August 28, 2014

Mr. Mark Beaumont, Director
Small Modular Reactor Licensing
Holtec International
One Holtec Drive
Marlton, NJ 08053

SUBJECT: FINAL SAFETY EVALUATION FOR HOLTEC INTERNATIONAL TOPICAL REPORT HI-2135649-NP, REVISION 3, "TOPICAL REPORT ON QUALITY ASSURANCE PROGRAM FOR HOLTEC INTERNATIONAL'S SMALL MODULAR REACTOR DESIGN CERTIFICATION" (TAC NO. RN6122)

Dear Mr. Beaumont:

By letter dated July 15, 2013, Holtec International submitted Topical Report (TR) HI-2135649-NP, Revision 1, "Topical Report on the Quality Assurance Program for Holtec International's 10 CFR Parts 50 & 52 Projects," for Nuclear Regulatory Commission (NRC) staff review (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML13200A042 and ML13200A043). By letter dated December 16, 2013, Holtec International submitted responses to the NRC's Requests for Additional Information (RAI) No.7290 related to TR HI-2135649-NP, Revision 1 (ADAMS Accession No. ML13352A025). This letter also provided Enclosure 2, TR HI-2135649-NP, Revision 2, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification" (ADAMS Accession No. ML13352A018). By letter dated April 29, 2014, Holtec International submitted Revision 3 of TR HI-2135649-NP, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification" (ADAMS Accession Nos. ML14121A369 and ML14121A370). Revision 3 of the Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification incorporated responses to the NRC's e-mail requesting clarification on Holtec's commitments dated March 26, 2014 (ADAMS Accession No. ML14085A403). By letter dated May 15, 2014, the NRC provided the draft safety evaluation (SE) for Topical Report HI-2135649-NP, Revision 3, to Holtec International to provide comments on any factual errors or clarity concerns contained in the draft SE (ADAMS Accession No. ML14134A020). Holtec International responded with comments by letter dated June 4, 2014 (ADAMS Accession No. ML14156A384).The NRC staff's disposition of Holtec International's comments on the draft SE are addressed, as appropriate, in the final SE enclosed with this letter.

On the basis of its review, the NRC staff concludes that Revision 3 of the Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification, as documented in the referenced letters, adequately describes the Holtec International quality assurance program (QAP). Accordingly, the NRC staff finds that the Holtec International QAP complies with the applicable NRC regulations and industry standards.

The enclosed SE defines the basis for acceptance of the TR. Our acceptance applies only to material provided in the TR, and we do not intend to repeat our review of material found acceptable in this SE during reviews of specific applications referencing in the TR. When the TR appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from this TR will be subject to a plant- or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that Holtec International publish the accepted version of this TR within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page.

Also, the accepted version must contain historical review information, including NRC requests for additional information and your responses after the title page. The accepted versions shall include a "-A" (designating accepted) following the TR identification symbol.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.

2. The RAIs and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the approved version of the TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, Holtec International and/or licensee's referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Joelle Starefos at (301) 415-6091, email Joelle.Starefos@nrc.gov.

Sincerely,

/RA/ Deborah Jackson for

Michael E. Mayfield, Director
Division of Advanced Reactors
and Rulemaking
Office of New Reactors

Project No.: 0798

Enclosure:
Final Safety Evaluation

The enclosed SE defines the basis for acceptance of the TR. Our acceptance applies only to material provided in the TR and we do not intend to repeat our review of material found acceptable in this SE during reviews of specific applications referenced in the TR. When the TR appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from this TR will be subject to a plant- or site-specific review in accordance with applicable review standards.

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1. The RAIs and RAI responses can be included as an Appendix to the accepted version.

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If you have any questions, please contact Joelle Starefos at (301) 415-6091, email Joelle.Starefos@nrc.gov.

Sincerely,

/RA/ Deborah Jackson for

Michael E. Mayfield, Director
Division of Advanced Reactors
and Rulemaking
Office of New Reactors

Project No.: 0798

Enclosure:
Final Safety Evaluation
DISTRIBUTION: See next page

ADAMS ACCESSION NO.: ML14174B150 ***via email** **NRO-002**

OFFICE	PM:NRO/DARR	NRO/DCIP	NRO/DCIP	BC:NRO/DARR	OGC(NLO)*	D:NRO/DARR
NAME	JStarefos	AArmstrong	KKavanagh (PPrescott for)	SMagruder	MCarpentier	MMayfield (DJackson for)
DATE	07/23/2014	07/29/2014	07/25/2014	07/29/2014	08/27/2014	08/28/2014

Letter to Mark Beaumont from Michael E. Mayfield dated August 28, 2014.

