Enclosure 2 to Document I.D. 2108009

HI-2135649-NP, Revision 2, "Topical Report on the Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification"

Topical Report On The Quality Assurance Program for Holtec International's Small Modular Reactor Design Certification

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This Topical Report provides the commitments and requirements for implementation of Holtec International's QA Program for the design of a Small Modular Reactor under the rules of 10 CFR part 50 or part 52. In this format, the Topical Report provides mandatory programmatic requirements under each of the applicable eighteen discrete general design criteria arranged in eighteen sections listed in the Table of Contents herein. Additional commitments that are beyond the specific purview of the eighteen criteria but are deemed to be necessary for ensuring comprehensive regulatory compliance are included in this Topical Report.

HOLTEC INTERNATIONAL

DOCUMENT ISSUANCE AND REVISION STATUS[1]

DOCUMENT NAME:	TOPICAL REPORT ON THE QA PROGRAM FOR HOLTEC INTERNATIONAL'S SMR DESIGN CERTIFICATION
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DOCUMENT CATEGORIZATION

In accordance with the Holtec Quality Assurance Manual and associated Holtec Quality Procedures (HQPs), this document is categorized as a:

☐ Calculation Package[3] (Per HQP 3.2)
☐ Technical Report (Per HQP 3.2) (Such as a Licensing Report)
☐ Design Criterion Document (Per HQP 3.4)
☐ Design Specification (Per HQP 3.4)
☑ Other (Specify): Topical Report

DOCUMENT FORMATTING

The formatting of the contents of this document is in accordance with the instructions of HQP 3.2 or 3.4 except as noted below:

DECLARATION OF PROPRIETARY STATUS

☑ Nonproprietary ☐ Holtec Proprietary ☐ Privileged Intellectual Property (PIP)

Notes

1. This document has been subjected to review, verification and approval process set forth in the Holtec Quality Assurance Procedures Manual. Password controlled signatures of Holtec personnel who participated in the preparation, review, and QA validation of this document are saved on the company's network. The Validation Identifier Record (VIR) number is a random number that is generated by the computer after the specific revision of this document has undergone the required review and approval process, and the appropriate Holtec personnel have recorded their password-controlled electronic concurrence to the document.

SUMMARY OF REVISIONS

Revision 1: 1) Modified text in various sections to clearly identify that this Topical Report is specific to design and testing activities to support certification of a Small Module Reactor; 2) In Part III added some text to several sections that would apply for some testing activities

Revision 2: This revision addresses comments from the NRC RAI and several other minor editorial changes: 1) Re-titled Topical Report to clarify that the report is specific to the design certification of Holtec's SMR; 2) corrected editorial error (additional period) in Abstract section and Part III, Section 1.18; 3) Added 1.2.7 and 1.2.8 to define primary responsibilities of the Director- Engineering Analysis and the Director- Engineering Design; 4) In 1.1, added the following-" 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." ; 5) in 2.5, replaced 10CFR50.55(f) with 10CFR50.54(a)(3); 6) In Section 2, changed "Table 1.1" to Table 1.2" to correct an editorial error.; 7) Modified second paragraph of Section 3 to provide additional clarification QAP education and responsibilities of personnel involved with design; 8) Replaced Sections 9 and 10 which was previously identified as not being applicable; 9) In Section 11, modified one sentence by adding "responsible authority (typically Holtec)" 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."; 10) Replaced Section 15 which was previously identified as not being applicable; 11) In Part III, updated 1.9, 1.10 and 1.15 which had previously been identified as not applicable; 12) In Part II, Section 10.3 and Part III, Section 1.5, removed extra space; 13) In Part IV, changed "FSAR" to "DCD" in several locations; 13) In Part II, 2.5, made it clear that the VP-Quality and president must review changes to the QAM and Holtec Quality Procedures; 14) Replaced "Small Module Reactors" with "Small Modular Reactor" in numerous locations; 15) In Part I, Section 1, General, reworded sentence to make clearer;

ABSTRACT

This Topical Report provides the description of Holtec International's Quality Assurance Program (QAP) for design and testing activities necessary for certification of a Small Modular Reactor. The QAP has been developed in accordance with quality assurance requirements set forth in 10CFR50 Appendix B and NQA-1; 2008 edition with 2009 addenda and Regulatory Guide 1.28, Revision 4 and per the guidance set forth in NUREG-0800.

