FINAL SAFETY EVALUTION BY THE OFFICE OF NUCLEAR REACTOR REGULATION FOR THE TOPICAL REPORT ON THE QUALITY ASSURANCE PROGRAM FOR HOLTEC INTERNATIONAL'S SMALL MODULAR REACTOR DESIGN AND CONSTRUCTION EPID NO. L-2023-TOP-0049

1.0 INTRODUCTION

By letter dated September 28, 2023 (Agencywide Documents Access and Management Systems (ADAMS) Package Accession No. ML23271A007; (Letter, ML23271A008)), Holtec International, Small Modular Reactor (SMR), LLC (hereafter referred to as Holtec) submitted HI-2230815, Revision 0, "Topical Report [(TR)] on the Quality Assurance Program [(QAP)] for Holtec International's Small Modular Reactor Design and Construction," (hereafter referred to as SMR LLC QAP TR) to the U.S. Nuclear Regulatory Commission (NRC) for review, to be used for a Construction Permit (CP) Application and/or a Limited Work Authorization (LWA). The SMR LLC QAP TR describes the activities covered by Holtec's QAP and is applicable to design, construction, procurement, and testing activities for Holtec's SMR.

Holtec stated that the 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 is consistent with 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 (ML17207A293). Holtec also stated that the SMR LLC QAP TR has been prepared consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Standard Review Plan (SRP) 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 (ML13164A017).

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 SRP Section 17.5, Revision 1 (ML15037A441). In lieu of requests for additional information (RAIs), the staff developed information needs based on the holes identified while writing the draft safety evaluation (SE). The information needs were addressed via three clarification calls and two revisions to the SMR LLC QAP TR. The NRC staff provided the initial set of information needs (ML24022A077) and held a public meeting with Holtec on January 26, 2024 (ML24039A003), to discuss the NRC staff's initial review. The NRC staff provided a second set of information needs (ML24079A078) and held a second public meeting with Holtec on March 27, 2024 (ML24107B151) to further discuss the NRC staff's review. By letter dated April 19, 2024, Holtec submitted Revision 1 of the SMR LLC QAP TR for NRC staff's review (ML24110A088). Subsequently, the NRC staff held a third public meeting with Holtec on May 31, 2024 (ML24152A002), to discuss any remaining items. By letter dated June 3, 2024, Holtec submitted Revision 2 of the SMR LLC QAP TR for NRC staff's review (ML24155A285).

2.0 REGULATORY EVALUATION

The regulatory requirements related to QA programs are, in part, set forth in the following regulations:

1. Appendix B to 10 CFR Part 50, which establishes QA requirements for the design, manufacture, construction, and operation of structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those SSCs; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying for nuclear power plants and fuel reprocessing plants.

2. 10 CFR 50.10(d)(3)(i), which requires an application for LWA to include a safety analysis report that demonstrates that activities conducted under the LWA will be conducted in compliance with the technically relevant Commission requirements in 10 CFR Chapter I applicable to the design of those portions of the facility with the scope of the LWA.

3. 10 CFR 50.34(a)(7), which requires an application for a CP to include a description of the QAP to be applied to the design, fabrication, construction, and testing of SSCs of the facility. The description of the QAP for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

3.0 EVALUATION

In evaluating the adequacy of the SMR LLC QAP TR, Revision 2, the NRC staff utilized the guidance contained in SRP Section 17.5, Revision 1. SRP Section 17.5 provides guidance to the NRC staff for the review of a QAP for design certification, combined license, early site permit, CP, and operating license applications. SRP Section 17.5 is based on Appendix B to 10 CFR Part 50 and describes regulatory and industry guidance determined to be acceptable methods for meeting the requirements of Appendix B to 10 CFR Part 50. The ASME standard NQA-1-2015 Edition, upon which the SMR LLC QAP TR is based, is endorsed with certain exceptions and clarifications by the NRC in RG 1.28, Revision 5. The NEI 11-04A, Revision 0, is a template developed by NEI to assist licensees and applicants in developing a QAP. However, this template was developed based on the ASME standard NQA-1-2008 Edition and NQA-1a-2009 Addenda, which are endorsed with certain exceptions and clarifications by the NRC in RG 1.28, Revision 4.

3.1 Quality Assurance Program Overview

Part I, Section 1, “General,” of the SMR LLC QAP TR states that Holtec’s Nuclear Quality Assurance Manual (HQAM) is the top-level policy document that establishes the QA program and policy and assigns major functional responsibilities for important to safety, including safety-related, activities conducted by or for Holtec. The HQAM describes the methods and establishes QA and administrative control requirements that meet the applicable codes and standards.

The Holtec Quality Assurance Program (HQAP) is defined by the HQAM along with the associated implementing documents such as procedures. Procedures and instructions that control Holtec's activities related to quality are required to be developed prior to commencement of those activities. Policies establish high-level responsibilities and authority for carrying out important administrative functions which are outside the scope of the HQAP. Procedures establish practices for certain activities which are common to all Holtec organizations performing those activities so that the activity is controlled and carried out in a manner that meets HQAP requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

The SMR LLC QAP TR provides a summary of the requirements set forth within the HQAP related to design, fabrication, construction, and testing activities necessary for Holtec's SMR. The SMR LLC QAP TR has been established to serve as the primary vehicle to describe the control of all important to safety, including safety-related, activities carried out by Holtec for activities including engineering, design, procurement, fabrication, construction, inspection and testing, and training and qualification, related to the design and construction of SMRs. Selected elements of the SMR LLC QAP TR are also applied to certain activities that are not safety- related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes QA requirements.

The SMR LLC QAP TR states that it complies with Appendix B to 10 CFR Part 50, 10 CFR Part 21, "Reporting of Defects and Noncompliance," ASME NQA-1-2015, Part I, "Requirements for Quality Assurance Programs for Nuclear Facilities," and applicable subparts from ASME NQA-1-2015, Part II, "Quality Assurance Requirements for Nuclear Facility Applications."

3.1.1 Organization

Part II, Section 1, "Organization," of the SMR LLC QAP TR describes the Holtec organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying the SMR LLC QAP TR implementation. The overall organizational structure includes corporate management and support staff, including interface responsibilities for multiple organizations that perform quality-related functions. Figure I.1.1, "SMR, LLC Organization," of the SMR LLC QAP TR depicts the reporting relationship, functional responsibilities, and authorities for organizations implementing and supporting the HQAP. Organizational structure and implementing procedures ensure quality is achieved and maintained by those assigned responsibility for performing the work, and that quality achievement is verified by those not directly responsible for performing the work.

The SMR LLC QAP TR states that the executive in charge of the quality organization is responsible for assuring that the size of the quality organization staff is commensurate with the duties and responsibilities assigned. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Regardless of the organizational structure, the person(s) assigned the responsibility for assuring effective execution of any portion of the HQAP, at any location where important to safety, including safety-related, activities are being performed, shall have direct access to the levels of management necessary to perform the required functions without hindrance. The SMR LLC QAP TR further states that those responsible for assuring that an appropriate QAP has been established and those verifying activities affecting quality shall have sufficient independence from

cost and schedule when opposed to safety function considerations. Such individuals shall also have the authority to stop work when deemed necessary due to identification of failing to follow HQAP requirements or where safety or SSC integrity may be jeopardized.