SUBJECT: FINAL SAFETY EVALUATION FOR HOLTEC INTERNATIONAL TOPICAL REPORT HI-2135649-NP, REVISION 3, "TOPICAL REPORT ON QUALITY ASSURANCE PROGRAM FOR HOLTEC INTERNATIONAL'S SMALL MODULAR REACTOR DESIGN CERTIFICATION" (TAC NO. RN6122)

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FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

REGARDING THE HOLTEC INTERNATIONAL TOPICAL REPORT

HI-2135649-NP, REVISION 3, "TOPICAL REPORT ON THE HOLTEC QUALITY ASSURANCE

PROGRAM FOR SMALL MODULAR REACTOR DESIGN CERTIFICATION"

PROJECT NO.: PROJ0798

1.0 INTRODUCTION

By letter dated July 15, 2013, Holtec International SMR, LLC. (Holtec), submitted for the U.S. Nuclear Regulatory Commission (NRC) staff review the Topical Report (TR) for its small modular reactor (SMR) design certification project TR HI-2135649-NP, Revision 1, "Topical Report on the Quality Assurance Program for Holtec International's 10 CFR Part 50 and Part 52 Projects," in accordance with the guidance of NUREG-0800, "Standard Review Plan (SRP) 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," dated March 2007 (ADAMS Accession No. ML13200A043).

By letter dated December 16, 2013, Holtec submitted responses to the NRC's Requests for Additional Information (RAI) No.7290 related to TR HI-2135649-NP, Revision 1 (ADAMS Accession No. ML13352A025). This letter also provided Enclosure 2, TR HI-2135649-NP, Revision 2, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification" (ADAMS Accession No. ML13352A018).

By letter dated April 29, 2014, Holtec submitted Revision 3 of TR HI-2135649-NP, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification" (ADAMS Accession No. ML14121A370). Revision 3 of HI-2135649-NP incorporated responses to the NRC's e-mail requesting clarification on Holtec's commitments dated March 23, 2014 (ADAMS Accession No. ML14085A403).

By letter dated May 15, 2014, the NRC provided the draft safety evaluation (SE) for Topical Report HI-2135649-NP, Revision 3, to Holtec International to provide comments on any factual errors or clarity concerns contained in the draft SE (ADAMS Accession No. ML14134A020). Holtec International responded with comments by letter dated June 4, 2014 (ADAMS Accession No. ML14156A384).

The Holtec quality assurance (QA) TR addresses the activities associated with the design certification of Holtec's SMRs. The QATR is based only on the applicable portions 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, 10 CFR Part 52 "Licenses, Certifications, and Approvals for Nuclear Power Plants," and the American Society of Mechanical Engineers (ASME) NQA 1-2008, "Quality Assurance Program Requirements for Nuclear Facilities," with 1a-2009 Addenda, as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction), dated June 2010 (ADAMS Accession No. ML100160003).

2.0 REGULATORY BASIS

The Commission's regulatory requirements related to QA programs for standard design certifications are set forth in 10 CFR 52.47(a)(19) and applicable portions of Appendix B to 10 CFR Part 50 (Appendix B).

Section 52.47(a)(19) of 10 CFR states that the final safety analysis report (FSAR) must include a description of the QA program to be applied to the design of the SSCs of the facility. Additionally, the description of the QA program for a nuclear power plant includes a discussion of how the applicable requirements of Appendix B will be satisfied.

Appendix B establishes the requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 EVALUATION

In evaluating the adequacy of the Holtec QATR, the NRC staff used the guidance contained in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (ADAMS Accession No. ML06319009) hereafter referred to as Section 17.5, which provides acceptance criteria for design certification, early site permit, combined license, construction permit, and operating license applicants. Section 17.5 is based on American Society of Mechanical Engineers (ASME) Standard NQA-1-1994 Edition, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME Standard NQA-1-2008 Edition and NQA-1a-2009 Addenda, upon which the Holtec QATR is based, incorporates the supplemental guidance into a single document, and is therefore in alignment with Section 17.5. In addition, NQA-1-2008 Edition and NQA-1a-2009 Addenda, hereafter referred to as NQA-1-2008, is endorsed by NRC RG 1.28, Revision 4.