The Topical Report follows the additional guidance of NEI 11-04 (Nuclear Generation Quality Assurance Program Description). Pursuant to the NEI guidance document, the Topical Report contains four primary parts, namely; 1.0: Introduction and Scope; 2.0 Quality Assurance Program Description; 3.0 Non-Safety Related Structures, Systems and component Quality Control; and 4.0 Regulatory Commitments.

POLICY STATEMENT

Holtec International performs design and testing activities of a Small Modular Reactor for certification. These activities shall be controlled and performed in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating License(s) and applicable laws and regulations of the state and local governments.

The Holtec Quality Assurance Manual (QAM) along with the associated implementing procedures provide for control of Quality Assurance Program (QAP) activities related to design and licensing activities that affect the quality of *safety-related* nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAP is also be applied to certain activities that are not *safety-related*, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAM is the top-level policy document that establishes the manner in which quality is to be achieved and presents Holtec's corporate approach for achievement and assurance of quality. The commitments in the QAM are expounded into actionable instructions in a series of implementing procedures known as Holtec Quality Procedures (HQPs). Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAM. The Vice President of Quality establishes overall expectations for effective implementation of the Quality Assurance Program (QAP) and is responsible for obtaining the desired end result. Compliance with the QAM and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the Holtec QAP.

Signed,

K P Singh

Dr. Krishna Singh
President- Holtec International

December 12th, 2013

GLOSSARY OF TERMS

Term	Description
Company	Holtec International
Component	A piece of equipment, such as a vessel, piping, pump valve, or core support structure, which will be combined with other components to form an assembly.
HQP	Holtec Quality Procedure
Inspection	A phase of quality control, which, by means of examination, observation, or measurements, determines the conformance of materials, supplies, components, parts, appurtenances, systems, processes, or structures to predetermined quality requirements.
Item	Any level of unit assembly, including structure, system, subsystems, subassembly, component, part, or material (also includes computer codes in the appropriate context).
M&TE	Measurement and Test Equipment
NDE	Non-Destructive Examination
Nonconformance	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.
NRC	Nuclear Regulatory Commission
Part	An item on which work is performed and which is attached to, and becomes part of, a component before completion of the component.
Procedure	A document that specifies or describes how an activity

Term	Description
	is to be performed. It may include methods to be employed, equipment or materials to be used, and sequence of operations.
Procurement Documents	Contractually binding documents that identify and define the requirements which items or services must meet in order to be considered acceptable by the purchaser.
Project Plan	Document generated for a project that defines the requirements for the project including, but not limited design basis, scope, QA requirements, etc.
Purchaser	The organization or organizations responsible for issuance and administration of a contract, subcontract, or purchase order.
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
Quality Assurance	All those planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.
Quality Control	Those quality assurance actions that provide means to control and measure the characteristics of an item, process, or facility against established requirements.
Safety Related	A class of structure, system, component, or part thereof whose failure could potentially: (a) Compromise the integrity of the reactor coolant pressure boundary; (b) Compromise the capability to shut down the reactor and maintain it in a safe condition; (c) Compromise the capability to prevent or mitigate the consequences of accidents which could result in significant potential offsite exposures; (d) Create a loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety.
Setpoint	The value of a process variable at which an engineered response function (usually a safety function) is actuated.

Term	Description
SSC	Structure, System, or Component
Supplier	Any organization under contract to furnish items or services. It includes the terms Vendor, Contractor, Subcontractor, Fabricator, and subtier levels of these where appropriate.
Testing	The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.
Verification	An act of confirming, substantiating, and assuring that an activity or condition has been implemented in conformance with the specified requirements.

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PART I INTRODUCTION

SECTION 1 GENERAL

Holtec International's Quality Assurance Manual (QAM) is the top-level policy document that establishes the quality assurance program and policy and assigns major functional responsibilities for activities conducted by or for Holtec for the areas identified in Table 1.1. The QAM describes the methods and establishes quality assurance and administrative control requirements that meet the applicable Codes and Standards identified in Table 1.2.

The Quality Assurance Program (QAP) is defined by the Holtec QAM (which describes the QA elements) 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 QAP. 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 QAP 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.

This Topical Report provides a summary of the requirements set forth within Holtec's QA Program related to design and testing activities for a Small Modular Reactor design certification.

1.1 Scope/Applicability

This Topical Report contains programmatic requirements that mirror and amplify the provisions of 10CFR50 Appendix B for applicable criteria related to design and testing activities. The Topical Report has been specifically established to serve as the primary vehicle to describe Holtec's QAP for the control of all safety significant activities carried out by the Company for activities listed in Table 1.1 and under the rules of the Codes and Standards identified in Table 1.2 under a seamless quality regimen.

