for operations for the CPA. The safety features and technologies of advanced reactors warrant fewer staffing levels than the current LWRs. What level of detail is the NRC expecting for these plans? What RG/NUREG will the NRC be using to verify staffing methodology, as the methodology should and will be different than the current LWR fleet? Since these are supposed to be preliminary, does a technical basis need to be provided for the Construction Permit Application (CPA)?	Refer to the response to Comment NRC-2022-0074-DRAFT-0006-2.
NRC-2022-0075-DRAFT-0004- 28	Engineering expertise onshift	Page 16	Please clarify how a site can meet the requirement for engineering expertise. Examples: can a site credit the training program if the safety features of the plant do not warrant engineering expertise? If transients are slow moving, can the engineering expertise be on-call or part of a licensee's Emergency Response Organization? Can the engineering expertise be remote? Please provide flexibility for advancements in nuclear safety instead of arbitrarily propagating requirements based on LWR technology. The requirement for engineering expertise on shift is based on LWR operating experience (Three Mile Island), comes from a Commission Policy statement (not a regulation), and may not be relevant to advanced reactor technologies. Is the NRC staff considering crediting the training program content, which is tailored to train plant staff to safely operate that	Refer to the response to Comment NRC-2022-0074-DRAFT-0006-4.

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			specific technology, as required engineering expertise? This should be especially considered if the training program teaches engineering fundamentals and principles required to operate that specific technology.	
NRC-2022-0078-DRAFT-0002-1	Number of licensed and non-licensed personnel	Section 11.2	Section 11.2 of DANU-ISG-2022- contains Acceptance Criterion m, which states, "The number of licensed and non-licensed personnel for onsite shift operating crews is sufficient to prevent the routine use of overtime." Government regulation of overtime is performed through the Fair Labor Standards Act and National Labor Relations Act which fall under the jurisdiction of the Department of Labor and National Labor Relations Board. The NRC does not have jurisdiction with respect to overtime and does not have a regulatory basis to consider the potential use overtime in the determination of a safety finding for construction permit, operating license, combined license, manufacturing license, standard design approval, or design certification applications. Nuclear utilities have negotiated with labor unions for pay, work hours, and other conditions of employment throughout the history of the industry as allowed by the National Labor Relations Act. These have routinely resulted in staffing levels that routinely make use of overtime while still complying with NRC regulations. A suggested rewording of this section is as follows: m. The number of licensed and non-licensed operators for onsite shift operating crews is sufficient to prevent the routine use of waivers to the workhour rule requirements of Subpart I of 10 CFR Part 26.	The NRC staff agrees with the comment. Section 11.2.m, is revised to read: "To address 10 CFR 26.205(c), the numbers of licensed and non-licensed personnel subject to § 26.205 are sufficient to allow shift schedules that prevent personnel impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. ~~The number of licensed and non-licensed personnel for onsite shift operating crews is sufficient to prevent the routine use of overtime~~."