3.1 Quality Assurance Program Overview

QATR HI-2135649-NP, Revision 3, provides the controls of Holtec's SMR design activities affecting the quality and performance of safety-related SSCs related to the design certification of the Holtec SMR.

Some of the 18 standard elements in Appendix B are not applicable to a design certification applicant and are recognized as not applicable in Section 17.5. Holtec has identified in the QATR certain standard elements as not being applicable for support of the SMR design. This approach is acceptable for a design certification applicant and is recognized in Section 17.5. For those elements identified as not being applicable, the NRC staff has not reviewed or approved the element.

3.1.1 Organization

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.A, for providing an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying Holtec's QA program implementation. The Holtec QATR establishes independence between the organization performing checking functions related to the QA program and the organization responsible for performing the function. In addition, the Holtec QATR provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Responsibility and authority for planning, establishing, and implementing an effective overall QA program are clearly described and defined.

In establishing its organization controls the Holtec QATR commits to implement the quality standards described in NQA-1-2008, Requirement 1, without clarifications or exceptions. The NRC staff determined the organization controls are in accordance with the guidance in Section 17.5, and therefore are acceptable.

3.1.2 Quality Assurance Program

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.B, for establishing the necessary measures to implement a QA program in order to ensure that the design of Holtec's SMR is in accordance with governing regulations and license requirements. The QA program applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design of the Holtec SMR and the managerial and administrative controls to be used to assure the Holtec SMR design complies with applicable regulatory requirements. Administrative controls of the QATR are in accordance with 10 CFR 50.54(a)(3).

Holtec identifies SSCs and activities to which the Holtec QA program applies and maintains for the design certification project. Holtec may delegate all or part of the activities for which they are responsible to others, but retains overall responsibility for QA program effectiveness.

The Holtec QATR provides for measures to assess the adequacy of the QA program and to ensure its periodic review is at least once each year or at least once during the life of the activity, where the activity is understood to be a general process such as design, whichever is shorter. In addition, consistent with Section 17.5, Paragraph II.B.8, the Holtec QA program applies a grace period of 90 days for audit activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

The Holtec QATR describes measures to establish and maintain indoctrination and training programs. These programs apply to personnel performing, verifying, or maintaining activities within the scope of the QA program. The measures described in Holtec's program assure that suitable proficiency is achieved and maintained consistent with the guidance of Section 17.5, Paragraphs II.S and II.T. The Holtec QATR provides the minimum training requirements for all personnel responsible for planning, implementing, and maintaining the Holtec QA program.

The Holtec QATR commits to implement the quality standards described in NQA-1-2008, Requirement 2, with the following exception:

- Section 400(a)(8) requires the date of certification expiration be included on the qualification record. Holtec considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

The NRC staff evaluated this exception, and concluded that this exception is acceptable, with the understanding that the qualification records are controlled as a QA record and are maintained and retrievable under Holtec's QA program.

In establishing its QA program controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 2, with the one exception described above. The NRC staff determined the QA program controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.3 Design Control

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.C.1, for establishing measures to control the design, design verification, and analysis activities of safety-related items and services that are subject to the provisions of the QA program. The Holtec QA program design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces. These provisions ensure that the design inputs (such as design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the Holtec QATR provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

Consistent with Section 17.5, Paragraph II.C.2, the Holtec design processes provide for design verification to ensure that items and activities subject to the provisions of the QA program are suitable for their intended application and consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to original design. The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization and the similarity with previously proven designs. Design verification activities are completed before the design outputs are used by other organizations for design work; before they are used to support other activities such as procurement, manufacture, or construction; or when such timing cannot be achieved before relying on the item to perform its intended design or safety function. Verification methods may include, design reviews, alternative calculations, and qualification testing.

