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

Note: In preparation for the January 26, 2024, public meeting with SMR, LLC (Holtec), the NRC Staff sent the following information needs to SMR, LLC (Holtec) on January 19, 2024.

Item 1 (10 CFR Part 50, Appendix B, Criterion I)

SRP, Section 17.5, Item A.6 states, in part, that "The organization description clearly identifies all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, etc.), and the lines of responsibility…For multiple organizations, the interface responsibilities are clearly defined." Item A.13 states, "The person for directing and managing the onsite QA program is identified and has appropriate organizational position, responsibility, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to ensuring that the QA program at the plant site is being effectively implemented."

Part II, Section 1.2, "Organizational Responsibilities of Key Personnel," of the SMR LLC Topical Report, HI-2230815, Revision 0, "Quality Assurance Program for Holtec International's Small Modular Reactor Design and Construction," (TR) describes the reporting relationships, functional responsibilities, and authorities for key upper management personnel in the Holtec International organization. The NRC staff reviewed this description and found that the SRP, Section 17.5, Items A.6 and A.13 have not been adequately addressed. Specifically, the onsite and offsite organizational elements have not been identified, the interface responsibilities are not clearly defined, and the person responsible for directing and managing the onsite QA program and his/her authority have not been identified. Further, the NRC staff did not find an organization diagram to depict adequate independence between those performing the QA functions and those performing the design, construction, procurement, and testing activities.

Information Need: Address Items A.6 and A.13 of SRP, Section 17.5.

Item 2 (Criterion I)

SRP Section 17.5, Item A.2 states, "The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations." Item A.4 states, in part, that "When major portions of the applicant's program are delegate: the applicant describes how responsibility is exercised for the overall program…the applicant evaluates the performance of work by the delegated organization at a frequency of once per year…Qualified individual(s) or organizational element(s) are identified within the applicant's organization as responsible for the quality of the delegated work prior to initiation of activities. Item A.5 states, "Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors ensure adequate direction of the QA program."

Part II, Section 1 of the TR does not describe whether any portions of the establishment and execution of the QA program may be delegated to others.

Information Need: Clarify whether any portions of the QA program will be delegated to others to establish and implement the QA program. If portions of the QA program will be delegated to others, address the acceptance criteria within SRP Section 17.5, Items A.2, A.4, and A.5.

Item 3 (Criterion II)

a) 10 CFR Part 50.55(f)(1) states "Each nuclear power plant or fuel reprocessing plant construction permit holder subject to the quality assurance criteria in appendix B of this part shall implement, pursuant to § 50.34(a)(7) of this part, the quality assurance program described or referenced in the Safety Analysis Report, including changes to that report."

   Part II, Section 2.5, "Issuance and Revision to Quality Assurance Program," of the TR did not mention whether the TR is governed in accordance with 10 CFR 50.55(f) for construction related activities.

   Information Need: Clarify whether 10 CFR 50.55(f) applies.

b) 10 CFR Part 52 sets forth the requirements for the issuance of early site permits (ESPs), standard design certifications (DCs), combined licenses (COLs), standard design approval (SDAs), and manufacturing license for nuclear power facilities licensed under Section 103 of the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act off 1974.

   Information Need: Clarify if Holtec intends to use the TR to apply for an ESP, DC, COL, SDA or Manufacturing License. If so, address the requirements set forth in 10 CFR Part 52.

Item 4 (Criterion II)

a) SRP 17.5, Section S, provides guidance for training and qualification for QA auditors and QA lead auditors. Section T provides guidance for training and qualification for inspection and test personnel.

   Part II, Section 2.6, "Personnel Training and Qualifications," of the TR states the requirements for qualification of QA lead auditors and for qualification of inspections, tests, and NDE personnel both comply with NQA-1 2015, Part 1, Requirement 2, except as modified per Paragraph 2.8 below. However, there is no Paragraph 2.8 in the TR.

   Information Need: Clarify Paragraph 2.8 and the exceptions taken to the requirements for qualification of both QA lead auditors and inspections, tests, and NDE personnel.

b) The TR does not mention the requirements for qualification of QA auditors, as described in Paragraph 304 "Auditors" of NQA-1 2015.

   Information Need: Clarify the requirements for qualification of QA auditors.

Item 5 (Criterion II)

Part II, Section 2.7, "NQA-1 Commitment/Exceptions" of the TR states that "Section 302 provides requirements for the qualification of inspection and test personnel. For test personnel, the requirements of this section shall apply only when Holtec International determines that testing activities warrant the need for test personnel to be qualified. When such cases exist, controlling procedures shall define the qualification requirements."