Part II, Section 1.2, “Organizational Responsibilities of Key Personnel,” describes the reporting relationships, functional responsibilities, and authorities for key upper management personnel in the Holtec organization. These positions include President, Chief Executive Officer of Holtec International, President-SMR, Chief Nuclear Officer (CNO), Executive in charge of Quality Assurance/Quality Control, Manager in charge of Procurement, Executive Director, Executive in charge of Licensing, and Executive in charge of Site.

The executive in charge of the quality organization has overall responsibility for the establishment and implementation of the SMR LLC QAP TR. This executive reports directly to the CNO and is assigned primary responsibility for verifying that the SMR LLC QAP TR is in place and is effective. This executive is also responsible for verifying that activities affecting quality have been performed in accordance with the SMR LLC QAP TR and applicable implementing procedures such as Holtec Quality Procedures (HQPs) and Holtec Standard Procedures (HSPs); and ensuring that adequate QA resources are applied to this oversight function. This executive may delegate SMR LLC QAP TR administration and verification to a senior QA person assigned to the SMR project but shall maintain overall responsibility for those delegated duties.

Onsite and offsite management positions within the quality organization report directly to the executive in charge of the quality organization. These managers are responsible for managing the onsite and offsite QA for the Holtec SMR project and include the following responsibilities:

1. Maintaining and updating the HQAM, SMR LLC QAP TR, and supporting procedures, evaluating compliance to QAP requirements, and managing QA organization resources.

2. Assuring compliance with regulatory requirements and procedures through audits and technical reviews.

3. Monitoring organizational processes to ensure conformance to commitments and licensing document requirements.

4. Ensuring that vendors providing quality services, parts, and materials to Holtec are meeting the requirements of applicable codes and standards through vendor audits, surveys, and surveillances.

5. Assuring that appropriate QA training and qualification activities are completed as applicable to personnel performing quality related activities.

6. Identifying, evaluating, and recording actual and potential quality problems in accordance with the SMR LLC QAP TR and HQP and HSP implementing procedures.

The SMR LLC QAP TR further states the management positions within the quality organization have sufficient independence from other Holtec priorities to bring forward issues affecting safety and quality and make judgements regarding quality in all areas regarding Holtec activities as appropriate. The managers in these positions are free from non-QA duties and can thus give full attention to ensuring that the SMR LLC QAP TR is effectively implemented. Where quality-related disagreements may exist between different Holtec organizations, the executive in charge of the quality organization will determine the final disposition.

Part II, Section 1.4, "NQA-1 Commitment," states that in establishing its organizational structure, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 1, "Organization." The NRC staff evaluated the descriptions of the roles and responsibilities of the various positions described in Part II, Section 1 of the SMR LLC QAP TR and concludes that it adequately describes 1) the QA functions performed by these positions, 2) the positions that are responsible for the establishment and effective implementation of the SMR LLC QAP TR, and 3) the authority, including the ability to stop work, and responsibilities of positions that perform verification of activities affecting safety-related functions. The NRC staff also evaluated the authority and organizational independence of persons and organizations performing QA functions and concludes that these persons and organizations have access and report to an appropriate level of management and have the requisite authority and independence.

Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 1, the NRC staff determined that Part II, Section 1 of the SMR LLC QAP TR conforms to the guidance of SRP Section 17.5, Subsection II, Item A, "Organization (Criterion I)." Therefore, the NRC staff determined that the organizational controls described in Part II, Section 1 of the SMR LLC QAP TR comply with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50.

3.1.2 Quality Assurance Program

Part II, Section 2, "Quality Assurance Program," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to implement the SMR LLC QAP TR. The objective of the SMR LLC QAP TR is to assure that Holtec's process and activities, including but not limited to, engineering, design, procurement, fabrication, construction, inspection and testing, training, and qualification, as identified in Table I.1.1, "QA Program Applicability," of the SMR LLC QAP TR, are in accordance with governing regulations and license requirements. It further states that the program is based on the requirements set forth in Appendix B to 10 CFR Part 50, 10 CFR Part 21, and ASME NQA-1-2015 with exceptions and applicable subparts, as described in Table I.1.2, "QA Program Requirements," of the SMR LLC QAP TR. The SMR LLC QAP TR applies to those quality-related activities that involve the functions of safety-related SSCs associated with the processes and activities identified in Table I.1.1 of the SMR LLC QAP TR. Holtec establishes and maintains a plant-level SSC classification listing of all safety-related SSCs and non-safety-related SSCs that are significant contributors to plant safety. A system that identifies SSCs and activities to which the HQAP applies is maintained at Holtec facilities. For non-safety-related SSCs that are significant contributors to plant safety, specific program controls are applied to those SSCs in a select manner, targeted at those characteristics or critical attributes that qualify an SSC as a significant contributor to plant safety.

The SMR LLC QAP TR provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate

analytical tools, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied. The SMR LLC QAP TR provides for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of that quality.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principal contractor has been approved as a supplier in accordance with the SMR LLC QAP TR. Periodic audits and assessments of the supplier's QAP are performed to assure compliance with the supplier's or principal contractor's QAP and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

The SMR LLC QAP TR also states that a grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backward by performing the activity early. Audit schedules are based on the month in which the audit starts. Furthermore, the SMR LLC QAP TR states that Holtec ensures through the systematic process that its suppliers of safety-related items and services meet the applicable requirements of Appendix B to 10 CFR Part 50, except where Holtec performs commercial grade dedication or implements applicable portions of its own HQAP on the supplier.

Part II, Section 2.2, "Responsibilities," Section 2.3, "Delegation of Work," and Section 2.4, "Periodic Review of the Quality Assurance Program," of the SMR LLC QAP TR describe the responsibilities of Holtec personnel in achieving acceptable quality, the personnel positions that may delegate all or part of the activities of planning, establishing, and implementing the SMR LLC QAP, and the periodic review of the implementation the SMR LLC QAP TR, or portions thereof, by the responsible Holtec organizations. Management of those organizations implementing the SMR LLC QAP TR, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter.

Part II, Section 2.5, "Issuance and Revision to Quality Assurance Program," of the SMR LLC QAP TR describes how changes to the SMR LLC QAP TR are controlled. New revisions to the HQAP implementing documents will be reviewed, at a minimum, by the executive in charge of the quality organization. Changes to the SMR LLC QAP TR shall follow the criteria set forth in 10 CFR 50.54, "Conditions of Licenses," and 10 CFR 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses," paragraph (f) for construction activities.