The Holtec QATR governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non-safety-related applications. Holtec and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of computer application and digital equipment software. The Holtec QATR states that the procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

In establishing its design controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 3. In addition, Holtec commits to NQA 1 2008, Subpart 2.7 for computer software and Subpart 2.14 for QA requirements for commercial grade items and services. There were no clarifications or exceptions. The NRC staff determined the design controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.4 Procurement Document Control

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. The Holtec QATR invokes applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) for the procurement of items and services.

Holtec QATR requires that documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of Appendix B. The Holtec QATR also allows for a supplier to work under the Holtec QA program. The scope of procurement includes engineering, design, testing, and testing services, as well as the procurement of safety-related software. Procurement of equipment or components to be installed in a Holtec SMR power plant are not within the scope of this QATR.

The Holtec QATR commits to NQA-1-2008 Requirement 4, 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 QA program, including implementing procedures, in lieu of the supplier having its own QA program.

   The staff evaluated this proposed alternative and determined that it provides adequate control for establishing, executing and the responsibilities for the quality assurance program. Therefore, the staff determined this clarification to be acceptable, because it is consistent with Section 17.5, paragraph II.D.2.d.

2. Section 300 and 400 of 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 quality assurance requirements of the procurement.

   The staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change, which is consistent with Section 17.5, paragraph II.D.3. Therefore, the staff concludes that this alternative is acceptable.

3. Procurement documents for commercial grade items that will be procured by Holtec for use as safety-related items shall contain technical and quality requirements as applicable, such

that the procured item can be appropriately dedicated in accordance with the Holtec QAM, Section 7, "Control of Purchased Material, Equipment, and Services."
This alternative is consistent with staff guidance in Generic Letter (GL) 89-02, “Actions to Improve the detection of Counterfeit and Fraudulently Marked Products,” dated March 21, 1989 and GL 91-05, “Licensee Commercial Grade Procurement and Dedication Programs,” dated April 9, 1991, as delineated in Section 17.5, paragraphs II.U.1.c and II.u.1.d.

In establishing its procurement document controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 4, with the exceptions described above. The NRC staff determined the procurement document controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.5 Instructions, Procedures, and Drawings

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QA program.

In establishing its controls for instructions, procedures, and drawings, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 5. There were no clarifications or exceptions. The NRC staff determined the controls for instructions, procedures, and drawings are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.6 Document Control

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.F, for establishing measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (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, unless other organizations are specifically designated. Holtec maintains a list of all controlled documents, identifying the current approved revision or date, so personnel can determine the appropriate document for use.

In establishing its document controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 6. There were no clarifications or exceptions. The NRC staff determined the document controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.7 Control of Purchased Material, Equipment, and Services

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the

supplier, source inspection, audit, and examination of items or services. The Holtec QATR establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through suppliers, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and frequency of procurement.

The Holtec QATR provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. The scope of procurement includes engineering, design and testing services, as well as the procurement of safety-related software. No equipment or components are being procured as part of Holtec's SMR design certification project. Therefore, the controls associated with this section of the Holtec QATR are limited to the control of applicable services.

The Holtec QATR also outlines acceptance actions, such as source verification, receipt inspection, certificates of conformance, and review of documentation (e.g., Certified Material Test Reports/Certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function.

The Holtec QATR commits to implement the quality standards described in NQA-1-2008, Requirement 7, with the following clarifications and exceptions:

1. Holtec considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection (ANI) Agencies, National Institute of Standards and Technology (NIST), or other State and Federal agencies which may provide items or services to Holtec are not required to be evaluated or audited.

   The staff acknowledges that 10 CFR Part 50 and Part 52 licensees, ANI agencies, the NIST, and other State and Federal agencies work under acceptable quality programs. The staff determined that this exception is acceptable as documented in a previous SE (ADAMS Accession No. ML13023A051). Holtec is still responsible for ensuring that the items or services conform to its Appendix B program, applicable ASME BPV Code requirements, and other regulatory requirements and commitments. Holtec is also responsible for ensuring that the items or services are suitable for the intended application and for documenting this evaluation. The proposed exception is acceptable on the basis that it provides an appropriate level of quality and safety.