Each of the programmatic commitments in this manual are elaborated as actionable instructions in implementing procedures called Holtec Quality Procedures (HQPs) and other supporting procedures and instructions.

Safety-related SSCs, under the control of the QAP, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAP may be applied to certain activities where regulations other than those specified in Table 1.2 establish QA requirements for activities within their scope.

The policy of Holtec is to assure a high degree of availability and reliability of the nuclear plant(s) and supporting equipment while ensuring the health and safety of all nuclear workers and the general public. To this end, selected elements of the QAM 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 quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1–2008 and NQA-1a-2009 Addenda, Part I, Section 400, apply to select terms as used in this document.

Table 1.1: QA Program Applicability

Equipment/Items	Primary Activities
Small Modular Reactor	Design and Testing to Support Certification

Table 1.2: QA Program Applicability

(The QAP complies with the following Codes and Standards)

Code of Federal Regulations	Miscellaneous Codes and Standards
10CFR21, 10CFR50 Appendix B, 10CFR52	ASME NQA-1-2008 and NQA-1a-2009 Addenda, Parts I and II, with specific reference to selected Part III sections, as identified in this document.

PART II QAP DETAILS

SECTION 1 ORGANIZATION

1.1 General

This section describes the Holtec organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAP implementation. The overall organizational structure includes corporate, management and support staff, including interface responsibilities for multiple organizations that perform quality-related functions. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

Holtec is comprised of numerous Divisions, all of whom may support the Company through the provisions of the QAP. Depending on the scope of a particular activity, one or more of these Divisions may be involved. The organizational structure of each Division is identified in a Holtec Quality Procedure (HQP) along with primary responsibilities of key personnel.

The Vice President of Quality is responsible to size the Quality Assurance staff 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 QAP, at any location where activities subject to the QAP are being performed, shall have direct access to the levels of management necessary to perform the required functions without hindrance.

Quality Assurance personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This authority extends to off-site work performed by suppliers that furnish safety-related services to Holtec.

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.

Figure 1.1 provides the Holtec organizational structure.

1.2 Organizational Responsibilities of Key Personnel

The following sections describe the reporting relationships, functional responsibilities, and authorities for key upper management and quality personnel in the Holtec organization.

1.2.1 President

The President of Holtec is responsible for all aspects of design, licensing and related activities. The President is also responsible for all technical and administrative support activities provided by Holtec and its contractors. The President directs the Executive Vice

President, Vice President of Engineering and Vice President of Operations in fulfillment of their responsibilities.

1.2.2 Executive Vice President (EVP)

The Executive Vice President reports directly to the Holtec President. The EVP has overall responsibility for ensuring that all project activities are carried out in accordance with the Company's QAP. The EVP ensures that the Company's corporate culture promotes free airing of views, vigorous implementation of the company's quality program, and a retribution-free work environment.

1.2.3 Vice President of Engineering (VPE)

The Vice President of Engineering (VPE) reports directly to the EVP. The VPE has responsibility for assuring that design and analysis work is performed in accordance with the QAP and that personnel in these areas are appropriately trained and qualified to perform their scope of work.

1.2.4 Vice President of Operations (VPO)

The Vice President of Operations (VPO) reports directly to the EVP. The VPO has overall responsibility for projects and project management.

1.2.5 Vice President of Quality (VPQ)

The Vice President of Quality (VPQ) reports directly to the President of Holtec. The VPQ has overall responsibility for the operation and implementation of the Holtec QAP. The VPQ assures that the QA organization is of a size commensurate with its duties and responsibilities.

1.2.6 Corporate Quality Assurance Manager and Quality Managers

The Corporate Quality Assurance Manager reports directly to the Vice President of Quality. The Corporate Quality Assurance Manager is responsible for maintaining and updating the QA Manual and supporting Holtec Quality Procedures, evaluating compliance to QAP requirements, and managing Quality Assurance Organization resources. The Corporate Quality Assurance Manager is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors providing quality services to Holtec are meeting the requirements of applicable Codes and Standards through vendor audits.

Division Quality Managers report directly to the Corporate Quality Assurance Manager. Division Quality Managers are responsible for the day to day implementation of the QAP at the applicable Holtec Division.

The Corporate Quality Assurance Manager and the Division Quality Managers are responsible for assuring that appropriate QA training and qualification activities are

completed as applicable to personnel performing quality related activities.