Part II, Section 2.6, "Personnel Training and Qualifications," describes the personnel training and qualification requirements. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance to safety of the activities, and include the following, as appropriate:

1. Education, experience, and proficiency of the personnel receiving training.

2. General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, Holtec procedures, and QA program requirements.

3. On-the-job training if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Part II, Section 2.7, “NQA-1 Commitment / Exceptions,” states that in establishing controls for the QA program, including qualification and training programs, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 2 and RG 1.28, Revision 5. It also states that the qualification requirements for inspection and test personnel, non-destructive examination (NDE) personnel, QA lead auditors and QA auditors comply with ASME NQA-1-2015, Part I, Requirement 2, with the following clarifications and exceptions:

- Prospective lead auditors, with comparable industry experience, may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

The NRC staff reviewed the descriptions of the measures and controls that Holtec has established in Part II, Section 2 of the SMR LLC QAP TR, as discussed above. The NRC staff concludes that the SMR LLC QAP TR adequately describes measures and controls for 1) ensuring that activities affecting quality are accomplished under suitably controlled conditions; 2) developing and maintaining a list of SSCs and activities under the control of the SMR LLC QAP TR in accordance with design documents; 3) identifying the scope of activities the SMR LLC QAP TR is applicable to; 4) verifying the effective implementation of the SMR LLC QAP TR; and 5) establishing a training and qualification program for those personnel implementing elements of the SMR LLC QAP TR. Based on this review, the NRC staff determined that the SMR LLC QAP TR conforms to the guidance of SRP Section 17.5, Subsection II, Item B, “Quality Assurance Program (Criterion II),” Item S, “Training and Qualification Criteria (Criterion II),” and Item T, “Training and Qualification – Inspection and Test (Criterion II).”

The NRC staff determined that the 90-day grace period audit extension is consistent with the guidance in RG 1.28, Revision 4, and an approved NRC SE for Southern Nuclear Company (ML051570349), as well as the requirements set forth in ASME NQA-1-2015, Part I, Requirement 18. The NRC staff also evaluated the exception taken to compliance with ASME NQA-1-2015, Part I, Requirement 2, with respect to lead auditors and determined this exception is acceptable because this exception is consistent with the guidance in Section C.1.a of RG 1.28, Revision 5. Therefore, the NRC staff determined that the HQAP controls, described in Part II, Section 2 of the SMR LLC QAP TR comply with the requirements of Criterion II, “Quality Assurance Program,” of Appendix B to 10 CFR Part 50.

3.1.3 Design Control

Part II, Section 3, “Design Control,” of the SMR LLC QAP TR states that Holtec has established and implements a process to control the design and design changes of items that are subject to the provisions of the SMR LLC QAP TR. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within Holtec and with suppliers. These provisions assure that design inputs, such as design bases and performance, regulatory, quality, and quality verification requirements, are correctly translated into design outputs, such as analyses, specifications, drawings, procedures, and instructions, so that the final design output contains or references appropriate acceptance criteria that can be

related to the design input in sufficient detail to permit verification as required. Changes to design are subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design documents are reviewed by individuals who are trained and qualified under the HQAP to ensure the documents contain the necessary QA requirements. QA personnel are included in the documented review and concurrence in quality related procedures associated with design, construction, and installation.

Part II, Section 3.2, "Design Inputs," states that applicable design inputs shall be identified and documented. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner.

Part II, Section 3.3, "Design Analysis," states that design analysis shall be sufficiently detailed such that a technically competent person in the area of the subject matter can review and understand the analysis and verify the adequacy of results without recourse to the originator.

Part II, Section 3.4, "Design Verification," states that design verifications are performed by technically competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. 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 Holtec competent to perform the verification.

Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the SSC's intended use. Design changes are subject to controls that include verification measures commensurate with those applied to the original design.

Part II, Section 3.7, "NQA-1 Commitment," states that in establishing its program for design control and verification, Holtec commits to compliance with ASME NQA-1-2015, Part I Requirement 3, "Design Control," and Part II, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications."

The NRC staff evaluated the description of design control measures that Holtec has established and determined that it conforms to the guidance of SRP Section 17.5, Subsection II, Item C, "Design Control and Verification (Criterion III)." Based on this evaluation and Holtec's commitment with the requirements of ASME NQA-1-2015, Part I, Requirement 3, and Part II, Subpart 2.7, the NRC staff concludes that the design control measures described in Part II, Section 3 of the SMR LLC QAP TR comply with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50.

3.1.4 Procurement Document Control

Part II, Section 4, "Procurement Document Control," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement

document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

1. Applicable technical, regulatory, administrative, quality and reporting requirements are invoked for procurement of items and services.

2. With the exception of items or services that go through a dedication process, procurement documents shall require suppliers to have a documented QA program that has been determined to meet applicable codes and/or standards.

3. Reviews and approval of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents. Reviews are performed by individuals other than the individual who prepared the procurement documents and by individuals that have received training under the HQAP.

4. Where contractors or subcontractors procure items or services, Holtec shall evaluate the contractor or subcontractor's procurement controls and/or the item or service shall go through a dedication or similar process.

Part II, Section 4.2, "NQA-1 Commitment / Exceptions," of the SMR LLC QAP TR states that in establishing controls for procurement, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 4, "Procurement Document Control," with the following clarifications and exceptions:

1. With regard to services performed by a supplier, Holtec procurement documents may allow the supplier to work under the Holtec HQAP, including implementing procedures, in lieu of the supplier having its own QA program.

2. Section 200 of ASME NQA-1-2015, Part I, Requirement 4 provides the content requirements for procurement documents. Procurement documents for items or services that will go through the dedication process need not contain the content requirements specified in ASME NQA-1-2015 but shall contain any necessary technical and/or quality requirements as applicable, such that the procured item can be appropriately dedicated.

3. Sections 300 and 400 of ASME NQA-1-2015, Part I, Requirement 4 require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes. Holtec may satisfy this requirement through the review of the procurement specification when the specification contains the technical and QA requirements of the procurement.

The NRC staff reviewed the descriptions of the measures and controls that are established to assure that applicable regulatory requirements, design bases, and other requirements are included in procurement documents or referenced in the documents for procurement of material, equipment, and services in Part II, Section 4 of the SMR LLC QAP TR, including a review of exceptions and clarifications taken to compliance with ASME NQA-1-2015, Part I, Requirement 4.

The NRC staff determined that:

1. The clarification with regard to service performed by a supplier is acceptable because the procurement document will require that a supplier work under the Holtec HQAP; and based on the conclusion of this SE, the SMR LLC QAP TR, which sets forth the requirements within the HQAP, meets the requirements of Appendix B to 10 CFR Part 50.

2. The exception to Section 200 of ASME NQA-1-2015, Part I, Requirement 4 is acceptable because Holtec will include technical and quality requirements in procurement documents for the purchase of commercial grade items or services that will undergo the dedication process per Part II, Section 7 of the SMR LLC QAP TR, in order for Holtec to use the commercial grade items or services as a safety-related items or services.

3. The clarification to Sections 300 and 400 of ASME NQA-1-2015, Part I, Requirement 4 is acceptable because Holtec may satisfy these requirements through a review of the procurement specification when the specification contains the technical and QA requirements of the procurement. The inclusion of technical and QA requirements in procurement documents is essential in the procurement process to ensure that the necessary requirements, including any regulatory requirements, are passed down from the Purchaser to the Supplier.

The NRC staff evaluated the description of measures that Holtec has established to ensure that purchased items and services are subject to appropriate quality and technical requirements and determined that the procurement document controls as described in Part II, Section 4, of the SMR LLC QAP TR conforms to the guidance of SRP Section 17.5, Subsection II, Item D, “Procurement Document Control (Criterion IV).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Requirement 4, the NRC staff determined that Part II, Section 4, of the SMR LLC QAP TR complies with the requirements of Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50.