2. When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

   A. The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the Holtec QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

   B. The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

C. A documented review (via placement on the approved vendor list) of the supplier's accreditation will be performed and will include a verification of the following:

i. The calibration laboratory holds a domestic (United States) accreditation by an NRC-approved accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." The following accrediting bodies apply:

a. NVLAP, A2LA, L-A-B, ACLASS, IAS

b. The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

The staff determined that the provisions of this exception are consistent with the guidance provided in Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications and as documented in a previous staff SE (ADAMS Accession No. ML052710224). The NRC staff expects full conformance to the guidance in Section 17.5, paragraph II.L.8 and subparagraph h. that the alternative method is limited to domestic calibration suppliers.

3. For Section 501, Holtec considers documents that may be stored in approved electronic media under Holtec or vendor control to comply with the intended requirement.

Paragraph 3.1.17 of this SE describes the controls the Holtec QATR establishes for electronic records. The staff determined the controls for electronic records are in accordance with the guidance in Section 17.5, and therefore are acceptable.

4. In establishing commercial grade item requirements, Holtec commits to compliance with NQA-l 2008, Section 700 and Subpart 2.14, with the following clarification:

A. For commercial grade items, quality verification requirements are established and described in Holtec documents to provide the necessary assurance an item will perform satisfactorily in service. The Holtec documents address, as applicable, determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

In establishing its controls for commercial-grade dedication, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Section 700 of Requirement 7 and Subpart 2.14 with the clarification that the commercial-grade dedication process is described in implementing procedures. The NRC staff determined the controls for commercial-grade dedication are in accordance with the guidance in Section 17.5, and therefore are acceptable.

5. Holtec will assume 10 CFR 21 reporting responsibility for all items that Holtec dedicates as safety related.

The NRC staff evaluated this clarification, and concluded that this clarification is acceptable with the understanding any work conducted under this QA program, Holtec assumes reporting responsibility.

In establishing its controls of purchased material, equipment, and services, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 7, with the exceptions and clarifications described above. The NRC staff determined the controls of purchased material, equipment, and services are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.8 Identification and Control of Materials, Parts, and Components

The Holtec QATR is for design and testing activities related to the certification of an SMR. This section is generally not applicable except when testing to support the design is warranted and as appropriate. Holtec has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items.

In establishing its controls for identification and control of materials, parts, and components, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 8. There were no clarifications or exceptions. The NRC staff determined the controls for identification and control of materials, parts, and components are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.9 Control of Special Processes

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.I, for establishing 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. Provisions include 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. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

In establishing its controls for special processes, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 9. There were no clarifications or exceptions. The NRC staff determined the controls for special processes are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.10 Inspection

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.J, for establishing 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. Types of inspections may include those verifications related to procurement, such as receipt inspection as well as inspections required as a result of any testing activities during the design process.

Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

In establishing its controls for inspection, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 10. There were no clarifications or exceptions. The NRC staff determined the controls for inspection are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.11 Test Control

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.K for establishing the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QA program will perform satisfactorily in service. Test programs include criteria for determining when testing is required in order to demonstrate that performance of equipment and plant systems is in accordance with design. Testing programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests when applicable. Tests are performed according to applicable procedures that include, as applicable and consistent with the effect on safety, instructions and prerequisites to perform the tests, use of proper test equipment, acceptance criteria, mandatory verification points, as necessary to confirm satisfactory test completion, any special qualification requirements for personnel and any special environmental conditions. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. Test records are traceable to the item(s) tested.

In establishing its test controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 11, and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to Requirement 3 for computer program testing. There were no clarifications or exceptions. The NRC staff determined the test controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.12 Control of Measuring and Test Equipment

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.L for establishing the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met. Procedures also address requirements for out of calibration conditions. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device. The suppliers of commercial-grade calibration services are controlled as described in Part II, Section 7 of the QATR.

In establishing its controls for M&TE, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 12. There were no clarifications or exceptions. The NRC staff determined the controls for M&TE are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.13 Handling, Storage, and Shipping

This element is not applicable to the Holtec SMR design certification application. Therefore, this element has not been reviewed or approved by the NRC staff.

3.1.14 Inspection, Test, and Operating Status

This element is not applicable to the Holtec SMR design certification application. Therefore, this element has not been reviewed or approved by the NRC staff.