The Corporate Quality Assurance Manager and the Division Quality Managers have sufficient independence from other Holtec priorities to bring forward issues affecting safety and quality and make judgments regarding quality in all areas regarding Holtec activities as appropriate. If the Division Quality Manager disagrees with any actions taken by the project management and is unable to obtain resolution, the Division Quality Manager shall inform the Corporate Quality Assurance Manager and bring the matter to the attention of the VPQ, who will determine the final disposition.

1.2.7 Director- Engineering Analysis

Responsible for the quality of the analysis work performed by the Company and for mentoring and developing training programs for analysts. The Director-Engineering Analysis reports directly to the Vice President-Engineering.

1.2.8 Director- Engineering Design

Responsible for the quality of the design work performed by the Company and for mentoring and developing training programs for Designers. The Director-Engineering Design reports directly to the Vice President-Engineering.

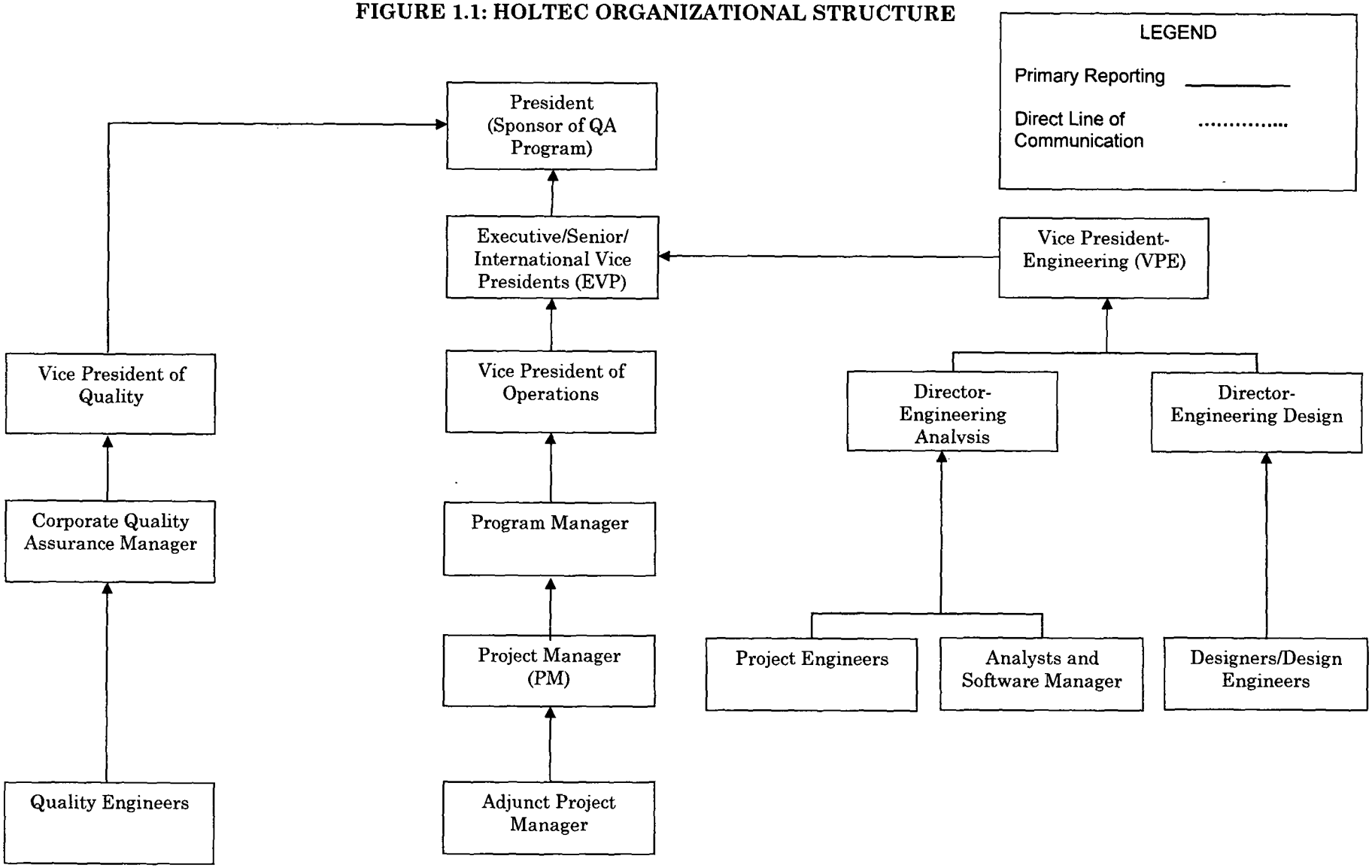
1.3 Quality Assurance Organizational Independence

Independence shall be maintained between the organization(s) performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification nor in certain applications where individuals within a specific organization did not perform the specific work and are appropriately qualified.

