Holtec Center, 555 Lincoln Drive West, Marlton, NJ 08053
Telephone (856)797-0900; Fax (856)797-0909

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USNRC Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Jan Mazza, Project Manager
SMR Licensing Branch 1
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Holtec International
Project Number – PRO0798

Subject: 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)

References: [1] Letter from J. Mazza (US NRC) to T. Marcille (Holtec International) dated November 18, 2013, "Request for Additional Information Letter No. 1 for the Review of Acceptance for Review of Holtec International SMR, LLC 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)

Dear Ms. Mazza:

This letter transmits Holtec International's response to the NRC's Request for Additional Information (RAI) provided in Reference [1]. In addition we are enclosing Revision 2 of the subject topical report. Please note that we have revised the title of this topical report as follows: "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification". As noted in the "Summary of Revisions" page, in addition to changing the report title, the text has been revised to address the NRC RAI's.

If you have any questions, please contact me at 856-797-0900, ext 3924 (email: m.beaumont@holtec.com).

Sincerely,

Mark Beaumont, Director
Small Modular Reactor Licensing
Holtec International

Cc: Tom Marcille, Holtec International
Mark Soler, Holtec International
Leigh Trocine, US NRC

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NRO

Stewart Magruder, US NRC

List of Enclosures:

Enclosure 1: Response to "Request for Additional Information Letter No. 1 for the Review of Acceptance for Review of Holtec International SMR, LLC 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)

Enclosure 2: Topical Report HI-2135649-NP, Revision 2

Enclosure 1 to Document I.D. 2108009

Response to Request for Additional Information No. 7290 RAI Letter No. 4

Holtec SMR-160 Pre-Application
Activities Holtec International
Docket No. PROJ 0798

17.05-1

Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, states in part, that, "Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility."

Holtec's quality assurance manual (QAM) is entitled, "Topical Report on The Quality Assurance Program for Holtec International's 10 CFR 50 & 52 Projects." Based on the information provided in Holtec's QAM, clarify your scope of activities related to 10 CFR Part 50 projects. Specifically, the title of the Holtec QAM does not reflect the scope of the QAM.

Holtec Response:

The Topical Report is intended to be specific to the design certification for Holtec's Small Modular Reactor (SMR). As such, we have re-titled the cover page to provide the additional clarification.

17.05-2

SRP Section 17.5, paragraph II.A.3 states in part that, "the QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. Functional responsibilities include activities such as preparing, reviewing, approving, and verifying designs."

Section 1.2, "Organizational Responsibilities of Key Personnel," of Holtec's QAM does not state the functional responsibilities for the organization responsible for the design. Provide clarification on the functional responsibilities for all the organization included in Figure 1.1 "Holtec Organization Structure."

Holtec Response:

Figure 1.1 of the Topical Report shows the Vice President of Engineering, Director-Engineering Analysis, Director- Engineering Design, Analysts, Designers, Project Engineers and Design Engineers. This encompasses the group of individuals involved with design. In order to provide additional details on the group responsible for design, we have added text to Section 1.2 to describe the primary role of the Director-Engineering Analysis and Director-Engineering Design.

17.05-3
SRP Section 17.5, paragraph II.A.10 states that, "personnel performing work activities such as, but not limited to, design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, and modification are responsible for achieving acceptable quality."

Provide clarification on how this requirement is being met in the proposed Holtec's QAM.

Holtec Response:

The following text has been added to Section 1.1- "All Company personnel performing work activities under Holtec's QA Program have the responsibility for assuring the requirements set forth within the QAP are followed and that an acceptable level of quality is achieved."

17.05-4
Section 2.5, "Issuance and Revision to Quality Assurance Program" of the Holtec's QAM states that, "administrative control of the QAP will be in accordance with 10 CFR 50.55(f)."

10 CFR 50.55(f) applies only to construction permits, early site permits, combined licenses, and manufacturing licenses. Clarify why the Holtec QAP is committing to the requirements of 10 CFR 50.55(f).

Holtec Response:

Holtec agrees that the reference to 10CFR50.55(f) would not be appropriate for a Topical Report specific to design certification only. The section has been revised to replace the 10CFR50.55(f) reference with10CFR50.54(a)(3).

17.05-5
Section 2, "Quality Assurance Program," of Holtec's QAM states, in part, that, "as described in Part III of the QAM, specific program controls are applied to nonsafety-related SSCs that are significant contributors to plant safety, for which the Codes listed in Table 1.1 are not applicable." However, Table 1.1 does not list the Codes but Table 1.2 does.

