A Holtec International Company

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Topical Report On The Quality Assurance Program for Holtec International's Small Modular Reactor (SMR) Design and Construction

Prepared by:	**Reviewed by:**	**Approved by:**
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Topical Report
On
The Quality Assurance Program
for
Holtec International's
Small Modular Reactor (SMR) Design and Construction

Holtec Report HI-2230815

Revision 2

The Topical Report provides mandatory programmatic requirements under each of the applicable eighteen criteria set forth in 10CFR50 Appendix B and NQA-1 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.

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ABSTRACT

This SMR Quality Assurance Program Topical Report provides a summary of the requirements set forth within Holtec International's Quality Assurance Program related to design, fabrication, construction, and testing activities for Holtec's SMR. The SMR Quality Assurance Program Topical Report has been prepared in accordance with the requirements of Title 10, Part 50 of the Code of Federal Regulations (10CFR50), "Domestic Licensing of Production and Utilization Facilities", Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and ASME NQA-1-2015 "Quality Assurance Program Requirements for Nuclear Facilities" as endorsed by Regulatory Guide 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)." This SMR Quality Assurance Program Topical Report was prepared consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" Section 17.5 and is based on the Nuclear Energy Institute (NEI) 11-04A, "Nuclear Generation Quality Assurance Program Description" template.

Pursuant to this guidance, the SMR Quality Assurance Program Topical Report contains four primary parts, namely, 1.0: Introduction and Scope; 2.0 Quality Assurance Program Description (QAPD); 3.0 Non-Safety Related Structures, Systems and Components (SSCs) Quality Control; and 4.0 Regulatory Commitments.

POLICY STATEMENT

Holtec International provides engineering design and analysis, manufacturing, and site services to a variety of industries including the power and process industries. In addition to designing and constructing SMRs, the Company supplies fabricated equipment/components and site construction services to a wide variety of industrial sectors including nuclear power plants. The Company also provides decommissioning services. For projects involving important to safety (to include safety-related) goods and services for nuclear plants, it is the policy of the Company to perform project activities in accordance with quality assurance practices described in the Holtec Nuclear Quality Assurance Manual (HQAM) and its daughter documents. This manual meets the provisions of 10CFR50 Appendix B, 10CFR71 Subpart H and 10CFR72 Subpart G. The manual also meets the provisions within NQA-1 except as specifically identified within this manual.

The HQAM is the top-level policy document that establishes the mechanisms in which quality is to be achieved and presents the Company's corporate approach for achievement and assurance of quality. The commitments in the HQAM are expounded into actionable instructions in a series of implementing procedures known as Holtec Quality Procedures (HQPs) and Holtec Standard Procedures (HSPs). Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the HQAM.

It is also the policy of the Company to perform all project activities in accordance with quality assurance practices described in the Company ISO 9001:2015 Quality Assurance Manual and its daughter documents.

It is the responsibility of the President of Holtec International to establish policies, goals, and objectives of the Quality Assurance Program and to establish the necessary quality organization to assure that the Company's Quality Assurance Program is being properly implemented in accordance with the stipulation of the HQAM and the ISO 9001:2015 QA Manual.

The Corporate Quality Assurance Manager is responsible for establishing and maintaining a Quality Assurance Program consistent with applicable codes and standards, for executing quality-related tasks specifically assigned by the President and/or Vice President of Quality of the Company, and for monitoring the program for strict compliance.

Personnel whose activities are governed by this manual are directly responsible for implementing the program and the procedures applicable to their activities.

The Company QA Program is developed and implemented in order to assure that the products and services provided by the Company are of a high quality, that the products and services meet the requirements of applicable codes and standards, and that the products and services meet the requirements of the Company's customers. As part of the Company QA Program, the Company has implemented mechanisms to evaluate areas for continual improvement in order to assure that the Company's quality objectives are always met.

The primary objectives of the Company Quality Assurance Program are:

1) Assuring compliance to statutory, regulatory, and customer contract requirements.
2) Providing a high level of quality to all products produced by the Company.
3) Ensuring customer satisfaction.

Signed,

Dr. Krishna Singh
Holtec International

PART I: INTRODUCTION

SECTION 1: GENERAL

Holtec International's Nuclear Quality Assurance Manual (HQAM) is the top-level policy document that establishes the quality assurance program and policy and assigns major functional responsibilities for important to safety (to include safety-related) activities conducted by or for Holtec International. The HQAM describes the methods and establishes quality assurance and administrative control requirements that meet the applicable codes and standards.

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

This SMR, LLC Quality Assurance Program Topical Report (SMR LLC QAP TR) provides a summary of the requirements set forth within the HQAP related to design, fabrication, construction, and testing activities necessary for Holtec's SMR. Holtec International (synonymous with Holtec) is used throughout this SMR LLC QAP TR as the organization responsible for the execution of the quality assurance activities.

1.1 Scope/Applicability

This SMR LLC QAP TR contains programmatic requirements that mirror and amplify the provisions of 10CFR50 Appendix B for applicable criteria related to design, fabrication, construction, and testing activities, pursuant to a 10CFR50 Construction Permit Application and/or Limited Work Authorization. The SMR LLC QAP TR has been specifically established to serve as the primary vehicle to describe the control of all important to safety (to include safety-related) activities carried out by Holtec International for activities listed in Table I.1.1 and under the rules of the codes and standards identified in Table I.1.2 under a seamless quality regimen.

Each of the programmatic commitments in this SMR LLC QAP TR are elaborated as actionable instructions in implementing procedures called Holtec Quality Procedures (HQPs), Holtec Standard Procedures (HSPs), and other supporting procedures and instructions.