1.4 NQA-1 Commitment

In establishing its organizational structure, Holtec commits to compliance with NQA-1-2008, Requirement 1.

FIGURE 1.1: HOLTEC ORGANIZATIONAL STRUCTURE



SECTION 2 QUALITY ASSURANCE PROGRAM

Holtec has established the necessary measures and governing procedures to implement the QAP as described in the QAM. Holtec is committed to implementing the QAP in all aspects of work that are important to safety as described and to the extent delineated in the QAM. The QAP includes monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, Holtec ensures through the systematic process described herein that its suppliers of safety-related services meet the applicable requirements of 10CFR50 Appendix B except where Holtec performs commercial grade dedication or implements applicable portions of its own QAP on the supplier. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Part II, Section 18.

The objective of the QAP is to assure that Holtec's processes as delineated in Table 1.1 are in accordance with governing regulations and license requirements. The program is based on the requirements set forth in the Codes and Standards identified in Table 1.2 of this document and as further described in the QAM. The QAP applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the processes identified in Table 1.1. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

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 1.2 are not applicable. The specific program controls, consistent with applicable sections of the QAM, are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualifies SSC as a significant contributor to plant safety.

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 Holtec QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAM and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

In general, the program requirements specified herein are detailed in implementing procedures that are either Holtec implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general 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 backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for Holtec are responsible for achieving

acceptable quality in the work covered by the QAP. This includes the activities delineated in Part I, Section 1.1. Holtec personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAP are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The Project Manager in conjunction with the Quality Manager are responsible to verify that processes and procedures comply with the QAM and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

Holtec retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 1, and corresponding Holtec procedures may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the appropriate level based upon their nature and effect, with technical advice or review as appropriate.

2.3 Site-Specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied to these activities.

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, 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. In this case, the activity is understood to be a general process such as design.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAP will be in accordance with 10 CFR 50.54(a)(3). Changes to the QAP are evaluated by the Corporate QA Manager to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAP. New revisions to the QAP documents (QAM, HQPs) will be reviewed, at a minimum, by the Vice President of Quality and approved by the President.

2.6 Personnel Training and Qualifications

Personnel assigned to implement elements of the QAP shall be capable of performing their assigned tasks. To this end, 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; and include or address the following, as appropriate:

- Education, experience, and proficiency of the personnel receiving training
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements
- On-the-job training, if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable Holtec procedures. Indoctrination includes, as appropriate, the administrative and technical objectives, requirements of the applicable codes and standards, and the QAM elements to be employed. Records of personnel training and qualification are maintained.

The minimum qualifications of the Corporate Quality Assurance Manager are a) engineering or related science degree plus three years of quality assurance related work; or a high school diploma plus seven years of quality assurance related work; or 10 years of quality assurance related work; and b) knowledge of applicable Codes and Standards. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements will not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications for the individuals responsible for supervising QA or QC personnel is that each has a high school diploma or equivalent and has a minimum of one year of experience performing quality verification activities. Individuals who do not possess these formal education and experience requirements will not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of individuals that are part of the Quality Engineering Department responsible for planning, implementing, and maintaining the programs for the QAM are that each has a high school diploma or equivalent and a minimum of one year of related work experience. Individuals who do not possess these formal education and minimum experience requirements will not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7 NQA-1 Commitment / Exceptions

In establishing qualification and training programs, Holtec commits to compliance with NQA-1-2008 Requirement 2 with the following clarifications and exceptions:

- 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.

SECTION 3 DESIGN CONTROL

Holtec has established and implements a process to control the design and design changes of items that are subject to the provisions of the QAP. 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 the 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 by inspection and test, as required. Design change processes and the division of responsibilities for design-related activities are detailed in Holtec and supplier procedures. Changes to design inputs and final designs are justified and 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 changes are reviewed and approved by the Holtec design organization or by other organizations so authorized by Holtec as appropriate.

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.

3.1 Design Verification

Holtec design processes provide for design verification to ensure that computer programs and activities subject to the provisions of the QAP are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to the original design.

Design verifications are performed by 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. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item or computer program under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. 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 item's intended use.

Holtec normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacturing, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

Holtec maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, assumptions, analyses and computer programs) and the sources of input that support the final output. Design records shall be sufficiently detailed such that a technically qualified individual in the subject area can review and understand the analysis and verify the adequacy of the results without recourse to the analysis preparer.

Design drawings reflect the properly reviewed and approved configuration of the plant or equipment.