3.1.5 Instructions, Procedures, and Drawings

Part II, Section 5, “Instructions, Procedures, and Drawings,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings, and where applicable, include quantitative or qualitative acceptance criteria to implement the SMR LLC QAP TR. The activity prescribed within the applicable document shall include sufficient detail that is commensurate with the complexity of the item or activity and for the need to assure consistent and acceptable results. Level of detail in applicable documents shall also consider the work environment and worker proficiency and capability.

Part II, Section 5.4, “NQA-1 Commitment,” states that in establishing controls for instructions, procedures, and drawings, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 5, “Instructions, Procedures, and Drawings.”

The NRC staff evaluated the description of measures that Holtec has established for ensuring that activities affecting quality are prescribed by and performed in accordance with written instructions, procedures, or drawings, and determined that these measures conform to the guidance of SRP Section 17.5, Subsection II, Item E, “Instructions, Procedures, and Drawings (Criterion V).” Based

on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 5, the NRC staff determined that Part II, Section 5, of the SMR LLC QAP TR complies with the requirements of Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50.

3.1.6 Document Control

Part II, Section 6, "Document Control," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are conducted to ensure that correct documents are employed. This section specifies the controls that are applied to documents and the types of documents to which these controls apply to.

Part II, Section 6.2, "Review and Approval of Documents," states that documents are reviewed by trained and knowledgeable persons other than the preparer for adequacy and to ensure QA measures have been appropriately applied.

Part II, Section 6.3, "Changes to Documents," states that changes to documents, other than those defined in implementing procedures as minor changes, are reviewed, and approved by the same organization that performed the original review and approval, or by a designated organization that is appropriately knowledgeable. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Part II, Section 6.4, "NQA-1 Commitment," states that in establishing provisions for document control, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 6, "Document Control."

The NRC staff evaluated the descriptions of measures and controls that Holtec has established for the preparation, issuance and revisions to documents and determined that these measures and controls conform to the guidance of SRP Section 17.5, Subsection II, Item F, "Document Control (Criterion VI)." Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 6, the NRC staff determined the Part II, Section 6, of the SMR LLC QAP TR complies with the requirements of Criterion VI, "Document Control," of Appendix B to 10 CFR Part 50.

3.1.7 Control of Purchased Material, Equipment, and Services

Part II, Section 7, "Control of Purchased of Material, Equipment, and Services," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to control purchased items and services to assure conformance with specified requirements. These controls include source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier (vendor), source inspection, audit, and examination of items or services.

Part II, Section 7.2, "Acceptance of Item and Service," describes measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the items or services important to safety, complexity, quantity, and the frequency of procurement. Measures to assure the quality of purchased items and services include 1) evaluation of prospective safety-related items and services suppliers to assure that only qualified suppliers are used; 2) use of audits of safety-related items and services

suppliers; 3) use of audits or commercial grade surveys conducted by outside organizations or other Holtec qualified suppliers for supplier qualification; and 4) use of annual evaluations performed for qualified safety-related suppliers. Provisions that are used to accept purchased items and services include 1) source verification; 2) receipt inspection, and 3) pre- and post-installation testing. Documentary evidence that materials and items conform to the procurement specifications shall be available prior to final installation or final use of the item.

Part II, Section 7.2 also states that Holtec may utilize audits or commercial grade surveys conducted by outside organizations or other Holtec qualified suppliers for supplier qualification, provided that the scope of the audit or commercial grade survey covers Holtec's needs, and the audit or commercial grade survey includes, to the extent necessary, an evaluation of applicable programmatic controls and verification of implementation. Holtec remains individually responsible for the adequacy of the audit. Documented annual evaluations are performed for qualified safety-related suppliers and those vendors that obtain a commercial grade survey to assure they continue to provide acceptable products and services.

Holtec maintains an Approved Vendor List (AVL) on Holtec's network which will list the qualification level of suppliers. Suppliers of safety-related items or services must be on the AVL prior to commencement of activities on safety-related purchase orders.

Documentary evidence that materials and items conform to the procurement specifications shall be available prior to final installation or final use of the item. This documentary evidence shall be retained by Holtec and shall be sufficient to identify the specific requirements such as codes, standards, or specifications met by the purchased items.

Part II, Section 7.3, "NQA-1 Commitment / Exceptions," states that in establishing controls for purchased items and services, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 7, "Control or Purchased Items and Services," and Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," with the following clarifications and exceptions:

1. When purchasing commercial grade calibration or testing services from a laboratory that maintains an accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), Holtec will implement the requirements of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Testing Services," Revision 1, as endorsed by an NRC SE (ML20322A019), which approves the use of NEI 14-05A, Revision 1.

2. Clarification to ASME NQA-1-2015, Part I, Requirement 7, Section 200 when direct evaluation of a supplier's facilities is not possible due to exigent conditions. Under exigent conditions, in lieu of on-site audits, Holtec allows an option to perform audits of suppliers remotely. It is recognized that not all audits can be performed remotely. Holtec will first assess whether a remote audit can be performed such that a thorough and complete evaluation of the supplier's QAP and its implementation can be made.

3. Clarification to ASME NQA-1-2015, Part I, Requirement 7, Section 501 regarding electronic media. Holtec considers documents that may be stored in approved electronic media under its control to comply with the intended requirements set forth in ASME NQA-1-2015, Part I, Requirement 7.

4. Clarification to ASME NQA-1-2015, Part II, Subpart 14, Paragraph 401 regarding the use of raw materials and its commercial dedication plan. Credible failure mode evaluations are not required for raw materials where material specifications exist. In such cases, the mechanical and chemical testing requirements of the material specification, any required NDE, one or more dimensions and markings for traceability, will be considered the critical characteristics unless otherwise documented within the dedication plan or corresponding documents.

5. Exception to ASME NQA-1-2015, Part II, Subpart 14, Paragraph 603 regarding source verification and conducting remote surveys during exigent conditions. Surveys can be performed at the supplier's facility, or under exigent conditions, may be performed remotely in a similar manner as remote audits.

The NRC staff evaluated the descriptions of measures and controls that Holtec has established for purchased items and services to assure conformance with specified requirements, including measures for dedication of commercial grade items and services, and determined that these descriptions and controls conform to the guidance of SRP Section 17.5, Subsection II, Item G, "Control of Purchased Material, Equipment, and Services (Criterion VII)."

The NRC staff evaluated the exceptions and clarifications to Holtec's commitment to compliance with ASME NQA-1-2015, Part I, Requirement 7, and Part II, Subpart 14, and determined that:

- Holtec's implementation of the guidance in NEI 14-05A, Revision 1 for purchasing commercial grade calibration or testing services from a laboratory that maintains an accreditation by an accrediting body recognized by the ILAC MRA in lieu of a commercial grade survey is acceptable because this is consistent with the NRC staff's current regulatory position regarding the acceptability of procuring commercial grade calibration and testing services from laboratories accredited by ILAC, as documented in NRC SE (ML20322A019) for NEI 14-05A, Revision 1.