Safety-related structures, systems, or components (SSCs), under the control of this SMR LLC QAP TR, are identified by design documents. The technical aspects of these SSCs are considered when determining program applicability, including, as appropriate, the SSC's design safety function.

The policy of Holtec International 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 SMR LLC QAP TR are also applied to certain activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements.

Table I.1.1: QA Program Applicability

The SMR LLC QAP includes, but is not limited to, the following primary processes related to the design and construction of SMR's:

Engineering
Design
Procurement
Fabrication
Construction
Inspection and Testing
Training and Qualification

Table I.1.2: QA Program Requirements

(The SMR LLC QAP complies with the following codes and standards)

Code of Federal Regulations	Miscellaneous Codes and Standards
10CFR21, 10CFR50 Appendix B	ASME NQA-1-2015 Part 1 with exceptions as listed in the applicable criteria of this SMR LLC QAP TR. Applicable subparts from Part 2 of ASME NQA-1-2015 as listed in each section within this SMR LLC QAP TR and with exceptions/clarifications as listed in the applicable section of this SMR LLC QAP TR.

PART II: SMR LLC QAP DETAILS

SECTION 1: ORGANIZATION

1.1 General

This section describes the Holtec International organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying the SMR LLC QAP implementation. The overall organizational structure includes corporate management and support staff, including interface responsibilities for multiple organizations that perform quality-related functions. Holtec International organizational structure and lines of communication are depicted in Corporate and Project Organization Charts (where applicable). The roles and responsibilities of managers and employees are also described in implementing procedures. Functional responsibilities and levels of authority related to quality are described throughout this SMR LLC QAP TR and in HQP and HSP implementing procedures. Descriptions of interfacing organizations are provided in applicable implementing procedures. Organizational structure and implementing procedures ensure quality is achieved and maintained by those assigned responsibility for performing the work, and that quality achievement is verified by those not directly responsible for performing the work.

Holtec International is comprised of numerous Divisions, all of whom may support SMR, LLC through the provisions of the HQAM. Depending on the scope of an activity, one or more of these Divisions may be involved.

The executive in charge of the quality organization is responsible for assuring that the size of the quality organization staff (Quality Assurance and Quality Control) is commensurate with the duties and responsibilities assigned.

The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Regardless of the organizational structure, the person(s) assigned the responsibility for assuring effective execution of any portion of the HQAP, at any location where important to safety (to include safety-related) activities are being performed, shall have direct access to the levels of management necessary to perform the required functions without hindrance.

Those responsible for assuring that an appropriate Quality Assurance Program has been established and those verifying activities affecting quality shall have sufficient independence from cost and schedule when opposed to safety function considerations. Such individuals shall also have the authority to stop work when deemed necessary due to identification of failing to follow HQAP requirements or where safety or SSC integrity may be jeopardized.

1.2 Organizational Responsibilities of Key Personnel

The following describes the reporting relationships, functional responsibilities, and authorities for key upper management personnel in the Holtec International organization. Figure II.1.1 depicts the SMR, LLC organization.

1.2.1 President/CEO of Holtec International

The President/CEO of Holtec International is responsible for overall Holtec policy and provides executive direction and guidance for Holtec as well as promulgates corporate policy through Holtec senior management

staff. The President/CEO of Holtec International also has ultimate responsibility for the development and execution of the HQAP.

1.2.2 President-SMR

The President-SMR reports directly to the President/CEO of Holtec International. The President-SMR provides top level leadership for the SMR, LLC organization and has ultimate responsibility for implementation of the SMR LLC QAP TR in all aspects of engineering, design, licensing, procurement, manufacturing, construction, and related activities.

1.2.3 Chief Nuclear Officer

The Chief Nuclear Officer (CNO) supports the President/CEO in overall responsibility of the HQAP and is delegated to perform any of the QA related activities of the President/CEO as specified in controlling procedures.

1.2.4 Quality Assurance/Quality Control

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

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

a) maintaining and updating the HQAM, SMR LLC QAP TR, and supporting procedures, evaluating compliance to Quality Assurance Program requirements, and managing quality assurance organization resources;
b) assuring compliance with regulatory requirements and procedures through audits and technical reviews;
c) monitoring organizational processes to ensure conformance to commitments and licensing document requirements;
d) ensuring that vendors providing quality services, parts, and materials to Holtec International are meeting the requirements of applicable codes and standards through vendor audits, surveys and surveillances;
e) assuring that appropriate QA training and qualification activities are completed as applicable to personnel performing quality related activities;
f) identifying, evaluating, and recording actual and potential quality problems in accordance with this SMR LLC QAP TR and HQP and HSP implementing procedures.

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

International organizations, the executive in charge of the quality organization will determine the final disposition.

1.2.5 Procurement

The manager in charge of procurement reports directly to the President-SMR and has the following primary responsibilities:

a) overall responsibility for ensuring that all related activities are carried out by trained and/or qualified personnel (as applicable) in accordance with the SMR LLC QAP TR;
b) ensuring that procurement activities are performed in accordance with the SMR LLC QAP TR;
c) coordination development of approved bidders' lists, as applicable;
d) commercial evaluation/validation of the bid/pricing data received;
e) coordination of bid reviews and subcontractor selection with QA and Executive Director;
f) participation in subcontractor qualification;
g) review of procurement documents with QA and Executive Director to establish the necessary level of supplier surveillance and to identify supplier quality control and document submittal requirements.

1.2.6 Executive Director

The Executive Director in charge of the SMR Project reports directly to the President-SMR and is responsible for:

a) assuring that design and analysis work is performed in accordance with the SMR LLC QAP TR;
b) that personnel in these areas are appropriately trained and qualified to perform their scope of work;
c) coordinating independent design reviews;
d) supporting procurement in the identification of approved bidders;
e) supporting procurement in the review of procurement documents, in conjunction with QA, to establish the necessary level of supplier surveillance and to identify supplier submittal requirements;
f) assuring adequacy and consistency of qualification and training of engineers and other technical personnel;
g) staffing as necessary with engineering and/or technical personnel;
h) analytical software control;
i) technical adequacy of design for the SMR project.