3.3 Computer Application and Digital Equipment Software

The QAP governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Computer program acceptability is pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. Holtec and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto is documented and approved by the assigned Computer Code Expert. The QAP is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAP requirements such as QA records.

3.4 Setpoint Control

Consistent with its role as the reactor designer and its responsibility to ensure that the safety significant systems are operated in the safest possible manner, the instrument and equipment setpoints that could affect nuclear safety shall be established by Holtec International. To ensure clarity, setpoints shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

- Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes defined by Holtec.

- Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.

3.5 NQA-1 Commitment

In establishing its program for design control and verification, Holtec commits to compliance with NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3. In addition, Holtec commits to NQA-1 Subpart 2.7 for computer software and NQA-1 Subpart 2.14 for Quality Assurance requirements for commercial grade items and services.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

Holtec has established the necessary measures and governing procedures to assure that purchased computer programs, 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:

- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, and 10 CFR 21) are invoked for procurement of computer programs, items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary and with the exception of items/services that are dedicated, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under Holtec's approved QA program).

Reviews 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.

4.1 NQA-1 Commitment / Exceptions

In establishing controls for procurement, Holtec commits to compliance with NQA-1-2008 Requirement 4, with the following clarifications and exceptions:

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

- Section 300 and 400 of Requirement 4 require the review of technical and Quality Assurance 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.

- 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."

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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 of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff, instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

Holtec's policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require: (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) verification of completion of significant steps, by initials or signatures or use of check-off lists as appropriate. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2008 and NQA-1a-2009 Addenda. In addition, procedures governing tests and inspections will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1 Commitment

In establishing procedural controls, Holtec commits to compliance with NQA-1-2008, Requirement 5.

SECTION 6 DOCUMENT CONTROL

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. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

- Identification of controlled documents
- Specified distribution of controlled documents for use at the appropriate location
- A method to identify the correct document (including revision) to be used and control of superseded documents
- Identification of individuals responsible for controlled document preparation, review, approval, and distribution
- Review of controlled documents for adequacy, completeness, and approval prior to distribution
- A method to ensure the correct documents are being used
- A method to provide feedback from users to improve procedures and work instructions
- Coordinating and controlling interface documents and procedures

The types of documents to be controlled include, but are not limited to:

- Drawings such as design, construction, installation, and as-built drawings
- Engineering calculations
- Design specifications
- Purchase orders and related documents
- Vendor-supplied documents
- Audit, surveillance, and quality verification/inspection procedures
- Inspection and test reports
- Instructions and procedures for activities covered by the QAP
- Technical specifications
- Nonconformance reports and corrective action reports

6.1 Review and Approval of Documents

Documents are reviewed by qualified and knowledgeable persons other than the preparer for adequacy and to ensure quality assurance measures have been appropriately applied. Procedures for design are also reviewed by the Quality Department to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

Prior to issuance or use, documents including revisions thereto, are approved by the

designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval or by a designated organization that is appropriately qualified and knowledgeable. The reviewing organization has access to pertinent background data or information upon which to base their approval. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3 NQA-1 Commitment

In establishing provisions for document control, Holtec commits to compliance with NQA-1-2008, Requirement 6.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Holtec has established the necessary measures and governing procedures to control purchased items and services to assure conformance with specified requirements. Such control provides for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.1 Acceptance of Item or Service

Holtec establishes and implements 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 item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions may include testing, as appropriate, during design activities. Verifications occur at the appropriate phases of the procurement process, and may include, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used. Qualified safety related suppliers are audited on a triennial basis. If required work is outside the scope that the supplier is currently qualified for based on the audit, a supplemental audit may be performed in order to increase the scope of the supplier's qualification.
- Holtec may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet Holtec requirements. Documented annual evaluations are performed for qualified safety related suppliers to assure they continue to provide acceptable products and services. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by Holtec with appropriate input from the supplier and be completed in order to assure the adequacy and compliance of the supplied items or services before relying on the item to perform its intended safety function.
- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1 Commitment / Exceptions

In establishing controls for purchased items and services, Holtec commits to compliance with NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

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

  - 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.

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

  - 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:

    - 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:

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

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

- 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.

- In establishing commercial grade item requirements, Holtec commits to compliance with NQA-1a-2009, Section 700 and Subpart 2.14, with the following clarification:

- 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.

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

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

As this Topical Report is for design and testing activities related to the certification of a Small Modular Reactor, this section is generally not applicable except where testing to support 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.