- Holtec's clarification to ASME NQA-1-2015, Part I, Requirement 7, Section 200 during exigent conditions is acceptable based on the following reasons:

    - A 25 percent extension of the triennial audit or survey interval is consistent with NRC staff's current position, as documented in NRC SE for Callaway (ML20216A681)

    - Use of remote assessments is in accordance with Electric Power Research Institute (EPRI) 3002020796, "Remote Assessment Techniques, Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," (ML21127A184), and is consistent with NRC staff's current position, as documented in NRC SE for Southern Nuclear Operating Company, Inc. (ML21161A201)

    - Use of remote source verification is in accordance with EPRI 3002019436-A, "Remote Source Verification During a Pandemic or Similar State of Emergency:

Screening Criteria and Process Guidance," (ML20300A384), and is consistent with NRC staff's current position, as documented in NRC SE (ML20244A016).

- The NRC staff notes that the COVID-19 related public health emergency expired on May 11, 2023; therefore, the provisions for audit extension, remote source verification and remote audits/surveys under exigent conditions, as described above, can no longer be used unless new exigent conditions exist.

- Holtec's position regarding storage of documents in approved electronic media under its control meets the intent of ASME NQA-1-2015 and is an acceptable alternative to Section 501 of ASME NQA-1-2015, Part I, Requirement 7, based on the NRC staff's evaluation of Holtec's use of electronic records, as document in Section 3.1.17 of this SE.

- For dedication of raw materials when material specifications exist, Holtec's alternative (i.e., use of mechanical and chemical testing requirements of the material specification, any required NDE, one or more dimensions and markings for traceability as critical characteristics) to ASME NQA-1-2015, Part II, Subpart 2.14, Paragraph 401 in lieu of credible failure mode evaluations is acceptable because it is consistent with the requirement in this Subpart, which states, "If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the items' design parameters and allowable become the critical characteristics and acceptance criteria."

Based on the evaluation above, the NRC staff determined the Part II, Section 7, of the SMR LLC QAP TR complies with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

3.1.8 Identification and Control of Materials, Parts, and Components

Part II, Section 8, "Identification and Control of Materials, Parts, and Components," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf-life. The identification of items is maintained from receipt and fabrication up to and including installation and use, so that the item can be traced to its documentation and be related to design or other applicable specifying documents. Identification locations and methods are selected so as not to affect the function or quality of the item.

Part II, Section 8.1, "NQA-1 Commitment," states that in establishing provisions for identification and control of items, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 8, "Identification and Control of Items."

The NRC staff evaluated the description of measures that Holtec has established to ensure identification and control of items to prevent incorrect use of defective items and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item H, "Identification and Control of Materials, Parts, and Components (Criterion VIII)." Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 8, the NRC staff determined that Part II, Section 8, of the SMR LLC QAP TR complies with the requirements

of Criterion VIII, “Identification and Control of Materials, Parts, and Components,” of Appendix B to 10 CFR Part 50.

3.1.9 Control of Special Processes

Part II, Section 9, “Control of Special Processes,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include, as applicable, assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process.

Part II, Section 9.2, “NQA-1 Commitment,” states that in establishing measures for the control of special processes, Holtec commits to compliance with ASME NQA-2015, Part I, Requirement 9, “Control of Special Processes.”

The NRC staff evaluated the description of measures that Holtec has established to assure special processes are controlled in accordance with procedures and instructions by qualified personnel and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item I, “Control of Special Processes (Criterion IX).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 9, the NRC staff determined that Part II, Section 9, of the SMR LLC QAP TR complies with the requirements of Criterion IX, “Control of Special Processes,” of Appendix B to 10 CFR Part 50.

3.1.10 Inspection

Part II, Section 10, “Inspection,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work.

Part II, Section 10.2, “Inspection Program,” states that the inspection program establishes inspections, as necessary, to verify quality; 1) at the source of supplied items or services; 2) in-process during fabrication at a supplier’s facility or at a Holtec facility; 3) for final acceptance of fabricated and/or installed items; 4) upon receipt of items; and 5) prior to service (i.e., post construction/pre-operational). The inspection program establishes requirements for planning inspections, method of inspection, inspection hold points, applicable acceptance criteria, and the frequency of inspection. Inspection plans are based on, as appropriate, the relative importance of the item, the complexity of the item, technical requirements to be met, and the design specification requirements. Inspections are performed in accordance with procedures, instructions, travelers, drawings, and specifications as applicable.

Part II, Section 10.2 also states that the inspection program establishes requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

Inspections must be performed by individuals other than those who performed the activity being inspected. Inspection results are documented by a qualified inspector and reviewed as necessary by an appropriately qualified individual. It further describes measures and controls for 1) nonconforming conditions identified during inspection activities; 2) modification, repair, rework, or replacement of items; and 3) indirect control by monitoring processing methods, equipment, and personnel when inspection of an item is impossible or disadvantageous.

Part II, Section 10.3, “Inspector Qualification,” states that Holtec has established qualification programs for personnel performing quality inspections as described in Part II, Section 2.0 of the SMR LLC QAP TR.

Part II, Section 10.4, “NQA-1 Commitment,” states that in establishing inspection requirements, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 10, “Inspection.”

The NRC staff evaluated the description of measures that Holtec has established to assure inspections are controlled in accordance with procedures and instructions by qualified personnel and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item J, “Inspection (Criterion X).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 10, the NRC staff determined that Part II, Section 10, of the SMR LLC QAP TR complies with the requirements of Criterion X, “Inspection” of Appendix B to 10 CFR Part 50.

3.1.11 Test Control

Part II, Section 11, “Test Control,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to demonstrate that items will perform satisfactorily in service. The test program includes, as appropriate, proof tests prior to installation, construction tests and preoperational tests. Test programs include criteria for determining when testing is required in order to demonstrate that performance of an item or items is in accordance with design. As applicable and consistent with the effect on safety, tests are performed according to procedures that include 1) instructions and prerequisites to perform the tests; 2) use of proper test equipment; 3) acceptance criteria; 4) mandatory verification points as necessary to confirm satisfactory test completion; 5) any special qualification requirements for personnel; and 6) any special environmental conditions.

Test results are documented and reviewed to assure that the test requirements have been satisfied. Test records are traceable to the item(s) tested. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the item deficiencies that caused the failure.

Part II, Section 11.2, “Computer Program Testing,” of the SMR LLC QAP TR states that Holtec establishes and implements provisions to assure that computer programs used in applications affecting safety are prepared, documented, verified, tested, and used such that the expected output is obtained, and configuration control maintained.

Part II, Section 11.3, “NQA-1 Commitment,” states that in establishing testing requirements, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 11, “Test Control,” and Part II, Subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.”

The NRC staff evaluated the description of the test program Holtec has established to assure all testing required to demonstrate SSCs will perform satisfactorily and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item K, “Test Control (Criterion XI).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 11, and Part II, Subpart 2.7, the NRC staff determined that Part II, Section 11, of the SMR LLC QAP TR complies with the requirements of Criterion XI, “Test Control” of Appendix B to 10 CFR Part 50.

3.1.12 Control of Measuring and Test Equipment

Part II, Section 12, “Control of Measuring and Test Equipment,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that are used for activities affecting quality. The provisions of such procedures cover equipment such as tools, gages, and instruments. Appropriate documentation will be maintained for M&TE to indicate the control status, when the next calibration is due, and identify any limitations on use of the M&TE. Calibration records that are traceable to the specific M&TE shall provide results of calibration. M&TE are calibrated at prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration is documented.