3.1.15 Nonconforming Materials, Parts, or Components

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.O, for establishing the necessary measures and governing procedures to control items, including services that do not conform to specified requirements, in order to prevent inadvertent use. Controls provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations. Nonconformance items are corrected or resolved before relying on the item to perform its intended safety function. Nonconformance items are evaluated for impact on the operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformance items of design requirements which are dispositioned “repair” or “use-as-is” are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy. Analysis of quality trends related to nonconforming conditions are performed periodically and reported to management. Significant trends are reported to management in accordance with Holtec procedures, regulatory requirements, and industry standards.

In addition, Holtec’s QA program provides for establishing the appropriate interfaces between the identification and control of nonconforming materials, parts, or components, and the non quality assurance reporting program in order to satisfy the requirements of 10 CFR Part 52 and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

In establishing its controls for nonconforming materials, parts, or components, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 15. There were no clarifications or exceptions. The NRC staff determined the controls for nonconforming materials, parts, or components are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.16 Corrective Action

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QA program provides for procedures to ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards.

The Holtec QATR also requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined, and actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities, or other similar situations, Holtec may delegate specific responsibilities for corrective actions, but Holtec maintains overall responsibility for the effectiveness of corrective action measures and the corrective action program.

In establishing its corrective action controls, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 16. There were no clarifications or exceptions. The NRC staff determined the corrective action controls are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.17 Quality Assurance Records

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for Holtec and include requirements for records administration including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The Holtec QATR establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.1.a(3) of RG 1.28, Revision 4, and NQA-1-2008 as applicable for the Holtec's SMR design certification project. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the Holtec QATR provides that those requirements will be met.

When using electronic records storage and retrieval systems, the Holtec QATR provides for compliance with the NRC guidance contained in NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks," Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11 1998, "Authentication of Records and Media," TG 15-1998, "Management of Electronic Records," TG 16-1998, "Software Configuration Management and Quality Assurance," and TG 21-1998, "Electronic Records Protection and Restoration."

The Holtec QATR commits to implement the quality standards described in NQA-1-2008, Requirement 17, and regulatory positions stated in Regulatory Guide 1.28, Rev 4, dated June 2010, with the following clarifications or exceptions:

- TG-11 Section 6.4.3 states that, "New tapes should be exercised for a minimum of four full passes prior to use for archive record recording." Modern premium data storage tapes are made specifically for archival purpose, and therefore have higher quality control and fault tolerance than tapes from the time that this standard was originally written. As such, Holtec does not perform tape exercising.

The NRC staff evaluated the technical merits of this exception, and concluded that this exception is acceptable.

In establishing its controls for QA records, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 17, with the one exception described above. The NRC staff determined the controls for QA records are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.1.18 Audits

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.R, for establishing the necessary measures and governing procedures to implement audits in order to verify that activities covered by the QA program are performed in conformance with the requirements established. The audit programs are also themselves reviewed for effectiveness as part of the overall Holtec audit process.

The Holtec QATR provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of program and procedures, as well as to determine if they are meaningful and comply with the overall Holtec QA program. Internal audits are performed with a frequency commensurate with the safety significance of the activity and in a manner which assures that audits of safety-related activities are completed; and/or with a frequency that ensures that an audit of all applicable QA program elements is completed within a period of once per year or at least once during the life of the activity, whichever is shorter. External audits determine the adequacy of supplier QA programs and are conducted as described in Section 7.1 of Holtec's QATR.

The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibility in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Corporate QA Manager.

The Holtec QATR provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions where indicated. In addition, where corrective action measures are determined necessary, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify the implementation and effectiveness of the assigned corrective actions.

In establishing its controls for audits, the Holtec QATR commits to implementing the quality standards described in NQA-1-2008, Requirement 18. There were no clarifications or exceptions. The NRC staff determined the controls for audits are in accordance with the guidance of Section 17.5, and therefore are acceptable.

3.2 Non-safety-Related SSC Quality Control

3.2.1 Non-safety-Related SSCs - Significant Contributors to Plant Safety

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.V.1, for establishing specific program controls to be applied to non-safety-related SSCs that are significant contributors to plant safety, but for which Appendix B is not applicable.

The Holtec QATR applies specific controls to such items in a selected manner, targeted toward those characteristics or critical attributes that render the SSC a significant contributor to plant safety, consistent with applicable sections of the Holtec QA program.