1.2.7 Licensing

The executive in charge of licensing reports directly to the President-SMR and is responsible for:

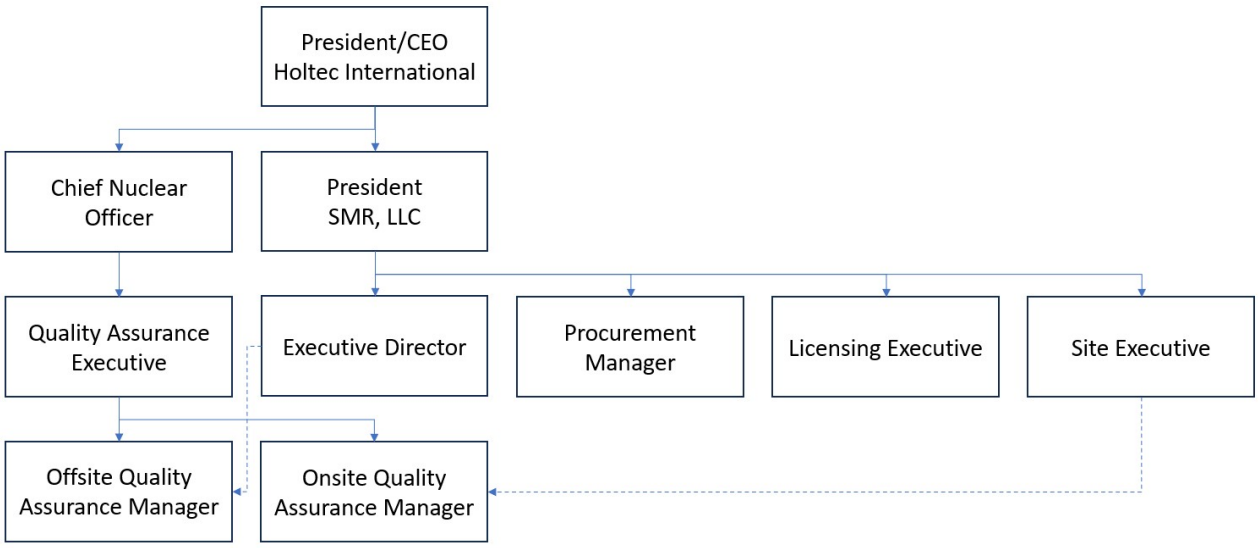
a) assuring that licensing work is performed in accordance with the SMR LLC QAP TR;
b) that personnel in these areas are appropriately trained and qualified to perform their scope of work.

1.2.8 Site

The executive in charge of the site is onsite, reports directly to the President-SMR, and is responsible for assuring that the day-to-day activities within the SMR project related to construction (including inspection and testing) are performed in accordance with the SMR LLC QAP TR. The site executive is also responsible for:

a) ensuring that all personnel onsite are aware of and comply with applicable HSP and HQP implementing procedures;
b) controlling further processing, delivery, or installation of nonconforming product or service until the deficiency or unsatisfactory condition has been corrected in accordance with this SMR LLC QAP TR and HSP and HQP implementing procedures;
c) interfacing with QA in implementing changes affecting quality;
d) providing support and access to QA for internal audits and/or surveillances;
e) provide support and access, when required, for audits;

Figure I.1.1: SMR, LLC Organization



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-1-2015 Part 1, Requirement 1.

SECTION 2: QUALITY ASSURANCE PROGRAM

2.1 General

Holtec International has established the necessary measures and governing procedures to implement the SMR LLC QAP TR as described in the HQAM. Holtec International is committed to implementing the SMR LLC QAP TR in all aspects of work that are important to safety (to include safety-related) as described and to the extent delineated herein. The SMR LLC QAP TR includes monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety (to include safety-related) are performed satisfactorily.

The objective of the SMR LLC QAP TR is to assure that Holtec International's processes and activities as delineated in Table I.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 I.1.2 of this document and as further described in this SMR LLC QAP TR. The SMR LLC QAP TR applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the processes and activities identified in Table I.1.1. Holtec International established and maintains a plant-level SSC classification listing of all safety-related SSCs and non-safety related SSCs that are significant contributors to plant safety. A list or system that identifies SSCs and activities to which this program applies is maintained at Holtec International facilities. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the SMR LLC QAP TR.

The SMR LLC QAP TR provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate analytical tools, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The SMR LLC QAP TR provides for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of that quality.

As described in Part III of the SMR LLC QAP TR, specific program controls are applied to non-safety related SSCs that are significant contributors to plant safety, for which the codes listed in Table I.1.2 are not applicable. The specific program controls, consistent with applicable sections of the SMR LLC QAP TR, are applied to those SSCs in a select manner, targeted at those characteristics or critical attributes that qualifies an 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 SMR LLC QAP TR. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAP and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

Except where noted in other sections of the SMR LLC QAP TR, a grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day 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.

Further, Holtec International ensures through the systematic process described herein that its suppliers of safety-related items and services meet the applicable requirements of 10CFR50 Appendix B except where Holtec International performs commercial grade dedication or implements applicable portions of its own HQAP on the supplier.

Throughout this report, the term "item(s)" denotes any level of unit assembly, including structure, system, subsystems, subassembly, component, part, or material (also includes computer codes in the appropriate context).

Senior management is regularly apprised of the adequacy of implementation of the SMR LLC QAP TR through the audit functions described in Part II, Section 18.