This section further states that procedures also address requirements for control and evaluation of out of calibration conditions. A calibration is performed when the accuracy of the equipment is suspect. When M&TE 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.

Part II, Section 12.2, “NQA-1 Commitment / Exceptions,” states that in establishing the provisions for control of M&TE, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 12, “Control of Measuring and Test Equipment.”

The NRC staff evaluated the description of measures that Holtec has established to control M&TE used in activities affecting quality, including calibration at specified intervals to maintain accuracy within necessary limits, and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item L, “Control of Measuring and Test Equipment (Criterion XII).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 12, the NRC staff determined that Part II, Section 12, of the SMR LLC QAP TR complies with the requirements of Criterion XII, “Control of Measuring and Test Equipment,” of Appendix B to 10 CFR Part 50.

3.1.13 Handling, Storage, and Shipping

Part II, Section 13, “Handling, Storage, and Shipping,” of the SMR LLC QAP TR states that Holtec 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 safety-related items. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item’s integrity and indicate the need for special controls. Special controls are provided when required to maintain acceptable quality.

This section further states that cleanliness controls for work on safety-related and risk-significant non-safety-related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure. This section also describes controls for special handling tools and equipment. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use. Operators of special handling and lifting equipment are experienced or trained, as appropriate, in the use of the equipment.

Part II, Section 13.2, "NQA-1 Commitment / Exceptions," states that in establishing provisions for handling, storage, packaging and shipping, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 13, "Handling, Storage, and Shipping," and Part II, Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities," Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities," and Subpart 2.3, "Quality Assurance Requirements for Housekeeping at Nuclear Facilities."

The NRC staff evaluated the description of measures that Holtec has established to control the handling, storage, packaging and shipping, cleaning and preservation of material and equipment to prevent damage or deterioration and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item M, "Handling, Storage and Shipping (Criterion XIII)." Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 13, and Part II, Subparts 2.1, 2.2 and 2.3, the NRC staff determined that Part II, Section 13, of the SMR LLC QAP TR complies with the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B to 10 CFR Part 50.

3.1.14 Inspection, Test, and Operating Status

Part II, Section 14, "Inspection, Test, and Operating Status," of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items in order to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, operated, or shipped. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels. Suitable marking methods such as tags, stamps, labels, or travelers are used to identify the test or inspection status of an item. Status may also be indicated by physical location such as a designated hold area. The status verification and tracking of temporary design changes (temporary modifications) are controlled by procedures. Maintenance or modifications that may affect the functioning of safety-related SSCs are performed in a manner to ensure quality at least equivalent to that specified in the original design bases and requirements, material specifications and inspection requirements.

Part II, Section 14.2, "NQA-1 Commitment," states that in establishing provisions for inspection, test, and operating status, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 14, "Inspection, Test, and Operating Status."

The NRC staff evaluated the description of measures that Holtec has established to 1) indicate the status of inspections and tests performed of items and components; 2) control temporary changes or modifications; and 3) indicate operating status of SSCs to prevent inadvertent

operation; and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item N, “Inspection, Test, and Operating Status (Criterion XIV).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 14, the NRC staff determined that Part II, Section 14, of the SMR LLC QAP TR complies with the requirements of Criterion XIV, “Inspection, Test, and Operating Status,” of Appendix B to 10 CFR Part 50.

3.1.15 Nonconforming Materials, Parts, or Components

Part II, Section 15, “Nonconforming Materials, Parts, or Components,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

This section also describes the measures for nonconforming items that are reworked, repaired, or dispositioned as use-as-is. Items that are reworked or repaired are inspected and tested, as appropriate, with the original inspection and test requirement or specified alternatives. Nonconformances to design requirements dispositioned as repair, or use-as-is are subject to design control measures commensurate with those applied to the original design. Technical justification for the acceptability of nonconforming items, dispositioned as use-as-is, or repair shall be documented. Nonconformance dispositions are performed by personnel that have 1) a competence in the specific area they are evaluating; 2) an adequate understanding of the requirements; and 3) access to pertinent background information.

Part II, Section 15.2, “Reporting,” states that the requirements of 10 CFR Part 21 apply to those items and services identified as safety-related. 10 CFR Part 21 reportability is evaluated for each applicable nonconformance. For construction, 10 CFR 50.55(e) applies.

Part II, Section 15.3, “NQA-1 Commitment,” states that in establishing measures for controls for nonconforming materials, parts, or components, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 15, “Control of Nonconforming Items.”

The NRC staff evaluated the description of measures that Holtec has established to 1) control materials, parts, or components that do not conform to requirements in order to prevent their inadvertent use, and 2) disposition nonconforming items for acceptance, rejection, repair, or rework, and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item O, “Nonconforming Materials, Parts, or Components (Criterion XV).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 15, the NRC staff determined that Part II, Section 15, of the SMR LLC QAP TR complies with the requirements of Criterion XV, “Nonconforming Materials, Parts, or Components,” of Appendix B to 10 CFR Part 50.

3.1.16 Corrective Action

Part II, Section 16, “Corrective Action,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Holtec procedures require all personnel to identify known conditions adverse to quality. Holtec procedures assure that

significant conditions adverse to quality are documented into Holtec's corrective action program in order to allow for identification of cause and determination of actions to prevent recurrence. Completed actions are verified. Significant conditions adverse to quality, significant adverse trends, the cause of the condition, and the corrective actions taken are documented and reported to responsible management. In the case of supplier working on safety-related activities, Holtec may delegate specific responsibilities for corrective actions, but Holtec maintains responsibility for the effectiveness of corrective action measures.

Part II, Section 16.2, "Reporting," states that the requirements of 10 CFR Part 21 apply to those items and services identified as safety-related. 10 CFR Part 21 reportability is evaluated for each condition that is adverse to quality. For construction, 10 CFR 50.55(e) applies.

Part II, Section 16.3, "NQA-1 Commitment," states that in establishing the provisions for corrective action, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 16, "Corrective Action."

The NRC staff evaluated the description of measures that Holtec has established to assure that 1) conditions adverse to quality are promptly identified and corrected, and 2) the cause of significant conditions adverse to quality is determined and corrective actions to preclude repetition are implemented and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item P, "Corrective Action (Criterion XVI)." Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 16, the NRC staff determined that Part II, Section 16 of the SMR LLC QAP TR complies with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

3.1.17 Quality Assurance Records

Part II, Section 17, Quality Assurance Records," of the SMR LLC QAP TR states that Holtec 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.

Part II, Section 17.2, "Quality Record Generation and Control," describes the controls to generate quality records that are legible, accurate, and completed as appropriate to the work accomplished. Records shall be clearly identified and allow direct traceability to associated items and activities as applicable. Required records are defined in controlling documents such as procedures and specifications.

Part II, Section 17.3, "Classification or Records," describes the record classification and retention time periods for both lifetime and non-permanent records. This section further describes the criteria for those records to be classified as lifetime records. Lifetime records shall be maintained for the life of the particular item while it is installed in the plant or stored for future use. The types of lifetime records are defined in controlling procedures.