The NRC staff has determined that this approach, as described in the Holtec QATR, is acceptable as it is in alignment with Section 17.5, Paragraph II.V.1.

3.2.2 Non-safety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for non-safety-related SSCs credited for regulatory events, the Holtec QATR follows the guidance of Section 17.5, paragraph II.V.2, and Holtec commits to implement the following regulatory guidance:

The quality requirements for the fire protection system is in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants," dated October 2009.

The quality requirements for anticipated transient without scram (ATWS) equipment is in accordance with NRC Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated January 16, 1985.

The quality requirements for station blackout (SBO) equipment is 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," dated August 1988.

The NRC staff has determined that this approach, as described in the Holtec QATR, is acceptable as it is in alignment with Section 17.5, Paragraph II.V.2.

3.3 Regulatory Commitments

The Holtec QATR follows the guidance of Section 17.5, Paragraph II.U, for establishing QA program commitments. Furthermore, Holtec commits to comply with the following NRC RGs and other QA standards to supplement and support the QA program:

RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated March 2007. Regulatory Guide 1.26 defines classification of systems and components.

RG 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," dated June 2010. Regulatory Guide 1.28 describes a method acceptable to the NRC for complying with the provisions of Appendix B with regard to establishing and implementing the requisite QA program for the design of nuclear power plants.

RG 1.29, Revision 4, "Seismic Design Classification," dated March 2007. RG 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

ASME NQA-1-2008, and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described above in Sections 3.1.1 through 3.1.18 of this safety evaluation.

NIRMA Technical Guides, as described in Section 3.1.17 of this safety evaluation.

4.0 CONCLUSION

Based on the evaluation of TR HI-2135649-NP, Revision 3, the NRC staff concludes that the QA program described in Holtec QATR follows the NRC guidance contained within, and conforms to the format of, Section 17.5. The NRC staff used the acceptance criteria of Section 17.5 as the basis for evaluating the acceptability of the Holtec's QA program in conformance with the provisions of 10 CFR 52.47(a)(19) and applicable portions of Appendix B to 10 CFR Part 50. The program description adequately describes how the requirements of Appendix B will be implemented. The NRC staff concludes that the proposed TR HI-2135649-NP, Revision 3, complies with 10 CFR Part 50 requirements for the QA program used by Holtec for design certification activities associated with SMRs and is therefore acceptable.

5.0 REFERENCES

1. 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," dated March 2007 (Agencywide Document Access and Management System (ADAMS) Accession No. ML06319009)

2. Submittal of Holtec Topical Report HI-2135649-NP, Revision 3, "Topical Report on Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification," dated April 29, 2014 (ADAMS Accession No. ML14121A370)

3. E-mail from J. Mazza to M. Beaumont RE: Regarding QAP Concern, dated March 26, 2014 (ADAMS Accession No. ML14085A403)

4. Submittal of Holtec International Response to Request for Additional Information related to Topical Report HI-2135649-NP, Revision 1, "Quality Assurance Program for Holtec International's 10 CFR Part 50 and Part 52 Projects" (TAC No. RX6122), dated December 16, 2013 (ADAMS Accession No. ML13352A025)

5. Submittal of Holtec Report HI-2135649-NP, Revision 2, "Topical Report on Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification," dated December 6, 2013 (ADAMS Accession No. ML13352A018)

6. ASME NQA 1-2008, "Quality Assurance Program Requirements for Nuclear Facilities" (with a2009 Addenda), New York, NY, dated March 14, 2008

7. RG 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction), dated June 2010 (ADAMS Accession No. ML100160003)

8. NRC Generic Letter 1988-18, “Plant Record Storage on Optical Disks,” dated October 20, 1988

9. RIS 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000 (ADAMS Accession No. ML003739359)

10. RG 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants," dated October 2009 (ADAMS Accession No. ML092580550)

11. NRC Generic Letter 1985-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated April 16, 1985 (ADAMS Accession No. ML031140390)

12. RG 1.155, "Station Blackout,” dated August 1988 (ADAMS Accession No. ML003740034)

13. RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” dated March 2007 (ADAMS Accession No. ML070290283)

14. RG 1.29, Revision 4, "Seismic Design Classification," dated March 2007 (ADAMS Accession No. ML070310052)