8.1 NQA-1 Commitment

In establishing provisions for identification and control of items, Holtec commits to compliance with NQA-1-2008, Requirement 8 as applicable for test activities related to design qualification.

SECTION 9 CONTROL OF SPECIAL PROCESSES

This section applies to nondestructive examination related to any required testing activities that would be considered to affect safety.

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 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.

9.1 NQA-1 Commitment

In establishing measures for the control of special processes, the Holtec commits to compliance with NQA-1-2008, Requirement 9.

SECTION 10 INSPECTION

This section applies to inspections related to any required testing activities and receipt inspection of applicable test equipment and items that would be considered to affect safety.

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. 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.

10.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), 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) as necessary to support testing activities, and (4) upon receipt of items.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item relative to safety, the complexity of the item, technical requirements to be met, and design specifications.

Inspection program documents establish 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.

Inspection results are documented by the qualified inspector, reviewed as necessary by an appropriately qualified individual and controlled by instructions, procedures, and drawings. Nonconforming conditions identified during inspection activities are evaluated and controlled as addressed in Section 15.

10.2 Inspector Qualification

Holtec has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3 NQA-1 Commitment

In establishing inspection requirements, Holtec commits to compliance with NQA-1-2008, Requirement 10.

SECTION 11 TEST CONTROL

Holtec has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAP 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: (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 evaluated by the organization performing the test and reviewed by a responsible authority (typically Holtec) 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 system or equipment deficiencies that caused the failure.

Except for computer program testing, which is addressed in Section 11.1, tests are performed and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAP. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2, as applicable.

11.1 NQA-1 Commitment for Computer Program Testing

Holtec establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end Holtec commits to compliance with the requirements of NQA-1a-2009, Requirement 11 and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, Requirement 3.

11.2 NQA-1 Commitment

In establishing provisions for testing, Holtec commits to compliance with NQA-1a-2009, Requirement 11.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Holtec has established 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.

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 bases for calibration is documented.

12.1 NQA-1 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, Holtec commits to compliance with NQA-1-2008, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

This Topical Report addresses design and testing activities to support certification of a Small Modular Reactor. As such, this criteria is not applicable.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

This Topical Report addresses design and testing activities to support certification of a Small Modular Reactor. As such, this criteria is not applicable.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Nonconformances are corrected or resolved prior to relying on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements 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.

15.1 Interface with the Reporting Program

Holtec has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of the applicable Codes and Standards listed in Table 1.2 during the design certification phase.

15.2 NQA-1 Commitment

In establishing measures for nonconforming materials, parts, or components, Holtec commits to compliance with NQA-1-2008, Requirement 15.

SECTION 16 CORRECTIVE ACTION

Holtec has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Holtec procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Holtec procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, Holtec documents establish the requirements for documentation and timely evaluation of the issue. 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 responsibility for the effectiveness of corrective action measures.

16.1 Interface with the Reporting Program

Holtec has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of the applicable Codes and Standards listed in Table 1.2.

16.2 NQA-1 Commitment

In establishing provisions for corrective action, Holtec commits to compliance with NQA-1-2008, Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

Holtec has the necessary measures and governing procedures 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.

17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, test, audits and other applicable quality records and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.1.a(3) of Regulatory Guide 1.28, Revision 4. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

When using optical disks for electronic records storage and retrieval systems, Holtec shall comply with the NRC guidance in Generic Letter 88-18, "Plant Record Storage on Optical Disks." Holtec will manage the storage of QA Records in electronic media in accordance with applicable Holtec procedures which shall meet the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998 with the following exception:

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.

17.3 NQA-1 Commitment / Exceptions

In establishing provisions for records, Holtec commits to compliance with NQA-1-2008, Requirement 17, and regulatory positions stated in Regulatory Guide 1.28, Rev 4, dated June, 2010.

SECTION 18 AUDITS

Holtec has established the necessary measures and governing procedures to implement audits to verify that activities covered by the QAP are performed in conformance with the established requirements and performance criteria are met. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of the implementation of Holtec's QAP are performed with a frequency commensurate with safety significance. Internal audits are performed to verify compliance and effectiveness of implementation of programs and procedures using a representative sample. Internal audits also provide a means to verify that processes and programs are meaningful and comply with the overall QAP.

Internal audits of selected aspects of the new plant licensing and design activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of the applicable safety-related activities are completed. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., design, procurement, surveillance, test), regulations, programs for training, retraining, and personnel qualification and corrective actions, including associated record keeping.

The audits are scheduled on a formal preplanned audit schedule and 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 Holtec's QAP is audited at least once each year. Additional audits may be performed as deemed necessary by management. 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 responsibilities 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 Quality Assurance Manager.