Part II, Section 17.4, "Record Storage and Maintenance," describes the requirements for record storage and maintenance. Records shall be stored in a manner that minimizes the risk of loss, damage, or destruction from 1) natural disasters such as winds, floods, or fires; 2) environmental conditions such as high and low temperatures and humidity; 3) infestation of insects, molds, or rodents; and 4) dust or airborne particles. In general, records are maintained electronically.

Where paper records are maintained, they shall be received and stored in an appropriate storage facility. This section also describes the requirements for storage of final records.

Part II, Section 17.5, “Electronic Records,” describes the requirements for electronic records. Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period. When using optical disks for electronic records storage and retrieval systems, Holtec complies with the NRC guidance in Generic Letter (GL) 88-18, “Plant Record Storage on Optical Disks.” This section further states that Holtec will manage the storage of QA records in electronic media consistent with the intent of Regulatory Issue Summary 00-018, “Guidance on Managing Quality Assurance Records in Electronic Media,” and the associated Nuclear Information Records Management Association, Inc. (NIRMA) guidelines Technical Guide (TG) 11-2011, “Authentication of Records and Media,” TG 15-2011, “Management of Electronic Records,” TG-16-2011, “Software Configuration Management and Quality Assurance,” and TG 21-2011, “Electronic Records Protection and Restoration.”

Part II, Section 17.6, “NQA-1 Commitment / Exceptions,” states that in establishing provisions for records, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirement 17, “Quality Assurance Records,” and the regulatory positions stated in RG 1.28, Revision 5.

The NRC staff evaluated the description of measures that Holtec has established to assure that sufficient records are maintained to furnish evidence of activities affecting quality and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item Q, “Quality Assurance Records (Criterion XVII).” Based on this evaluation and Holtec’s commitment with ASME NQA-1-2015, Part I, Requirement 17, and RG 1.28, Revision 5, the NRC staff determined that Part II, Section 17 of the SMR LLC QAP TR complies with the requirements of Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50.

3.1.18 Audits

Part II, Section 18, “Audits,” of the SMR LLC QAP TR states that Holtec has established the necessary measures and governing procedures to implement audits to verify that activities covered by the SMR LLC QAP TR are performed in conformance with the established requirements.

Part II, Section 18.2, “Internal Audits,” states that internal audits are performed with a frequency commensurate with the relative importance of the activity being audited. Internal audits are performed to verify compliance and effectiveness of implementation of programs and procedures. Audits are scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity, and to assure that each applicable element of the SMR LLC QAP TR is audited at least once each year or at least once during the life of the activity, whichever is shorter. Additional audits may be performed as deemed necessary by management.

Part II, Section 18.3, “External Audits,” describes that audits of safety-related items and services suppliers are conducted on a triennial basis, as described in Part II, Section 7, of the SMR LLC QAP TR. An audit of supplier is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program. Where sufficient work has not yet been completed, an initial programmatic audit may occur to verify that the QA program adequately addresses QA requirements, and a follow up implementation audit can be

performed when sufficient work has occurred. If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period.

Part II, Section 18.4, "Conducting Audits," states that audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with pre-planned and approved audit plans or checklists, under the direction of a qualified lead auditor. Audit reports are generated. Any audit findings are identified and follow up action is performed to verify appropriate corrective actions have been implemented.

Part II, Section 18.5, "NQA-1 Commitment," states that in establishing the independent audit program, Holtec commits to compliance with ASME NQA-1-2015, Part I, Requirements 18, "Audits," with the following exception:

- ASME NQA-1-2015, Part I, Requirement 18, Section 200, states that, "A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance." As discussed in Part II, Section 7, of the SMR LLC QAP TR, Section 7.2 states "A grace period not to exceed 25 percent of the audit or survey interval shall be allowed under exigent conditions." Further details related to this increased grace period are provided in Part II, Section 7, of the SMR LLC QAP TR.

The NRC staff evaluated the description of measures that Holtec has established to assure that a comprehensive system of planned and periodic audits is carried out to verify compliance with all aspects of the SMR LLC QAP TR and determined that this description conforms to the guidance of SRP Section 17.5, Subsection II, Item R, "Audits (Criterion XVIII)."

The NRC staff also evaluated Holtec's proposed exception to its commitment to compliance with ASME NQA-1-2015, Part I, Requirement 18, Section 200, and determined that the exception is acceptable, as documented in Section 3.1.7 of this SE.

Based on this evaluation and Holtec's commitment with ASME NQA-1-2015, Part I, Requirement 18, the NRC staff determined that Part II, Section 18 of the SMR LLC QAP TR complies with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

3.2 Non-Safety-Related SSC Quality Control

Part III, Section 1, "Non-Safety-Related SSCs Significant Contributors to Plant Safety," of the SMR LLC QAP TR describes program controls that are applied to non-safety-related SSCs that are significant contributors to plant safety. The specific program controls are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSCs significant contributors to plant safety. The section further describes the 18 graded requirements for those non-safety-related items and activities that are considered to be significant contributors to plant safety.

Part III, Section 2, "Non-Safety-Related SSCs Credited for Regulatory Events," of the SMR LLC QAP TR describes the following three commitments that apply to the design and construction aspects 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:

1. Holtec commits to implement quality requirements to the fire protection system in accordance with Staff Regulatory Guidance 1.7, “Quality Assurance,” of RG 1.189, Revision 5, “Fire Protection for Nuclear Power Plants,” dated October 2023.

2. Holtec 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,” dated April 1985.

3. Holtec commits to implement the quality requirements to SBO equipment in accordance with Regulatory Position 3.5, “Quality Assurance and Specific Guidance for Station Blackout Equipment that is Not Safety-Related,” and Appendix A, “Quality Assurance Guidance for Non-Safety Systems and Equipment,” of RG 1.155, “Station Blackout,” dated August 1988.

The NRC staff evaluated the descriptions in Part III, Sections 1 and 2 of the SMR LLC QAP TR that are applied to 1) significant contributors to plant safety, but not safety-related SSCs, and 2) non-safety-related SSCs credited for certain regulatory events, respectively, and determined that these descriptions conform to the guidance in SRP Section 17.5, Subsection II, Item U, “Non Safety-Related SSC Quality Controls.”

3.3 Regulatory Commitments

Part IV, “Regulatory Commitments,” of the SMR LLC QAP TR identifies the following RGs and standards to supplement and support the SMR LLC QAP TR:

1. Holtec commits to RG 1.26, “Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” Revision 6, dated December 2021, for classification of SSCs.

2. Holtec commits to RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 5, dated October 2017, for QA program criteria.

3. Holtec commits to RG 1.29, “Seismic Design Classification,” Revision 6, dated July 2021, for seismic design classification.
4. Holtec commits to RG 1.164, “Dedication of Commercial-Grade Items for use in Nuclear Power Plants,” Revision 0, dated June 2017, and will identify conformance and exceptions for the applicable regulatory position guidance provided in this RG in SMR application documents.

5. Holtec commits to RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, dated January 2017, and will identify conformance and exceptions for the applicable regulatory position guidance provide in this RG in SMR application documents.

6. Holtec commits to RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21,” Revision 0, dated April 2018, and will identify conformance and exceptions for the applicable regulatory position guidance provide in this RG in SMR application documents.

7. Holtec commits to ASME NQA-1-2015, Parts I and II, as described in Part II of the SMR LLC QAP TR with specific identification of exceptions or clarification.

