Analysis of Public Comments on Draft DANU-ISG-2022-06

Advanced Reactor Content of Application Project

Chapter 12, "Post-manufacturing and construction Inspection, Testing, and Analysis Program"

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-2022-0074-DRAFT-0006	ML23229A120	Nuclear Energy Institute	Ben Holtzman
NRC-2022-0075-DRAFT-0004	ML23234A052	X-Energy, LLC	Travis Chapman

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NRC-2022—0074-DRAFT-0006- 1	General	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,	The NRC staff disagrees with this comment. The NRC staff is considering expanding the applicability of advanced reactor content of application project (ARCAP) guidance documents beyond non-light water reactors (non-LWRs). However, expansion of the guidance beyond non-LWRs at this time is premature. The final interim staff guidance (ISG) continues to note that the NRC staff 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). It is envisioned that the 10 CFR Part 53 guidance would be applicable to both LWR and non-LWRs. Should the 10 CFR Part 53 rulemaking include requirements

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			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.	for both LWR and non-LWRs the NRC staff envisions that the concepts found in the ARCAP ISGs guidance would be expanded 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.
NRC-2022—0074-DRAFT-0006- 2			The purpose and descripting (*sic*) discussion of the ISG should be revised to be clear how this ISG applies to an ML application since by definition the ML does not authorize construction, installation or operation. 10 CFR 52.1 defines a manufacturing license as a license issued under subpart F, authorizing the manufacture of nuclear power reactors but not their construction, installation, or operation at the sites on which the reactors are to be operated. On page 2 of DANU-ISG-2022-06 it is noted that the	The NRC staff agrees with this comment. Refer to the response to Comment NRC-2022-0074- DRAFT-0006- 4.

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			guidance in the ISG is limited to the portion of non-LWR application associated with the development of a risk-informed post-construction inspection, testing, and analysis program (PITAP) and the staff review of that portion of the application. The applicability of the ISG clearly includes applications for MLs. Given the definition of an ML it is not clear how guidance on a PITAP is applicable to an ML.	
NRC-2022—0074-DRAFT-0006- 3		p. 5, Application Guidance, 1st sentence	The ISG should be revised regarding MLs to clearly distinguish between post-manufacturing inspection and testing that would be expected to be addressed in the factory and post-construction inspection and testing. One example of language that addresses post-manufacturing inspection comes from the draft proposed Part 53, specifically 53.620(b)(3): "post-manufacturing inspection and acceptance process must be established and implemented before transporting a manufactured reactor or portions of a manufactured reactor for installation at a commercial nuclear plant. The process must consider the results of inspections, tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been	The NRC staff partially agrees with this comment. Refer to the response to Comment NRC-2022-0074- DRAFT-0006- 4 regarding "post-manufacturing" text versus "post-construction" text. Regarding the clarity of the manufacturing license (ML) application content guidance, the ISG states (on page 5) that an ML application should describe the Phase 1 program, which includes the requirements in 10 CFR 52.157(f)(17) regarding quality assurance criteria (i.e., Criterion III, Design Control; Criterion X, Inspection; and Criterion XI, Test Control), and 10 CFR 52.158 which requires ITAAC. For clarity, the following new paragraph will be added after the third paragraph in the "Application Guidance" section regarding ML applications: "For an ML application, the Phase 1 program description should address inspections, tests, and analyses that the licensee who will be operating the reactor shall perform and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been completed in accordance with the ML (refer to 10 CFR 52.157(f)(17) and 10 CFR 52.158)."