Information Need: Clarify above statement to provide criteria for determining when a testing activity would warrant the need for test personnel to be qualified in accordance with Section 302 of NQA-1 2015, Part I, Requirement 2.

Item 6 (Criterion III)

SRP 17.5, Section C, Items 8 and 9 state, respectively, "The QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements," and "QA personnel are included in the documented review and concurrence in quality related procedures associated with design, construction, and installation."

The NRC staff reviewed Part II, Section 3, "Design Control," of the TR and did not find information regarding the participation of QA personnel in design and analysis activities.

Information Need: Clarify the role of QA in the design process.

Item 7 (Criterion III)

SRP Section 17.5, Subsection C, Item 19 provides the guidance for design verification activities when the designer's immediate supervisor is the verifier. Items 19.a.ii and 19.a.iii state, respectively, "The need is individually documented and approved in advance by the supervisor's management," and "QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse."

Part II, Section 3.4, "Design Verification," of the TR states, "A supervisor of the preparer may perform the verification provided that a) The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or b) the supervisor is the only available associate in the Company competent to perform the verification."

The NRC staff reviewed the information in Part II, Section 3.4 of the TR regarding supervisors acting as verifiers and found that it does not address Items 19.a.ii and 19.a.iii of SRP 17.5 regarding the need for documentation and advanced approval by the supervisor's management, and the need for QA audits to cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

Information Need: Address these two areas.

Item 8 (Criterion VII)

Appendix B to 10 CFR Part 50 establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components. The definition of safety-related is found in 10 CFR Part 50.2.

Part II, Section 7.2, "Acceptance of Item or Service," of the TR states the following:

> "Prospective safety significant items and service suppliers are evaluated to assure only qualified suppliers are used. Such evaluations are completed on a graded approach based on the safety significance of the item or service being provided."

"Qualified safety significant items and service suppliers are audited on a triennial basis. The triennial period begins when the first audit is performed."

Information Need: Clarify the difference(s) between the terms "safety-related" and "safety significant" and clarify what structures, systems and components are subjected to the requirements in Part II, Section 7.0 of the TR.

Item 9 (Criterion VII)

a) Part II, Section 7.2 of the TR lists the conditions for a 25% grace period audit or survey extension under exigent conditions. Specifically, Item e) states that:

> "If there is no ongoing receipt inspection or operating experience with which to analyze the supplier since the last audit or survey, a documented evaluation shall be performed and include, as appropriate, the following: i) Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions. ii) Results of previous source verifications, audits, survey and receiving inspection activities. iii) Operating experience of identical or similar products furnished by the same supplier. iv) Results of audits from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), or NRC inspection)."

Similar wording is stated in an NRC Safety Evaluation (SE) for Callaway (ML20216A681), dated August 6, 2020, which approved the 25% audit extension frequency under exigent condition. However, the SE specifically states, in part:

> "If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include, as appropriate, the following:
>
> i. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
>
> ii. Results of previous source verifications, audits, survey and receiving inspection activities.
>
> iii. Operating experience of identical or similar products furnished by the same supplier.
>
> iv. Results of audits and inspection from other sources (e.g. customer, ASME, or NRC inspection)."

In the SE, the documented evaluation is to be performed annually.

Information Need: Clarify the frequency of the documented evaluation of suppliers when a grace period not to exceed 25 percent of audit or survey is invoked under exigent conditions. Clarify if TR will follow the guidance in EPRI TR 300202096, "Remote Assessment Techniques, Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions."

b) Part II, Section 7.2 of the TR contains a statement:

> “Documented annual evaluations are performed for qualified safety significant suppliers (excluding important to safety category C suppliers) and those vendors that get a commercial grade survey to assure they continue to provide acceptable products and services. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). Annual evaluations are not required to be completed for suppliers who received an audit or survey during the last half of the previous year or where an audit or survey is scheduled in the first three months of the current year.”

Information Need: Clarify this statement and the timeline in which annual evaluations are not required to be completed for suppliers. Specifically, for those suppliers that received an audit or survey during the last half of the previous year, or where an audit or survey is scheduled in the first three months of the current year, how are these suppliers evaluated if the documented evaluation exceeds a one-year time frame.