8. Holtec commits to NEI 14-05A, Revision 1, as endorsed by NRC SE (ML20322A019).

9. Holtec commits to NIRMA TGs as described in Part II, Section 17 of the SMR LLC QAP TR.

The NRC staff evaluated the RGs and standards described in Part IV of the SMR LLC QAP TR and determined that they conform to the guidance of SRP Section 17.5, Subsection II, Item V, "Quality Assurance Program Commitments," and are consistent with NRC endorsed standards.

4.0 CONCLUSION

The SMR LLC QAP TR delineates the policies, processes, and controls for QA requirements established by Holtec for U.S. licensed SMRs. The SMR LLC QAP TR provides for control of activities that affect the quality of safety-related SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily inservice.

The SMR LLC QAP TR may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC regulations and policies establish programmatic controls.

The NRC staff used the acceptance criteria set forth in SRP Section 17.5 as the basis for evaluating the compliance of the SMR QAP LLC TR, with the provisions of Appendix B to 10 CFR Part 50 and concludes that the SMR QAP LLC TR satisfies the acceptance criteria in SRP Section 17.5. The NRC staff concludes the SMR LLC QAP TR meets the requirements in Appendix B to 10 CFR Part 50, and is therefore, acceptable.

5.0 LIMITATIONS AND CONDITIONS

This Holtec SMR LLC QAP TR is specific to activities affecting the quality and performance of items and services supporting a CP and/or LWA. Any other application referencing the approved revision of the Holtec SMR LLC QAP TR, Revision 2, shall provide a description in its QAP that meets Appendix B to 10 CFR Part 50 and associated regulatory requirements.

6.0 REFERENCES

1. Holtec Letter to the U.S. Nuclear Regulatory Commission (NRC), "SMR, LLC Submittal of Licensing Topical Report, 'Quality Assurance Program for Holtec International's Small Modular Reactor Design and Construction'," dated September 28, 2023. (ML23271A007)

2. American Society of Mechanical Engineers NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facilities."

3. NRC, Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, dated October 2017. (ML17207A293)

4. Nuclear Energy Institute (NEI) 11-04A, “Nuclear Generation Quality Assurance Program Description,” Revision 0, dated May 2011. (ML13164A017)

5. 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,” Revision 1, dated August 2015. (ML15037A441)

6. NRC Feedback to Holtec, “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,” dated January 19, 2024. (ML24022A077)

7. NRC Public Meeting Summary, “U.S. Nuclear Regulatory Commission Summary of the January 26, 2024, Observation Preapplication Public Meeting with SMR, LLC (A Holtec International Company) to Discuss the Staff Information Needs for the Topical Report on the Quality Assurance Program for Holtec International’s Small Modular Reactor Design and Construction,” dated February 23, 2024. (ML24039A003)

8. NRC Feedback to Holtec, “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,” dated March 19, 2024. (ML24079A078)

9. NRC Public Meeting Summary, “U.S. Nuclear Regulatory Commission Summary of the March 27, 2024, Observation Preapplication Public Meeting with SMR, LLC (A Holtec International Company) to Discuss the Staff Information Needs for the Topical Report on the Quality Assurance Program for Holtec International’s Small Modular Reactor Design and Construction,” dated April 30, 2024. (ML24107B151)

10. Holtec Letter to the U.S. NRC, “SMR, LLC Submittal of Licensing Topical Report, ‘Quality Assurance Program for Holtec International’s Small Modular Reactor Design and Construction,’ Revision 1,” dated April 19, 2024. (ML24110A088)

11. NRC Public Meeting Summary, “U.S. Nuclear Regulatory Commission Summary of the May 31, 2024, Preapplication Public Meeting with SMR, LLC (A Holtec International Company) to Discuss the Topical Report on the Quality Assurance Program for Holtec International’s Small Modular Reactor Design and Construction,” dated June 4, 2024. (ML24152A002)

12. Holtec Letter to the U.S. NRC, “SMR, LLC Submittal of Licensing Topical Report, ‘Quality Assurance Program for Holtec International’s Small Modular Reactor Design and Construction,’ Revision 2,” dated June 3, 2024. (ML24155A285)

13. NRC, RG 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 4, dated June 2010. (ML100160003)

14. NRC Safety Evaluation (SE), “Joseph M. Farley Nuclear Plant, Units 1 and 2, Edwin I. Hatch Nuclear Plant, Units 1 and 2, and Vogtle Electric Generating Plant, Units 1 and 2 –

Safety Evaluation Proposed Change to the Quality Assurance Program," dated June 17, 2005. (ML051570349)

15. NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Testing Services," Revision 1, dated May 2020. (ML20135H229)

16. NRC SE, "Final Safety Evaluation by the Office of Nuclear Reactor Regulation for the Nuclear Energy Institute Technical Report 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revisions 1," dated November 23, 2020. (ML20322A019)

17. NRC SE, "Callaway Plant, Unit No. 1 – Operating Quality Assurance Manual Change Revision 34b," dated August 6, 2020. (ML20216A681)

18. Southern Nuclear Letter to the U.S. NRC, "Edwin I. Hatch Nuclear Plant, Units 1 and 2; Joseph M. Farley Nuclear Plant, Units 1 and 2; Vogtle Electric Generating Plant, Units 1 and 2, Quality Assurance Topical Report – Reduction in Commitment (Pandemic Related)," dated May 7, 2021, (EPRI 3002020796, "Remote Assessment Techniques, Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions). (ML21127A184)

19. NRC SE, "Edwin I. Hatch Nuclear Plant, Units 1 and 2; Joseph M. Farley Nuclear Plant, Units 1 and 2; Vogtle Electric Generating Plant, Units 1 and 2; and Associated Independent Spent Fuel Storage Facilities – Reduction in Commitment to the Quality Assurance Topical Report," dated June 22, 2021. (ML21161A201)

20. Electric Power Research Institute 3002019436-A, "Remote Source Verification During a Pandemic or Similar State of Emergency, Screening Criteria and Process Guidance." (MI20300A384)

21. NRC SE, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance," dated September 16, 2020. (ML20244A016)

22. NRC, Generic Letter (GL)88-18, "Plant Record Storage on Optica Disks," dated October 1988.

23. NRC, Regulatory Issue Summary 00-018, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 2000.

24. NRC, RG 1.189, "Fire Protection for Nuclear Power Plants," Revision 5, dated October 2023. (ML23214A287)

25. NRC, GL 85-06, "Quality Assurance Guidance for ATWS Equipment that is not Safety Related," dated April 1985.

26. NRC, RG 1.155, "Station Blackout," dated August 1988. (ML003740034)

27. NRC, RG 1.26, “Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” Revision 6, dated December 2021. (ML21232A142)

28. NRC, RG 1.29, “Seismic Design Classification,” Revision 6, dated July 2021. (ML21155A003)

29. NRC, RG 1.164, “Dedication of Commercial-Grade Items for use in Nuclear Power Plants,” Revision 0, dated June 2017. (ML17041A206)

30. NRC, RG 1.231, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” Revision 0, dated January 2017. (ML16126A183)

31. NRC, RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21,” Revision 0, dated April 2018. (ML17338A072)