2.2 Responsibilities

Personnel who work directly or indirectly for Holtec International are responsible for achieving acceptable quality in the work covered by the SMR LLC QAP TR. This includes the activities delineated in Table I.1.1. Holtec International personnel performing inspection or verification activities are responsible for verifying the achievement of acceptable quality.

2.3 Delegation of Work

Holtec International retains and exercises the responsibility for the scope and implementation of an effective SMR LLC QAP. Positions identified in Part II, Section 1, and corresponding Holtec International procedures may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others within their department, 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.

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the SMR LLC QAP, 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

Changes to the SMR LLC QAP TR are evaluated by the executive in charge of the quality organization to ensure that such changes do not degrade safety for previously approved quality assurance controls. New revisions to the HQAP implementing documents (HSPs, and HQPs) will be reviewed, at a minimum, by the executive in charge of the quality organization.

Changes to the SMR LLC QAP TR shall follow the criteria set forth in 10CFR50.54, "Conditions of licenses," and 10CFR50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses," (f).

2.6 Personnel Training and Qualifications

Personnel assigned to implement elements of the SMR LLC QAP TR shall be capable of performing their assigned tasks. To this end, Holtec International establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the SMR LLC QAP TR 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 to safety 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, Holtec 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 HSPs. Indoctrination includes, as appropriate, the administrative and technical objectives, requirements of the applicable codes and standards, and the SMR LLC QAP elements to be employed. Records of personnel training and qualifications are maintained. Records for inspection and test personnel, non-destructive examination (NDE) personnel and lead auditors meet the specific record content requirements of NQA-1-2015, Part 1, Requirement 2.

Requirements for qualification of quality assurance lead auditors, quality assurance auditors, and technical specialists are prescribed in written procedures. Qualification requirements comply with NQA-1-2015, Part 1, Requirement 2 except as modified per paragraph 2.7 below.

Requirements for qualification of inspectors, testers and NDE personnel are prescribed in written procedures. Qualification requirements comply with NQA-1-2015, Part 1, Requirement 2.

2.7 NQA-1 Commitment / Exceptions

In establishing controls for the QA Program, including qualification and training programs, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 2 and RG 1.28, Revision 5 with the following clarifications and exceptions:

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

SECTION 3: DESIGN CONTROL

3.1 General

Holtec International has established and implements a process to control the design and design changes of items that are subject to the provisions of the SMR LLC QAP TR. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within Holtec International and with suppliers. These provisions assure that design inputs (such as design bases and performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification, as required. Design change processes and the division of responsibilities for design-related activities are detailed in Holtec International procedures. Changes to design are subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design documents are reviewed by individuals who are trained and qualified under the HQAP to ensure the documents contain the necessary QA requirements. QA personnel are included in the documented review and concurrence in quality related procedures associated with design, construction, and installation.

3.2 Design Inputs

Applicable design inputs shall be identified and documented. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner.

3.3 Design Analysis

Design analysis shall be sufficiently detailed such that a technically competent person in the area of the subject matter can review and understand the analysis and verify the adequacy of results without recourse to the originator.

3.4 Design Verification

Holtec International design processes provide for design verification to ensure that SSCs and activities subject to the provisions of the SMR LLC QAP TR 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 technically competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. A supervisor of the preparer may perform the verification provided that a) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or b) the supervisor is the only available associate in Holtec competent to perform the verification. The need for supervisor verification is documented and approved in advance by the supervisor's management.

The extent of the design verification required is a function of the importance to safety of the SSC 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 SSC's intended use.

Design verification should be performed prior to releasing the design for procurement, manufacturing, construction, or use. Where this cannot be done due to such circumstances as insufficient data, scheduling needs, etc. appropriate controls shall be in place to assure the SSCs conform to final design requirements. In all cases, the design verification must be completed prior to relying upon the SSC to perform its required function.

3.5 Design Records

Holtec International 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 records 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.

Section 16 of the SMR LLC QAP TR addresses requirements for when errors are detected in approved design documents that could adversely affect SSCs.

3.6 Computer Application and Digital Equipment Software

The SMR LLC QAP TR governs the development, procurement, testing, maintenance, control, and use of computer applications and digital equipment software when used in safety-related applications and designated non-safety 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 International and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer applications 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 are documented and approved by authorized personnel. The SMR LLC QAP TR 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 SMR LLC QAP TR requirements such as QA records.

3.7 NQA-1 Commitment

In establishing its program for design control and verification, Holtec International commits to compliance with NQA-1-2015, Part 1 Requirement 3, Part 2, and Subpart 2.7 "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications".

SECTION 4: PROCUREMENT DOCUMENT CONTROL

4.1 General

Holtec International has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes; requirements for reporting of nonconforming conditions) are invoked for procurement of items and services. 10CFR21 requirements shall also be invoked 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.

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

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

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

4.2 NQA-1 Commitment / Exceptions

In establishing controls for procurement, Holtec International commits to compliance with NQA-1-2015, Part 1, 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 International HQAP, including implementing procedures, in lieu of the supplier having its own quality assurance program.

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

- 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 International may satisfy this requirement through the review of the procurement specification when the specification contains the technical and quality assurance requirements of the procurement.

SECTION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 General

Holtec International 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 SMR LLC QAP TR. 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 and revising such documents.

5.2 Instruction, Procedure and Drawing Adherence

Holtec International's policy is that instructions, procedures, and drawings are used and followed verbatim when such documents exist and apply.

5.3 Instruction, Procedure and Drawing Content

The activity prescribed within the applicable document shall include sufficient detail that is commensurate with the complexity of the item or activity and for the need to assure consistent and acceptable results. Level of detail in applicable documents shall also consider the work environment and worker proficiency/capability.