The results of each internal audit are captured in an audit report and are reported in writing to the President of Holtec. Additional internal distribution is made to other concerned management levels and to management of the internal audited organizations or activities in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted as deemed warranted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related items and/or services are conducted as described in Section 7.1. Audits of suppliers are conducted to verify the adequacy of the supplier's QA Program.

18.2 NQA-1 Commitment

In establishing the independent audit program, Holtec commits to compliance with NQA-1-2008, Requirement 18.

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

SECTION 1 NONSAFETY-RELATED SSCS - SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, 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 SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities for those items and activities considered to be significant contributors to plant safety.

1.1 Organization

The organizational structure as defined in Part II, Section 1 still applies though specific responsibilities defined in Part II may not apply.

1.2 QA Program

Holtec QA requirements for nonsafety-related SSCs are established in this section of the QAM. A separate QAM is not required.

1.3 Design Control

Holtec has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4 Procurement Document Control

Procurement documents for items and services obtained by or for Holtec include or reference documents describing applicable design bases, design requirements, and other requirements as applicable and as necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5 Instructions, Procedures, and Drawings

Holtec provides documents such as, but not limited to, written instructions and drawings to direct the performance of activities affecting quality. The method of instruction employed provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable performance.

1.6 Document Control

Holtec controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7 Control of Purchased Items and Services

Holtec employs measures, such as inspection of items or documents upon receipt to ensure that applicable purchased items and services conform to appropriate procurement documents.

1.8 Identification and Control of Purchased Items

This Topical Report addresses design and testing activities to support certification of a Small Modular Reactor. As such, this criteria is not applicable.

1.9 Control of Special Processes

Holtec employs process and procedure controls for nondestructive examination. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

Holtec uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11 Test Control

Holtec employs measures to identify required testing to support design activities. These tests are performed in accordance with test instructions or procedures as appropriate.

1.12 Control of Measuring and Test Equipment (M&TE)

Holtec employs measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13 Handling, Storage, and Shipping

This Topical Report addresses design and testing activities to support certification of a Small Modular Reactor. As such, this criteria is not applicable.

1.14 Inspection, Test, and Operating Status

This Topical Report addresses design and testing activities to support certification of a Small Modular Reactor. As such, this criteria is not applicable.

1.15 Control of Nonconforming Items

Holtec employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16 Corrective Action

Holtec employs measures to ensure that conditions adverse to quality are properly identified, reported, and corrected.

1.17 Records

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

1.18 Audits

If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings and test activities as appropriate. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2 NON-SAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

The following criteria apply to the design and licensing aspects applicable to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related;

- Holtec commits to implement quality requirements to the fire protection system in accordance Regulatory Position 1.7, "Quality Assurance," in RG 1.189, Revision 2, October 2009; "Fire Protection for Operating Nuclear Power Plants."

- Holtec commits to implement the quality requirements for ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That is Not Safety Related.".

- Holtec commits to implement quality requirements for SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment that is Not safety Related," and appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155,Revison 0, 1998; "Station Blackout".

PART IV REGULATORY COMMITMENTS

(Note: This Part only applies for design and licensing activities for a nuclear plant under Holtec's own docket under the rules of 10 CFR 50 and 52.)

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the Holtec QAP. Holtec complies with these standards to the extent described or referenced. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein. See Design Control Document (DCD) Chapter 1 for the Holtec evaluation of conformance with the guidance in NRC Regulatory Guides in effect six months prior to the submittal date of the application.

Regulatory Guides:

Regulatory Guide 1.26, (Revision 4, March 2007) - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

Holtec identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in DCD Chapter 1 and/or 3.

Regulatory Guide 1.28, (Rev. 4, June 2010), Quality Assurance Program Criteria (Design and Construction)

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design of nuclear power plants.

Holtec identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in DCD Chapter 1.

Regulatory Guide 1.29, (Revision 4, March 2007) - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

Holtec identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in DCD Chapter 1.

Standards:

ASME NQA-1-2008 Edition with NQA-1a-2009 Addenda - Quality Assurance Requirements for Nuclear Facility Applications

Holtec commits to NQA-1-2008 with NQA-1a-2009 Addenda, Parts I and II, as described in Part II of this document with specific identification of exceptions or clarification. Holtec commits to NQA-1-2008 with NQA-1a-2009 Addenda, and Part III only as specifically noted in Part II of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

Holtec commits to NIRMA TGs as described in Part II, Section 17.