Item 10 (Criterion VII)

Part II, Section 7.3 “NQA-1 Commitment/Exceptions” of the TR lists the conditions for which commercial grade calibration and testing services can be procured from a calibration or testing laboratory that is accredited by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutal Recognition Arrangement (MRA). Specifically, six conditions are specified for the procurement documents requirement for calibration services, and four conditions are specified for the procurement documents requirement for testing services.

Wording stated in an NRC SE (ML20322A019), dated November 23, 2020, which concluded that Revision 1 of the NEI 14-05A “Guidelines for the Use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for using laboratory accreditation by Accreditation Bodies that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services.

The NRC staff identified two discrepancies between the wording in Part II, Section 7.3 of the TR and the approved wording in the NRC SE.

a) The first discrepancy is that in the NRC SE Section 3.4, “Implementation of the ILAC Accreditation Process in Lieu of a Commercial-Grade Survey,” the conditions are granted for a licensee or supplier to procure calibration or testing services by ILAC MRA signatories “in lieu of a commercial-grade survey” as part of the commercial-grade dedication process. However, in Part II, Section 7.3 of the TR, the same conditions are listed for procuring calibration or testing services for ILAC MRA signatories, however, it states that:

   > “When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided the supplier maintains an accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) under the following conditions:”

> "When purchasing commercial grade testing services from a testing laboratory, procurement source evaluation and selection measures need not be performed provided the supplier maintains an accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) under the following conditions:"

The intent of the NRC SE is that a commercial-grade survey is not needed for calibration or testing laboratories that are accredited by the ILAC MRA.

Information Need: Clarify the statement "procurement source evaluation and selection measures need not be performed provided the suppliers maintained…"

b) The second discrepancy is that in the NRC SE, there is a condition that is not found in the TR. Specifically, this condition from the NRC SE states:

> "The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments."

Information Need: Address why this condition was not included in the TR for both calibration and testing services.

c) SMR (Holtec) did not identify whether the TR will conform to the guidance to NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1.

Information Need: If it is the intent of the TR to conform to NEI 14-05A, add this commitment to Part IV, "Regulatory Commitments" of the TR.

<u>Item 11 (Criterion XII)</u>

SRP 17.5, Section L, Item 5 provides guidance for out of calibration measuring and test equipment (M&TE). It states "M&TE found out of calibration is tagged or segregated and not used until it is recalibrated. 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. If any measuring or test equipment is consistently found out of calibration, it is repaired or replaced. A calibration is performed when the accuracy of the equipment is suspect."

NQA-1 2015, Part 1, Requirement 12, Paragraphs 303, "Control,' and 303.2, "Corrective Action," provide requirements for out of calibration M&TE and the corrective action that need to be taken when an M&TE is found to be out of calibration.

Part II, Section 12.1 "General" of the TR states that "Procedures also address requirements for control and evaluation of out of calibration conditions."

Information Need: Clarify the statement in Part II, Section 12.1 of the TR regarding whether these procedures will address the guidance and requirement in SRP 17.5 and NQA-1 2015 for out of calibration M&TE.

Item 12 (Criterion XIII)

SRP 17.5, Section M, Items 5 and 7 provide guidance for cleanliness controls and storage of chemicals.

NEI 11-04A, Revision 0, Section 13, Subsection 13.1 provides housekeeping practices and control of cleanliness of facilities and materials.

a) The NRC staff reviewed Part II, Section 13, "Handling, Storage, and Shipping," of the TR and found that it does not address the guidance in SRP 17.5 Items M.5 and M.7 regarding housekeeping control such as cleanliness controls and storage of chemicals.

   Information Need: Address these two items.

b) Part II, Section 13.1 in the TR states:

   > "Holtec International has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to prevent deterioration. These provisions include specific procedures, when required, to maintain acceptable quality of the items important to safety."

   The Policy Statement of the TR states:

   > "For projects involving safety significant (safety-related and important to safety) goods and services for nuclear plants……"

   Safety-related items are not the same as important to safety items.

   Information Need Clarify what items (safety significant, safety-related or important to safety) are controlled under the requirements of Part II, Section 13 of the TR.

c) In addition, NEI 11-04A Rev. 0 lists the following NQA-1 Subparts as part of its NQA-1 commitments:

   1) Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities."

   2) Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities"

   3) Subpart 2.3, "Quality Assurance Requirements for Housekeeping at Nuclear Facilities,"

   Information Need: Clarify whether the TR commits to these Subpart requirements.

Item 13 (Criterion XIV)

SRP 17.5, Section N, Items 5 and 6 provide guidance for temporary modifications and maintenance/modifications of safety-related items.