Provide clarification on which table the codes are listed.

Holtec Response:

This was a typographical error that has been corrected in Revision 2 of the Topical Report. The correct reference is Table 1.2.

17.05-6
SRP 17.5, Section C.1.n, states that, "the QA role in design and analysis activities is defined. Design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements consistent with the requirements of 10 CFR 50.34(f)(3)(iii)(H)."

Provide clarification on how this requirement is being met in Holtec's proposed QAM.

Holtec Response:

As noted in Section 2.6, "Holtec establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the QAP to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities". This training includes a review of QA Program requirements applicable to the specific work activities. As noted in Section 3 of the Topical Report, "Design documents are reviewed by individuals knowledgeable in the QAP to ensure the documents contain the necessary QAP requirements." Thus, as part of the preparation and review of design documents, the individuals involved with the preparation and review are also assuring full compliance to the quality requirements. In order to provide additional clarification in the Topical Report, the Section 3 text referenced above has been modified as follows-

"Design documents are prepared and reviewed by technical individuals who have been educated about the applicable QAP requirements to ensure the documents contain and implement the necessary QAP requirements."

17.05-7
SRP 17.5, Section C.1.q, states that, "quality assurance personnel are included in the documented review and concurrence of quality-related procedures associated with design consistent with the requirements of 10 CFR 50.34(f)(3)(iii)(C)."

Provide clarification on how this requirement is being met in Holtec's proposed QAM.

Holtec Response:

Section 6.1 of the Topical Report states that- "Procedures for design are also reviewed by the Quality Department to ensure quality assurance measures have been appropriately applied." This should address the requirement.

17.05-8
Criterion X, "Inspection," of Appendix B to 10 CFR Part 50 states that, "a program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity."

Section 3, "Design Control," of Holtec's QAM states that, "these provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs specifications, (such as analyses, 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 by inspection and test, as required."

Section 7.1, "Acceptance of Item or Service" of Holtec's QAM states, in part that, "provisions are made for accepting purchased items and services, such as source verification, receipt inspection, certificate of conformance (CofC), and document reviews."

However, Section 10, "Inspection," of Holtec's QAM notes that this Topical Report addresses design and testing activities to support certification of a Small Module Reactor. As such, this criteria is not applicable.

Provide clarification on why inspection activities are not envisioned for the Holtec SMR design certification project.

Holtec Response:

During the development of the Topical Report, Holtec had considered that some level of testing would be necessary during the design phase but had not considered inspection as being necessary. However, upon further review, we recognize that inspection activities could apply both during receipt inspection of equipment related to testing as well as inspection during test activities. As such, we have updated Section 10 to address inspection activities. Without fully knowing what inspections might be warranted, we have also included new text for Section 9 "Special Processes". The inclusion of applicability of section 9 and 10 has also required us to update Part III of the Topical Report for Special Processes and Inspection.

17.05-9
SRP 17.5, Section K.5, states that, "test results are documented and evaluated by a responsible authority to ensure the test requirements have been satisfied."

Provide clarification on how this requirement is being met in the proposed Holtec's QAM.

Holtec Response:

In Section 11, we have updated the text as follows- "Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority (typically Holtec) to assure that the test requirements have been satisfied."

17.05-10
SRP 17.5, Section O.1, states that, 'a nonconforming item (a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate) is properly controlled to prevent its inadvertent test, installation, or use. As appropriate, procedures are used for the identification, documentation, segregation, disposition and notification of the nonconforming items to the affected organizations."

In the Glossary of Terms of the QAM, Holtec defines a nonconformance as, "a deficiency in characteristic, documentation or procedure which renders the quality of an item unacceptable or indeterminate. Examples of nonconformances include: physical defects, test failures, incorrect or inadequate documentation or deviation from prescribed processing, inspection or test procedures, etc."

However, Section 15, "Nonconforming Materials, Parts or Components," of Holtec's QAM notes that this Topical Report addresses design and testing activities to support certification of a Small Module Reactor. As such, this criteria is not applicable. Provide clarification on the process envisioned for Holtec SMR design certification project to capture

nonconformances identified during design and testing activities.

Holtec Response:

Holtec uses its corrective action program process to address errors in calculations and drawings. As such, it was originally determined that the nonconformance process, which is typically used by Holtec for fabrication and procurement related activities would not apply. However, with recognition of the potential testing activities, it is recognized that the potential for issuance of nonconformances on received items, manufactured test components and performance of test activities could exist. As such, we have updated Section 15 to address nonconformances. We have also updated the Nonconformance section in Part III of the Topical Report.