

**U.S. NUCLEAR REGULATORY COMMISSION SUMMARY OF THE DECEMER 6, 2022,**  
**OBSERVATION PREAPPLICATION PUBLIC MEETING**  
**WITH SMR, LLC (A HOLTEC INTERNATIONAL COMPANY)**  
**TO DISCUSS THE SMR-160 QUALITY ASSURANCE PROGRAM**

**Meeting Summary**

The U.S. Nuclear Regulatory Commission (NRC) held an observation public meeting on December 6, 2022, with SMR, LLC (SMR), a Holtec International Company, to discuss preapplication items for the SMR-160 quality assurance (QA) program. Specifically, SMR (applicant) requested the meeting to discuss questions related to its previously approved topical report for developing a design certification (DC) application.<sup>1</sup>

This virtual preapplication observation public meeting had attendees from SMR, LLC, Holtec International, LLC, the NRC staff, and members of the public.

The following summarizes the discussion during the open session of the public meeting:

- In reference to the NRC's 2014 evaluation of a topical report for the quality assurance program for a design certification application, the NRC staff clarified that Standard Review Plan (SRP) Section 17.5 provides review guidance for quality assurance, and SRP 17.1 provides additional review guidance related to construction activities.<sup>2,3</sup> The NRC staff noted that an applicant will need to determine the applicability of each SRP section for the application planned for submission.
- The applicant noted that the NRC reviewed and approved Revision 3 of the SMR-160 QA topical report using the initial issuance of SRP 17.5 from 2007 and requested how the QA program for a DC application is different from the QA program for a construction permit (CP). In response, the NRC staff noted that the QA program description (QAPD) for a DC application would cover those activities for the design of the plant while the QAPD for a CP application would cover those activities for the designing and building the plant. For example, a CP QAPD would include quality requirements for those construction activities in the future while a DC application would not. The NRC staff

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<sup>1</sup> US NRC, "Final Safety Evaluation for Holtec International Topical Report HI-2135649-NP, Revision 3, Topical Report on Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification" (Tac No. RN6122)," dated August 28, 2014. (Agencywide Documents and Access Management System (ADAMS) Accession No. ML14174B150. Package ML14253A519.)

<sup>2</sup> US NRC, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," Revision 1, dated August 2015. (ML15037A441)

<sup>3</sup> US NRC, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 17.1, "Quality Assurance During the Design and Construction Phases," Revision 2, dated July 1981. (ML052350349)

noted that a more recent revision to SRP 17.5 issued in 2014 would apply, and the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Paragraph 50.34(h) related to an evaluation of an application against the SRP in effect 6 months before the docket date of the application. The NRC staff clarified some of the QA requirements for the different phases of licensing: 10 CFR 50.54(a)(3) governs changes a licensee makes in its quality assurance program, 10 CFR 50.55(f)(3) governs changes a CP holder makes in its quality assurance program, and 10 CFR 50.4(b)(7)(ii) governs changes to an NRC-accepted quality assurance topical report from non-licensees, i.e., design certification applicant/holder or vendor.

- The NRC encouraged the submission of a new topical report to support a CP application consistent with the requirements in 10 CFR 50.34(a)(7).
- The applicant requested a timeline for the review and approval of a new topical report for a CP QAPD. The NRC staff responded that the review and approval process would depend on whether the QAPD follows the SRP and the available NRC staff resources at the time of the submission.
- The applicant requested whether there was a precedent for using a common QA program that covers different aspects of a business because SMR (Holtec) has an NRC approved QA program for decommissioning, and packaging and transportation of radioactive material (10 CFR Part 71). The NRC staff responded that a common QA program could exist for the nuclear steam supply system but that the construction has a different focus. The NRC staff noted that it had, in the past, expended approximately 500 hours to review an applicant's QA program topical report supporting any potential application submitted under 10 CFR Parts 50 or 52. This level of effort contrasts with the typical 80-hour review for a QAPD topical report supporting a particular application.
- The applicant indicated that it may not be the CP holder or owner-operator (licensee) in the future. The NRC staff clarified 10 CFR Part 50, Appendix B applies only to applicants and licensees. A vendor need not have an NRC-approved QAPD (or quality assurance program) if the vendor or designer is not the applicant (or future licensee). The applicant for the CP and who will eventually be the licensee receiving the operating license will need to meet the 10 CFR Part 50, Appendix B requirements including Criterion II which states, "The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix."
- In response to a request from the member of the public, the NRC staff provided a link to the NRC evaluation of Revision 3 of the QA topical report referenced during the meeting.

The meeting was adjourned at 1:30 pm.