The NRC staff reviewed Part II, Section 14, “Inspection, Test, and Operating Status,” of the TR and found that it does not address the guidance in SRP 17.5, Section N, Items 5 and 6 regarding temporary modifications and maintenance/modifications of safety-related items.

Information Need: Address these two items if SMR (Holtec) intends to apply for either a DC or ESP with the TR.

Item 14 (Criterion XV)

Part II, Section 15.2, “10CFR21,” states “10CFR21 is considered to apply to those items and services identified as safety-related. 10CFR21 reportability is evaluated for each applicable nonconformance.”

Information Need: Clarify if the TR also complies with the reporting requirements in 10 CFR Part 50.55(e) for construction.

Item 15 (Criterion XVI)

a) SRP 17.5, Section P, “Corrective Action (Criterion XVI),” Item 4 states “The program requires all personnel to identify conditions that are adverse to quality.”

   The NRC staff reviewed Part II, Section 16, “Corrective Action,” of the TR and found that it does not address the guidance provided in SRP 17.5, Section P, Item 4 regarding which personnel are responsible to identify conditions that are adverse to quality.

   Information Need: Address this item.

b) ***Information Need***: Address 10 CFR Part 21 reportability requirement for conditions adverse to quality and significant conditions adverse to quality to clarify if any conditions adverse to quality and significant conditions adverse to quality would result in a 10 CFR Part 21 reportability evaluation. Address if the TR also complies with the reporting requirements in 10 CFR Part 50.55(e) for construction.

Item 16 (XVII)

Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50, states, in part, “Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.”

a) SRP 17.5, Section Q, “Quality Assurance Record (Criterion XVII),” Items 2, 3, and 4 reiterates these requirements.

   Part II, Section 17.1, “General,” of the SMR LLC QAP TR states:

   > “Holtec International has the necessary measures and governing procedures to ensure that sufficient quality assurance records are generated to furnish documentary evidence that items and services meet specified quality requirements. Such records shall be identified, reviewed, approved, maintained, and must be retrievable.”

Information Need: Address the requirements in Criterion XVII of Appendix B to 10 CFR Part 50 to clarify if records, such as operating logs, inspection results, qualification of personnel, etc. are considered quality assurance records and are controlled under the requirements of Part II, Section 17 of the TR.

b) SRP 17.5, Section Q, Item 7 provides guidance on QA records in electronic media.

Information Need: Clarify if SMR (Holtec) intends to follow the guidance in Generic Letter GL-88-18, "Plant Record Storage on Optical Disks," and Regulatory Issue Summary RIS 00-018, "Guidance on Managing Quality Assurance Records in Electronic Media," and the associated Nuclear Information Records Management Association, Inc. (NIRMA) TG 11-2011, TG 15-2011, TG 16-2011, and TG 21-2011.

Item 17 (Criterion XVIII)

a) SRP 17.5, "Section R, "Audits (Criterion XVIII)," Item 7 states "Audits provide a comprehensive independent evaluation of activities and procedures."

NEI 11-04A, Section 18.2, "Internal Audits," states "Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of *[construction, fabrication, operating, refueling, maintenance, and modification]* activities including associated record keeping."

Part II, Section 18.2, "Internal Audits," of the TR states:

> "Internal audits are performed to verify compliance and effectiveness of implementation of programs and procedures using a representative sample."

Information Need: Clarify the meaning of a "representative sample" when conducting internal audits.

b) Part II, Section 18.5, "NQA-1 Commitment," of the TR states

> "NQA-1 Requirement 18 states that, "All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to 2 yrs. based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements." As noted in 18.2 of the QAM, internal audits of all applicable QA Program elements are performed annually with no allowance to extend to two years."

The audit extension of 1 year allowance in NQA-1-2015, Part I, Requirement 18, Paragraph 201.2 "Nuclear Facilities After Placing the Facility Into Operation," is for internal audits of applicable QA program elements after the facility has been placed into operation, hence, it does not apply to design and construction. While the QAP TR states that "As noted in 18.2 of the QAM, internal audits of all applicable QA Program elements are performed annually with no allowance to extend to two years," Part II, Section 18.2 of the TR does not account

for audit frequency requirements when the life of an activitzIny is shorter than a year, as stated in Paragraph 201.1 of Part I, Requirement 18 of NQA-1-2015.

Information Need: Address this discrepancy.

Item 18 (Part III: Nonsafety-Related SSC Quality Control)

a) SRP Section 17.5, Section U, "Nonsafety-Related SSC Quality Controls," Item 1.q states "Records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, and inspection and test activities have been met."