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			completed in accordance with the ML." The first sentence notes the PITAP is generally divided into two phases: Phase 1 is the preoperational phase (prior to initial fuel loading) and Phase 2 is initial startup testing (initial fuel loading and initial power ascension). The application should describe how all tests identified in the Phase 1 program can be performed prior to loading fuel. The expected content for an ML application to address Phase 1 is not clear. As background, 52.157 does not explicitly address post-manufacture inspection or testing although 52.158 includes a requirement for ITAAC to demonstrate the reactor has been manufactured in conformity with the manufacturing license, the provisions of the Act, and the Commission's rules and regulations. 52.157(f)(21) does require justification that compliance with the interface requirements of paragraph (f)(20) is verifiable through inspections testing, or analysis. The method to be used for this verification must be included as part of the proposed ITAAC required by 52.158.	In addition, the following change is being made to the last paragraph of the application guidance section: "For COLs referencing a ML, much of the post-manufacturing ~~construction~~ inspection and testing to resolve ITAAC may be performed at the manufacturer's facility and not at the COL final site. The COL holder has the responsibility for verifying ITAAC are complete. As noted below the COL holder could rely on testing performed at the manufacturing facility to verify ITAAC completion. The requirement for ITAAC to be included in ML applications (i.e., 10 CFR 52.158(a)) states, in part, the following: " The following footnote 5 has also been added to the last paragraph of the application guidance section: "The NRC staff notes there are potential business models that could involve a manufacturing licensee also holding a combined license for the purpose of operational testing. Such a model could involve completion of some of the ITAAC at the manufacturing facility under the COL held by the manufacturer. Under this business model the COL holder for where the reactor is eventually installed (i.e., deployment site COL holder) would be responsible to ensure the ITAAC completed at the manufacturing facility have been maintained and would also be responsible for verifying the ITAAC are complete for those ITAAC performed at the site. These business models and the potential for future guidance in this area were discussed during a September 11, 2023, public meeting (see: https://www.nrc.gov/pmns/mtg?do=details&Code=20230975). The NRC staff will update this ISG, as appropriate, pending further direction from the Commission on this matter. The following footnote 6 has also been added.

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				An ML holder may also seek a CP/OL or COL to conduct some or all of the ITP in the factory before delivery to the deployment site. In these cases, the OL or COL for the factory testing would specify what portions of the ITP would be conducted in the factory and the deployment site. The OL or COL would specify what remaining tests may be conducted at the deployment site. ML holders considering such an approach are encouraged to discuss their intentions during the pre-application phase of the review. Acceptance Criteria F.(8) was changed as follows to clarify that ML ITAAC (along with combined license (COL), and design certification (DC)) inspections, tests, analyses and acceptance criteria (ITAAC) should be provided as a standalone document. The change is as follows: Applications for a COL, DC, or ML include the ITAAC ~~either~~ as a standalone document.~~ or as part of the PITAP~~"
NRC-2022—0074-DRAFT-0006- 4		Bottom of p.6	There are two proposed changes: (1) revise the title and structure of the ISG to address post-manufacturing and post-construction; (2) restructure the guidance to make clear expectations for post-construction activities that are appropriate for CP, OL, and COLs versus the expectations for MLs. The discussion of the postconstruction activities for sites that will utilize a reactor manufactured under an ML, the inspection activities should address construction and installation activities for the manufactured reactor.	The NRC staff agrees with this comment. The following changes are made to this ISG: 1. The ISG title is changed to "Post-manufacturing and construction Inspection, Testing, and Analysis Program." 2. On page 2, "The guidance in this ISG is limited to the portion of a non-LWR application associated with the development of a risk-informed post-construction (or post-manufacturing for an ML application) inspection, testing, and analysis program…" 3. On page 2 "manufactured, constructed and will be operated…" 4. On page 2, "integration of post-manufacturing and post-construction quality assurance…" 5. On Page 6, "For MLs, much of the post-manufacturing ~~construction~~ inspection and testing…"

Commented [JO1]: The paragraph is changed to add the definition of the term ITAAC.

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			The language in the last paragraph on Page 6 states, "For MLs, much of the post-construction inspection and testing to resolve ITAAC may be performed at the manufacturers facility and not at the final site." The text goes on to address the ML ITAAC requirements in 52.158(a). This language continues to confuse "manufacturing" and "construction" and is an unnecessary complication in the guidance.	6. On pages 9, 10, and 12 revise "post-construction" to "post-construction (and post-manufacturing if applicable)." Also refer to the response to comment NRC-2022-0074-DRAFT-0006-3.
NRC-2022—0074-DRAFT-0006– 5	Pre-operational test program	p. 6	Please confirm that this ISG is not adding additional requirements beyond what is required to be provided in a CPA per 10 CFR 50.34(a)(7) by removing or rewording the last sentence from the first paragraph of page 6. The last sentence of the first paragraph on page 6 states: "If the application is for a CP, the PITAP description can be limited to the Phase 1 (described below) inspection, testing, and verification that would be required by 10 CFR Part 50, Appendix B, along with a description of the scope, objectives, and programmatic controls associated with the pre-operational test program (prior to initial fuel loading)." This implies requirements that go beyond the quality assurance program descriptions required in	The NRC staff partially agrees with this comment. The referenced text regarding the pre-operational test program is referring to 10 CFR 50, Appendix B, Criterion XI, "Test Control," which requires, in part, that a test program shall be established to assure that all testing required to demonstrate that structures, systems, and components (SSCs) will perform satisfactorily in service is identified and performed in accordance with written test procedures. The ISG text on page 6 has been clarified as follows: "If the application is for a CP [construction permit], the PITAP description can be limited to the Phase 1 (described below) inspection, testing, and verification that would be required by 10 CFR Part 50, Appendix B, ~~along with~~ which should include a description of the scope, objectives, and programmatic controls associated with the pre-operational test program…"

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			10 CFR 50.34(a)(7) and does not appear to be consistent with the first sentence of the second paragraph of the application guidance on page 5: "…program elements required by the quality assurance program under § 50.34(a)(7)."	
NRC-2022-0075-DRAFT-0004-29	Pre-operational test program	p. 6	Please remove the last sentence from the first paragraph of page 6. The last sentence of the first paragraph on page 6 of DANU-ISG-2022-06 states, "If the application is for a CP, the PITAP description can be limited to the Phase 1 (described below) inspection, testing, and verification that would be required by 10 CFR Part 50, Appendix B, along with a description of the scope, objectives, and programmatic controls associated with the pre-operational test program (prior to initial fuel loading)." This implies requirements that go beyond the quality assurance program descriptions required in 10 CFR 50.34(a)(7) and does not appear to be consistent with the first sentence of the second paragraph of the application guidance on page 5 which specifically refers to "…program elements required by the quality assurance program under § 50.34(a)(7)." Can the staff confirm that this ISG is not adding additional requirements beyond	Refer to the response to Comment NRC-2022-0074- DRAFT-0006– 5.

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			what is required to be provided in a construction permit application per 10 CFR 50.34(a)(7)?	
NRC-2022-0075-DRAFT-0004-30	CP and OL scope	Sections A-E	Provide a list in the guidance of which items apply for construction permit applications. It is unclear in sections A-E which portions are required to be described in a construction permit application and which portions are required for an operating license application, for those licensing under 10 CFR 50.	The NRC staff disagrees with this comment. The Application Guidance section on pages 5 and 6 describes which parts of the PITAP program (Phases 1 and 2) apply to CP and operating license (OL) applications. For example, it states that for a CP, the PITAP description can be limited to descriptions of the Phase 1. In summary: • Section A guidance applies to Phase 1. • Section B guidance applies to Phase 2. • Sections C, D, and E guidance apply to both Phases 1 and 2. • Section F guidance is staff review guidance, and it applies to both Phases 1 and 2. No change has been made to this ISG.
NRC-2022-0075-DRAFT-0004-31	General	Sections A-E	Please clarify the items in A-E apply to different license application types. Specifically, please list which items apply to 10 CFR 50 licenses. Some of the items in sections A-E imply that 10 CFR 52 processes should be applied for 10 CFR 50 licenses, for example D.6 [sic] requires establishing a plant review committee to review, evaluate, and disposition verification results.	The NRC staff partially agrees with this comment. The guidance in Sections A and B is applicable to applicants as described on pages 5 and 6 of the ISG. The guidance in Sections C – E is applicable to both Part 50 and Part 52 applicants. The text in item E.6, referenced in the comment, is revised to make it more generic, as follows: "(6) establishing a defined set of qualified operating and technical plant personnel ~~review committee~~ to review, evaluate, and disposition the inspection, test, and verification results"
NRC-2022-0075-	Part 50 scope	Sections A-E	Please remove items from sections A-E which go beyond what is	The NRC staff disagrees with this comment.

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DRAFT-0004-32			required in 10 CFR 50 and existing guidance. Some of the items in sections A-E do not appear to be regulatory requirements or aligned with RG 1.70 or RG 1.206.	The guidance in Sections A through E of the ISG is based in Section XI of Appendix B to 10 CFR Part 50, and aligns with other existing guidance in RG 1.68, RG 1.33, and SRP (NUREG-0800) Section 14.2. This guidance describes how an applicant can meet the requirements in 10 CFR Parts 50 and 52 related to pre-operational and startup test programs and does not add new requirements. No change has been made to this ISG.