

**Revised Information Needs Provided by the NRC Staff for the Topical Report on
the Quality Assurance Program for Holtec International's
Small Modular Reactor (SMR) Design and Construction
Holtec Report HI-2230815**

By letter dated September 28, 2023 (Agencywide Document Access and Management Systems (ADAMS) Accession No. ML23271A007), Holtec International Company, SMR, LLC (Holtec) submitted Topical Report (TR), HI-2230815, Revision 0, "Quality Assurance Program for Holtec's Small Modular Reactor Design and Construction," to the U.S Nuclear Regulatory Commission (NRC) for review. This TR describes the activities covered by Holtec's Quality Assurance Program and is applicable to design, construction, procurement, and testing activities.

Holtec stated that this SMR LLC Quality Assurance Program Topical Report (SMR LLC QAP TR) has been prepared in accordance with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and American Society of Mechanical Engineers (ASME) NQA-1 2015, "Quality Assurance Program Requirements for Nuclear Facilities," as endorsed by NRC Regulatory Guide (RG) 1.28, Quality Assurance Program Criteria (Design and Construction)," Revision 5. This SMR LLC QAP TR has also been prepared consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," and is based on the Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description" template.

The NRC staff reviewed the information provided in the SMR LLC QAP TR against the quality assurance (QA) requirements in Appendix B to 10 CFR Part 50, and in accordance with the review guidance in Standard Review Plan (SRP) Section 17.5, Revision 1. Based on this review, the NRC staff provided its Information Needs (ADAMS Accession No. ML24022A077) and held a public meeting with Holtec on January 26, 2024 to discuss the NRC staff's initial review. Subsequently, Holtec submitted a draft Revision 1 of the SMR LLC QAP TR for NRC staff review. The NRC staff reviewed the draft Revision 1 of the SMR LLC QAP TR and identified the following remaining items to be addressed.

1) Information Need Item 2

The NRC staff noted that the positions of Vice President of Operations and Engineering Executive from Revision 0 of the SMR LLC QAP TR are no longer in the draft Revision 1 of the SMR LLC QAP TR. In addition, the two responsibilities that belonged to the Engineering Executive in Revision 0 of SMR LLC QAP TR:

- a) assuring that design and analysis work is performed in accordance with the Holtec International Quality Assurance Program (HQAP);
- b) that personnel in these areas are appropriately trained and qualified to perform their scope of work;

are now under the responsibilities of Executive Director, which is a new position per draft Revision 1 of the SMR LLC QAP TR.

The NRC staff requests the applicant to clarify and ensure that these responsibilities are under the proper authority since these responsibilities are design and engineering in nature.

2) Information Need Item 3

Holtec committed to 10 CFR Part 50.55 (f)(1) for QA requirements for a Construction Permit. The NRC staff requests the applicant to revise the text in the draft Revision 1 of the SMR LLC QAP TR to state "10 CFR 50.55 (f)," instead of "10 CFR 50.55(f)(1)" since the entire paragraph under 10 CFR 50.55(f) applies.

3) Information Need Item 4

It is unclear to the NRC staff what are the requirements for QA auditors (not QA lead auditors). The statement in Section 2.6 of the draft Revision 1 of the SMR LLC QAP TR regarding QA auditors states:

"Requirements for training and/or qualifications (as applicable) for auditors and technical specialists that participate in audits are provided within controlling procedures."

The NRC staff requests Holtec to clarify if they intend to commit to NQA-1 2015, Part 1, Requirement 2 for QA auditors, similar to the positions of QA lead auditors, and inspectors, testers, and NDE personnel.

4) Information Need Item 7

In the draft Revision 1 of the SMR LLC QAP TR, Holtec added a statement that states:

“The need for supervisor verification is documented and approved in advance by the supervisor’s management.”

to address SRP 17.5, Section C, Item 19.a.ii. However, Item 19.a.iii, which states “QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse,” is not addressed. The NRC staff requests Holtec to address SRP 17.5, Section C, Item 19.a.iii.

5) Information Need Item 11

In the draft Revision 1 of the SMR LLC QAP TR, Holtec added a statement that states:

“A calibration is performed when the accuracy of the equipment is suspect.”

However, it does not address the measures Holtec needs to establish for extent of conditions when an M&TE is found to be out of calibration.

SRP 17.5, Section L, Item 5 specifically states, in part, that “When M&TE is found out of calibration, an evaluation is made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.” NQA-1 2015 Part 1, Requirement 12, Paragraph 303.2 “Corrective Action,” specifically states, in part, that “When measuring and test equipment is lost, damaged, or found to be out-of-calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated.” The NRC staff requests Holtec to address SRP 17.5, Section L, Item 5.

6) Information Need Item 13

The NRC staff requested Holtec to address SRP 17.5, Section N, Items 5 and 6 during the Information Needs public meeting. Holtec clarified that the QAP is intended for a Part 50 Construction Permit. The review standards in SRP 17.5, Section N applies to Construction Permit applicants (It states “NOT APPLICABLE TO DC AND ESP APPLICANTS”). Therefore, the NRC staff requests Holtec to address these two items regarding temporary modifications and maintenance/modifications of safety-related items.

7) Information Need Item 15

In the draft Revision 1 of the SMR LLC QAP TR, Holtec added a statement that states:

“Holtec procedures require personnel to identify known conditions adverse to quality.”

However it does not specify if all personnel are required to identify conditions that are adverse to quality, as delineated in SRP 17.5, Section P, Item 4. The NRC staff requests Holtec to clarify if all Holtec personnel are required to identify conditions that are adverse to quality.

In addition, Holtec added Section 16.2, “Reporting,” to the draft Revision 1 of the SMR LLC QAP TR, which states:

“10CFR21 (for construction, 10CFR50.55(e) applies) is considered to apply to those items and services identified as safety-related. 10CFR21 (for construction, 10CFR50.55(e) applies) reportability is evaluated for each applicable nonconformance.”

The NRC staff believes that it is Holtec’s intention for this statement to apply to conditions that are adverse to quality, not nonconformance. The NRC staff requests Holtec to clarify.

8) Information Need Item 18

Holtec added “inspection” to Part III, Section 1, Subsection 1.17, “Records” in the draft Revision 1 of the SMR LLC QAP TR. Holtec also added language in Subsection 1.18, “Audits,” similar to SRP 17.5, Section U, Item 1.r to address activities when audits are not performed. However, it doesn’t include “inspection” activity.

The NRC staff requests the applicant to clarify if inspection activities are included in Subsection 1.18.

9) Information Need Item 19

For fire protection system, the draft Revision 1 of the SMR LLC QAP TR references Revision 4 of RG 1.189. A new Revision 5 of RG 1.189 was issued to fix some administrative changes from Revision 4. The NRC staff requests the applicant to reference Revision 5 of RG 1.189 instead.