   Part III, Section 1, "Nonsafety-related SSCs Significant Contributors to Plant Safety," Subsection 1.17, "Records," of the TR states:

   > "Holtec International employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control and test activities have been met."

   Information Need: Clarify if inspection activities are part of the requirements in Part III, Section 1, Subsection 1.17 of the TR.

b) SRP Section 17.5, Section U, Item 1.r, states, in part, "Audits independent of line management are not required, if line management periodically reviews and documents the adequacy of the supplier's process and takes any necessary corrective action. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate."

   Part III, Section 1, Subsection 1.18, "Audits" of the TR states, in part,

   > "If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and test activities as appropriate."

   The NRC staff reviewed Part III, Section 1, Subsection 1.18 of the TR and found that it does not address the guidance in SRP 17.5, Section U, Item 1.r for activities when audits are not performed.

   Information Need: Address, specifically, what measures are in place to control those activities when audits are not performed.

Item 19 (Non-Safety-Related SSCs Certified for Regulatory Events)

SRP Section 17.5, Item U.2, "Non-Safety-Related SSCs Credited for Regulated Events," identified three criteria that are applicable to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related. Specifically, it lists the following:

a. The applicant or holder commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants."

b. The applicant or holder commits to implement the quality requirements to ATWS equipment in accordance with GL 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related.”

c. The applicant or holder commits to implement quality requirements to SBO equipment in accordance with Regulatory Position 3.5 “Quality Assurance and Specific Guidance for SBO Equipment that Is Not Safety Related,” and Appendix A, “Quality Assurance Guidance for Non-Safety Systems and Equipment,” in RG 1.155 “Station Blackout.”

Part III, Section 2, “Non-Safety-Related SSCs Credited for Regulatory Events,” of the TR lists three similar criteria:

- Holtec International commits to implement quality requirements to the fire protection system in accordance with Staff Regulatory Guidance 1.7, “Quality Assurance,” in RG 1.189, Revision 4, May 2021; “Fire Protection for Nuclear Power Plants.”

- Holtec International implements the quality requirements for non-safety-related, safety significant ATWS equipment in accordance with Part III, Section 1.

- Holtec International implements the quality requirements for non-safety-related, safety significant SBO equipment in accordance with Part III, Section 1.

Information Need: Clarify if TR intends to commit to GL 85-06 for ATWS and RG 1.155 for station blackout. If not, address the Items U.2.b and U.2.c in SRP 17.5.

Item 20 (Part IV, Regulatory Commitments)

a) Part IV, “Regulatory Commitments” of the TR identifies NRC RG 1.26, 1.28 and 1.29, as well as NQA-1-2015 that have been selected to supplement and support the TR. This section identifies the extent of conformance to these RGs and QA standards. However, it is unclear to the NRC staff whether SMR (Holtec) intends to commit to these RGs.

   Information Need: Clarify whether TR intention is to commit to these RGs,or provide an alternative on how to comply with the applicable regulatory requirements.

b) The NRC staff found that the TR does not include commitments to RG 1.164, Revision 0, RG 1.231, Revision 0, RG 1.234, Revision 0, RG 1.8, Revision 4. These RGs provide guidance on acceptable methods to comply with regulatory requirements for commercial-grade dedication, evaluation and reporting requirements in 10 CFR Part 21, qualification and training of personnel, and the managerial and administrative quality assurance controls during operation.

   Information Need: Clarify whether it intends to commit to these RGs, or whether alternative methods will be used to comply with the applicable regulatory requirements.

Item 21 (Request for Clarification)

Information Need: Address the following inconsistencies:

a) Section 1.4, “NQA-1 Commitment,” states that Holtec commits to compliance with NQA-1-2015, Part I, but did not state which requirement in NQA-1-2015, Part I.
b) Section 16.2, “NQA-1 Commitment,” states that Holtec commits to compliance with NQA-1-2015, Part Requirement 16, but did not state which “Part” in NQA-1-2015.
c) Section 17.6, “NQA-1 Commitment / Exceptions” states, in part, that Holtec commits to compliance with NQA-1-2015, Requirement 17, and…” but did not state which “Part” in NQA-1-2015.
d) Part IV, “Regulatory Commitments,” lists the RGs Holtec complies with and identifies a few exceptions, stating, in part, “Holtec will identify conformance and exceptions for the applicable regulatory position guidance provide in this regulatory guide in SAR Chapter…” However, the term “SAR” is not defined in the TR.