5.4 NQA-1 Commitment

In establishing controls for instructions, procedures and drawings, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 5.

SECTION 6: DOCUMENT CONTROL

6.1 General

Holtec International 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

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
- Instructions and procedures for activities covered by the SMR LLC QAP

6.2 Review and Approval of Documents

Documents are reviewed by trained and knowledgeable persons other than the preparer for adequacy and to ensure quality assurance measures have been appropriately applied. Such review and approval shall occur prior to distribution and use of the document.

6.3 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 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.

6.4 NQA-1 Commitment

In establishing provisions for document control, Holtec International commits to compliance with NQA-1- 2015, Part 1, Requirement 6.

SECTION 7: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 General

Holtec International 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 (vendor), source inspection, audit, and examination of items or services.

7.2 Acceptance of Item or Service

Holtec International 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.

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

- Prospective safety-related items and service suppliers are evaluated to assure only qualified suppliers are used.
- Qualified safety-related items and service suppliers are audited on a triennial basis. The triennial period begins when the first audit is performed. A grace period of 90 days is allowed. Where such grace period is used, the date for the following audit or survey shall be based on the original expiration date. A grace period not to exceed 25 percent of the audit or survey interval shall be allowed under exigent conditions with the following requirements:

    a) Holtec International shall prioritize completing audits or surveys of affected suppliers based on their relative importance and any issues with the supplier. Audits are initiated early enough to ensure effective QA during engineering, design, procurement, manufacturing, construction and installation, inspection, and testing. However, the audit or survey shall be completed within the 25 percent grace period.

    b) There is verification that the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50. For suppliers with delinquent surveys, Holtec shall ensure that the suppliers have maintained adequate documented programmatic controls in place for the activities affecting quality.

    c) The alternative method of the 25 percent extension discussed above is applicable to domestic and international suppliers.

    d) Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions.

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

Engineers (ASME), or NRC inspection). When remote assessments are necessitated by exigent conditions, the guidance provided in EPRI TR 3002020796, "Remote Assessment Techniques, Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," shall be implemented.

f) If the contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the supplier will provide documented justification the change(s) are adequately addressed by its quality assurance program controls.

- Holtec International may utilize audits or commercial grade surveys conducted by outside organizations or other Holtec qualified suppliers for supplier qualification provided that the scope of the audit or commercial grade survey covers Holtec needs and the audit or commercial grade survey includes, to the extent necessary, an evaluation of applicable programmatic controls and verification of implementation. Holtec International remains individually responsible for the adequacy of the audit.

- Audits of suppliers are not necessary for procuring items that are relatively simple and standard in design, manufacturing, and testing, or that are adaptable to standard automated inspections or tests of the end product to verify quality characteristics after delivery.

- Documented annual evaluations are performed for qualified safety-related suppliers and those vendors that get a commercial grade survey to assure they continue to provide acceptable products and services. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted).

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

- Provisions are made for accepting purchased items and services. This may include one or more of the following: source verification, receipt inspection, and pre- and post-installation testing.

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

- When Commercial Grade Items (CGI) or Commercial Grade Services (CGS) for safety related applications are intended to be used, the applicable requirements of NQA-1-2015, Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall apply with exceptions noted in 7.3 below.

7.3 NQA-1 Commitment / Exceptions

In establishing controls for purchased items and services, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 7, and NQA-1-2015, Part 2, Subpart 2.14 "Quality Assurance Requirements for Commercial Grade Items and Services," with the following clarifications and exceptions:

- When purchasing commercial grade calibration or testing services from a laboratory that maintains

an accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), Holtec will implement the requirements of Revision 1 of NEI 14-05A, as endorsed by NRC Final Safety Evaluation ML20322A019.

- Part 1, Requirement 7 Section 200 requires that prior to award of contract, the Purchaser shall evaluate the supplier's capability to provide items or services in accordance with requirements of the procurement documents. One of the allowed options is that the supplier's technical and quality capability shall be determined by direct evaluation of the facilities, personnel, and the implementation of the supplier's quality assurance program. Under exigent conditions, in lieu of on-site audits, Holtec allows an option for remotely performed audits of the supplier. It is recognized that not all audits can be performed remotely. Holtec International must first assess whether a remote audit can be performed such that a thorough and complete evaluation of the supplier's QA Program and its implementation can be made. The following conditions must be met in order to conduct a fully remote assessment:

    a) In-person, on-site presence of audit personnel is not possible due to exigent conditions;

    b) The supplier has been previously qualified by a traditional audit/survey (a fully remote audit cannot be used to qualify a new supplier); While not absolutely necessary, if practical, additional confidence in a fully remote audit can be obtained if at least one member of the fully remote audit team (preferably the audit leader and the technical specialist) is familiar with the supplier's facility and participated in the most recent audit of the supplier. As an alternative, the audit leader could consult with the audit leader(s)and technical specialist(s) from previous audits.

    c) A review of the procurement history since the last triennial or other regularly scheduled audit, including receipt inspection results, does not identify potential issues that could not be addressed without on-site, in-person presence during the audit; and

    d) An evaluation of the various program processes that need to be evaluated is completed that leads to the determination that on-site presence is not required to observe any of the technical and quality requirements of interest because remote techniques alone can be used to successfully complete activities associated with assessing the technical and quality requirements of interest.

    Once it is established that a remote audit is a viable option, the following requirements shall apply:

    a) The Audit Team must have access to the QA Manual, second level procedures and other necessary documents that define the controls and implementation of the QA Program in order to perform a complete programmatic review;

    b) The Audit Team must have access or be provided all requested documentation to show objective evidence to support implementation of the QA Program. This would include, but not be limited to such documents as training records, internal/external audits, nonconformance reports, qualification records, corrective action reports, manufacturing records, etc.

    c) The audited entity must be able to support remote real time observation of the performance of activities that are required to be observed as part of the objective evidence to support implementation of the QA Program. This includes the technological capabilities to provide sufficient visual clarity and mobility as well as audio. Such activities to be observed may include, but not be limited to welding, inspection, machining, material processing, testing,

etc. In addition, observation requirements may include real time verification of such things as calibration stickers affixed to measuring and test equipment (M&TE), nonconformance tags appropriately attached to applicable items, item traceability markings, etc.

d) The audited entity must provide the necessary time and support to allow for a thorough and efficient audit.

e) The remote aspect of the audit cannot change how the audit is performed, how objective evidence is selected and what activities are observed. The control of the audit and the selection of necessary objective evidence must be done by the audit team in order to retain true independence and assure that a thorough and complete audit is performed.

f) In observing activities on a shop floor, the audited entity is providing the auditor with the means of visual observation through computer, phone, or other means; however the auditor must direct what he/she wants to specifically see and not allow the audited entity to make that determination.

g) In selecting documents to evaluate, the remote performance-based audit cannot change how documents are selected. The auditor should be selecting the documents to look at rather than the audited entity selecting them.

- Part 1, Requirement 7, Section 501, Holtec International considers documents that may be stored in approved electronic media under its control to comply with the intended requirement.

- In Subpart 2.14, paragraph 401, credible failure mode evaluations are not required for raw materials where material specifications exist. In such cases, the mechanical and chemical testing requirements of the material specification, any required NDE, one or more dimensions and markings for traceability will be considered the critical characteristics unless otherwise documented within the dedication plan or corresponding documents.

- In Subpart 2.14, paragraph 603, surveys can be performed at the supplier's facility or, under exigent conditions may be performed remotely in a similar manner to that described above for remote audits.

- When remote source verification is a necessary basis for acceptance of an item or service during exigent conditions, the guidance provided in EPRI-3002019436-A, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance," shall be implemented.

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

8.1 General

Holtec International has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained from receipt and fabrication up to and including installation and use so that the item can be traced to its documentation and be related to design or other applicable specifying documents. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.2 NQA-1 Commitment

In establishing provisions for identification and control of items, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 8.

SECTION 9: CONTROL OF SPECIAL PROCESSES

9.1 General

Holtec International has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include, as applicable, assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Records are maintained as appropriate for the currently qualified personnel, processes, and equipment for each special process.

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.

9.2 NQA-1 Commitment

In establishing measures for the control of special processes, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 9.

SECTION 10: INSPECTION

10.1 General

Holtec International has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.2 Inspection Program

The inspection program establishes inspections as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a Holtec facility, (3) for final acceptance of fabricated and/or installed items, (4) upon receipt of items, and (5) prior to service (i.e., post construction/pre-operational).

The inspection program establishes requirements for planning inspections, such as method of inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, and the frequency of inspection to be applied. Inspection plans are based on, as appropriate, the relative importance of the item, the complexity of the item, technical requirements to be met, and design specification requirements. Inspections are performed in accordance with written procedures, instructions, travelers, drawings, and specifications as applicable.

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. Inspections must be performed by individuals other than those who performed the activity being inspected.

Inspection results are documented by the qualified inspector and reviewed as necessary by an appropriately qualified individual. Nonconforming conditions identified during inspection activities are evaluated and controlled as addressed in Part II, Section 15.0.

Inspection documentation shall include the following as applicable:

- Item inspected;
- Date of inspection;
- Name of inspector;
- Identification of calibrated M&TE used;
- Type of observation;
- Results or acceptability;
- Reference to information on action taken in connection with nonconformances.

Modifications, repairs, rework, or replacements to items that have already been inspected shall require a re-inspection to the extent necessary based on the modification, repair, rework, or replacement.

If inspection of items is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.

10.3 Inspector Qualification

Holtec International has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2.0.

10.4 NQA-1 Commitment

In establishing inspection requirements, Holtec International commits to compliance with NQA-1-2015. Part 1, Requirement 10. See exceptions under Part II, Section 7.0.

SECTION 11: TEST CONTROL

11.1 General

Holtec International has established the necessary measures and governing procedures to demonstrate that items will perform satisfactorily in service. The test program includes, as appropriate, proof tests prior to installation, construction tests and preoperational tests. Test programs include criteria for determining when testing is required in order to demonstrate that performance of an item or items is in accordance with design. Tests are performed according to 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 reviewed to assure that the test requirements have been satisfied. Test records are traceable to the item(s) tested. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the item deficiencies that caused the failure.

Test records, at a minimum and as applicable, shall identify the item tested, date of test, tester or data recorder, type of observation, results and acceptability, action taken in connection with any deviations noted, and the person evaluating the test results.

Tests are performed and results documented in accordance with applicable technical and regulatory requirements.

11.2 Computer Program Testing

Holtec International establishes and implements provisions to assure that computer programs used in applications affecting safety are prepared, documented, verified, and tested, and used such that the expected output is obtained, and configuration control maintained. Procedures are in place to address controls for both Holtec International-generated computer programs and computer programs Holtec International-purchased computer programs.

11.3 NQA-1 Commitment

In establishing testing requirements, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 11 and NQA-1-2015 Part 2, Subpart 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications”.

SECTION 12: CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

Holtec International has established the necessary measures and governing procedures to control the calibration, maintenance, and use of M&TE that are used for activities affecting quality. The provisions of such procedures cover equipment such as tools, gages, and instruments. Appropriate documentation will be maintained for M&TE to indicate the control status, when the next calibration is due, and identify any limitations on use of the M&TE. Calibration records that are traceable to the specific M&TE shall provide results of calibration.

M&TE are calibrated at prescribed intervals, or prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration is documented.

Procedures also address requirements for control and evaluation of out of calibration conditions. A calibration is performed when the accuracy of the equipment is suspect. When measuring and test equipment is lost, damaged, or found to be out-of-calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested, shall be evaluated.

Calibration and control measures are not required for rulers, tape measures, levels, and other similar devices, if normal commercial equipment provides adequate accuracy.

12.2 NQA-1 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 12.

SECTION 13: HANDLING, STORAGE, AND SHIPPING

13.1 General

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

Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

Cleanliness controls for work on safety-related and risk-significant non-safety related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure.

Special or additional handling, storage, shipping, cleaning, and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals or prior to use. Operators of special handling and lifting equipment are experienced or trained, as appropriate, in the use of the equipment. Where required, Holtec complies with applicable hoisting, rigging and transportation regulations and codes.

Provisions are described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials.

13.2 NQA-1 Commitment / Exceptions

In establishing provisions for handling, storage, packaging and shipping, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 13, and Subpart 2.1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Facilities,” Subpart 2.2, “Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities,” and Subpart 2.3, “Quality Assurance Requirements for Housekeeping at Nuclear Facilities.”

SECTION 14: INSPECTION, TEST, AND OPERATING STATUS

14.1 General

Holtec International has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items in order to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, operated, or shipped. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

Suitable marking methods such as tags, stamps, labels, or travelers are used to identify the test or inspection status of an item. Status may also be indicated by physical location such as a designated hold area.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers, and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, and status tracking.

Maintenance or modifications which may affect functioning of safety-related SSCs shall be performed in a manner to ensure quality at least equivalent to that specified in original design bases and requirements, materials specifications and inspection requirements.

14.2 NQA-1 Commitment

In establishing provisions for inspection, test and operating status, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 14.

SECTION 15: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 General

Holtec International has established the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

Nonconforming items are segregated and/or tagged and/or otherwise identified until such time as disposition of the condition is completed and appropriate actions, as applicable, are taken.

Nonconformances are corrected or resolved prior to relying on the item to perform its intended safety function. Items that are reworked or repaired are inspected and tested, as appropriate, with the original inspection and test requirements or specified alternatives.

Nonconformances are evaluated for impact to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned as repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Technical justification for the acceptability of a nonconforming item, dispositioned as use-as-is or repair shall be documented. Nonconformance dispositions are performed by personnel that have a) competence in the specific area they are evaluating; b) an adequate understanding of the requirements; and c) access to pertinent background information.

15.2 Reporting

10CFR21 (for construction, 10CFR50.55(e) applies) is considered to apply to those items and services identified as safety-related. 10CFR21 (for construction, 10CFR50.55(e) applies) reportability is evaluated for each applicable nonconformance.

15.3 NQA-1 Commitment

In establishing measures for controls for nonconforming materials, parts, or components, Holtec International commits to compliance with NQA-1-2015, Part 1, Requirement 15.

SECTION 16: CORRECTIVE ACTION

16.1 General

Holtec International has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Holtec procedures require all personnel to identify known conditions adverse to quality. Holtec procedures assure that significant conditions adverse to quality are documented into Holtec's corrective action program in order to allow for identification of cause and determination of actions to prevent recurrence. Completed actions are verified. Significant conditions adverse to quality, significant adverse trends, the cause of the condition, the corrective actions taken are documented and reported to responsible management.

In the case of suppliers working on safety-related activities, Holtec International may delegate specific responsibilities for corrective actions but Holtec International maintains responsibility for the effectiveness of corrective action measures.

16.2 Reporting

10CFR21 (for construction, 10CFR50.55(e) applies) is considered to apply to those items and services identified as safety-related. 10CFR21 (for construction, 10CFR50.55(e) applies) reportability is evaluated for each condition that is adverse to quality.

16.3 NQA-1 Commitment

In establishing provisions for corrective action, Holtec commits to compliance with NQA-1- 2015, Part 1 Requirement 16.

SECTION 17: QUALITY ASSURANCE RECORDS

17.1 General

Holtec International has the necessary measures and governing procedures to ensure that sufficient quality assurance records are generated to furnish documentary evidence that items and services meet specified quality requirements. Records of activities for design, engineering, procurement, construction, inspection and test, installation, pre-operation, startup, and audits and their retention times are defined in appropriate procedures. Such records shall be identified, reviewed, approved, maintained, and must be retrievable.

17.2 Quality Record Generation and Control

Documents which are designated as quality records shall be legible, accurate, and completed as appropriate to the work accomplished. Records shall be clearly identified and allow direct traceability to associated items and activities as applicable. Required records are defined in controlling documents such as procedures and specifications.

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel. For all records, electronic signatures using personal authorization codes shall be considered equivalent to handwritten signatures. An electronic record of review and approval of documents shall be maintained in the Holtec network for applicable documents. Records may be originals (including master copies), reproduced copies, or electronically archived.

Corrections shall be performed through a formal revision process in accordance with the applicable type of document and in accordance with applicable procedures. For corrections to written records where revision control may not apply, corrections shall be made by placing a single line crossed out with initials and date of the change. Such corrections may be performed by the individual responsible for recording the erroneous information, the immediate supervisor of the individual who recorded the erroneous information, or quality organization personnel. For corrections to electronic records where revision control may not apply, corrections shall be made only by authorized personnel.

17.3 Classification of Records

Record classification and retention time periods are specified in controlling procedures. Records are classified as lifetime or non-permanent. Lifetime records are those records which meet one or more of the following criteria:

a) Those of significant value in demonstrating capability for safe operation;
b) Those of significant value in maintaining, reworking, repairing, replacing, or modifying the item;
c) Those of significant value in determining the cause of an accident or malfunction of an item;
d) Those which provide required baseline data for in-service inspection.

Lifetime records shall be maintained for the life of the particular item while it is installed in the plant or stored for future use. The types of lifetime records are defined in controlling procedures.

Non-permanent records are those records which do not meet the definition for Lifetime Quality Assurance Records but show evidence that an activity was performed in accordance with the applicable requirements. Retention times for non-permanent records are defined in controlling procedures.

17.4 Record Storage and Maintenance

Records shall be stored in a manner that minimizes the risk of loss, damage, or destruction from:

a) Natural disasters, such as winds, floods, or fires;
b) Environmental conditions such as high and low temperatures and humidity;
c) Infestation of insects, mold, or rodents;
d) Dust or airborne particles.

Depending on the specific media used for record storage, provisions shall be made to prevent damage from other harmful conditions such as excessive light, stacking and electromagnetic fields.

In general, records are maintained electronically. Where paper records are maintained, they shall be received and stored in an appropriate storage facility.

Storage of final records shall meet one of the following two requirements:

a) Single storage consists of a storage facility, vault, room, or container with a minimum two-hour fire rating;
b) Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to meet the requirements for single storage listed above.

Access to final storage facilities shall be controlled in order to limit access to authorized personnel.

17.5 Electronic Records

The following requirements apply for electronic records:

a) No deletion or modification of records unless authorized pursuant to applicable record retention rules;
b) Redundancy such as system backup, dual storage or other appropriate means are provided;
c) Legibility is required of each record;
d) Records media are properly maintained;
e) Inspections to ensure no degradation of records;
f) Records are acceptably converted into any new system before the old system is taken out of service.

When records are duplicated or transferred to the same media or to different media for the purposes of maintenance or storage, the duplication or transfer shall be controlled to assure that the record content, legibility, and ability to retrieve is maintained. Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period.

When using optical disks for electronic records storage and retrieval systems, Holtec International complies with the NRC guidance in Generic Letter GL-88-18. Holtec International will manage the storage of QA records in electronic media consistent with the intent of Regulatory Issue Summary RIS 00-018, and NIRMA guidelines TG 11-2011, TG 15-2011, TG 16-2011, and TG 21-2011.

17.6 NQA-1 Commitment / Exceptions

In establishing provisions for records, Holtec commits to compliance with NQA-1-2015, Part 1, Requirement 17, and regulatory positions stated in Regulatory Guide RG 1.28 Rev 5.

SECTION 18: AUDITS

18.1 General

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

18.2 Internal Audits

Internal audits of the implementation of SMR LLC QAP TR are performed with a frequency commensurate with the relative importance of the activity being audited. Internal audits are performed to verify compliance and effectiveness of implementation of programs and procedures. Internal audits also provide a means to verify that processes and programs are meaningful and comply with the overall SMR LLC QAP TR.

The audits are scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity and to assure that each applicable element of the SMR LLC QAP TR is audited at least once each year or at least once during the life of the activity, whichever is shorter. Additional audits may be performed as deemed necessary by management. Audit results are provided to responsible management.

18.3 External Audits

Audits of suppliers, when required, are conducted as described in this section and also under Part II, Section 7. An audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA Program. Where sufficient work has not yet been completed, an initial programmatic audit may occur to verify the QA Program adequately addresses QA requirements and a follow up implementation audit can be performed when sufficient work has occurred.

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

18.4 Conducting Audits

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. Audit reports are generated. Any audit findings are identified and follow up action is performed to verify appropriate corrective actions have been implemented.

18.5 NQA-1 Commitment

In establishing the independent audit program, Holtec commits to compliance with NQA-1-2015, Part 1, Requirement 18 with the following exceptions:

ASME NQA-1-2015, Part 1 Requirement 18 Section 200, states that, “A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance.” As discussed in Section 7, Subsection 7.1, “A grace period not to exceed 25 percent of the audit or survey interval shall be allowed under exigent conditions.” Further details related to this increased grace period are provided in Part II, Section 7.

PART III: NON-SAFETY RELATED SSC QUALITY CONTROL

SECTION 1: NON-SAFETY RELATED SSCS SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to non-safety related SSCs, for which 10CFR50, 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 SMR LLC QAP TR to the non-safety 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 International quality assurance requirements for non-safety related SSCs are established in this section of the SMR LLC QAP TR.

1.3 Design Control

Holtec International has design control measures to ensure that the 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 International 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 International 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 International 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 International 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

Holtec International employs measures, where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf-life restrictions for the items.

1.9 Control of Special Processes

Holtec International employs process and procedure controls for special processes such as welding, heat treating, and nondestructive examination. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

Holtec International 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

Holtec International employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14 Inspection, Test, and Operating Status

Holtec International employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15 Control of Nonconforming Items

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

1.17 Records

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

1.18 Audits

Holtec International employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection 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 18).

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

The following criteria apply to the design and construction aspects applicable to fire protection (10CFR50.48), anticipated transients without scram (ATWS) (10CFR50.62), and the station blackout (SBO) (10CFR50.63) SSCs that are not safety-related.

- Holtec International commits to implement quality requirements to the fire protection system in accordance with Staff Regulatory Guidance 1.7, "Quality Assurance," in RG 1.189, Revision 5, October 2023; "Fire Protection for Nuclear Power Plants."

- Holtec International commits to implement the quality requirements to ATWS equipment in accordance with GL 85-06, "Quality Assurance Guidance For ATWS Equipment That Is Not Safety Related."

- Holtec International commits to implement the quality requirements to SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment that is Not Safey Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155, "Station Blackout."

PART IV: REGULATORY COMMITMENTS

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 SMR LLC QAP TR. