

From: [Carolyn Lauron](#)
To: [Justin Hawkins](#)
Cc: [Greg Cranston](#); [Manny Savoc](#)
Subject: NRC Staff response to Questions re: Quality Assurance (Project 99902049)
Date: Monday, July 10, 2023 1:49:00 PM

Hi Justin –

Please find the NRC staff response to the SMR (Holtec) questions regarding quality assurance.

If you have questions or need more information, please let us know.

Thanks,
Carolyn

Background:

Just to ensure alignment, we (SMR-160) plan to submit a NEW QAPD LTR in and around October 2023. These clarification questions are to ensure we are meeting the NRC staff's expectations. Once we receive feedback on the questions below, we may want to follow-up with a short call to answer any additional questions from the staff prior to submitting the NEW QAPD LTR.

Questions:

1. DANU-ISG-2022-01 "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap – May 2023," (ML22048B546) page 23 states, "... For example, a quality assurance plan description for a CP application should cover the design, fabrication, construction, postconstruction, and pre-operational testing activities."
Question for NRC Staff: Should the post-construction and pre-operational testing activities be included in the SMR LLC QAPD TR?
2. DANU-ISG-2022-01 "Review of Risk-Informed, Technology-Inclusive Advanced Reactor Applications—Roadmap – May 2023," (ML22048B546) Appendix C page states, "...The staff should review the applicant's quality assurance program description (QAPD) applied to activities for design, fabrication, construction, and testing of the safety-related and safety-significant SSCs of a facility or facilities that may be constructed on the site. The staff will normally plan to inspect the implementation of the QAPD prior to the start of included activities."
Question for NRC Staff: Does NRC plan to inspect /audit the implementation of the SMR LLC QAPD?
Question for NRC Staff: Does the current Holtec International QAM cover the SMR-160 design activities that are underway? Or does the Holtec SMR-160 design activities covered under the current TR from 2014 even though it is a DC TR?
3. DG-1403 (RG 1.28, Revision 6) Reason for Revision, "... The previous version of RG 1.28 (Revision 5) (Ref. 8) approved the use of NQA-1b-2011 (Ref. 9) Addenda to ASME NQA-1-2008 (Ref. 10), NQA-1-2012 (Ref. 11), and NQA-1-2015 (Ref. 12), with certain clarifications and regulatory positions. The staff determined that the NQA-1-

2017, NQA-1-2019, and NQA-1-2022 provide the most current guidance for QA.”
(References 1 and 2)

Question for NRC Staff: Holtec plans to submit its SMR LLC QAPD TR in the Fall of 2023.

Which version of version of RG 1.28 the should the SMR LLC QAPD TR reference?
Can Revision 5 be referenced after Revision 6 is adopted?

NRC Staff Response:

1. Yes, a Quality Assurance (QA) program for a Construction Permit (CP) needs to cover all activities that are authorized including post construction and pre-operational programs. NUREG-0800, Standard Review Plan (SRP) Section 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants,” provides the latest review guidance the NRC staff relies on to assess an applicant’s overall QA program. (Reference 3)

2. a. For a CP application, the NRC staff typically conducts an inspection of the implementation of the applicant’s QA program as part of the review of the application. The NRC staff will follow the same inspection procedures for a Combined License (COL) applicant, in accordance with IMC 2502, “Construction Inspection Program: Pre-Combined (Pre-COL) Phase,” and IP 35017, “Quality Assurance Implementation Inspection.” (References 4 and 5)

Section 2502-07, “Types of Inspections,” Subsection 07.01, “Post-Docketing QA program Inspection,” of IMC 2502 provides further details on the inspection the NRC staff conducts upon acceptance and docketing of an applicant’s QA program.

b. The NRC staff is unfamiliar with the ongoing Holtec activities and is therefore, not in position to answer this question.

3. Revision 6 of RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” is not yet issued. Based on the anticipated timing of the Holtec submittal, the applicant should follow Revision 5 of RG 1.28.

References:

1. U.S. Nuclear Regulatory Commission (NRC), Draft Guide, DG-1403, Proposed Revision 6 to Regulatory Guide (RG) 1.28, “Quality Assurance Program Criteria (Design and Construction),” dated April 2023.
<https://www.nrc.gov/docs/ML2230/ML22304A054.pdf>
2. U.S NRC, RG 1.28, Revision 5, “Quality Assurance Program Criteria (Design and Construction),” dated October 2017.
<https://www.nrc.gov/docs/ML1720/ML17207A293.pdf>
3. U.S. NRC, NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition.” <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/>
4. U.S. NRC, Inspection Manual Chapter (IMC) 2502, “Construction Inspection Program: Pre-Combined License (Pre-COL) Phase,” dated July 2, 2020.

<https://www.nrc.gov/docs/ML1932/ML19324E320.pdf>

5. U.S. NRC, Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection," dated December 12, 2020.

<https://www.nrc.gov/docs/ML2025/ML20259A220.pdf>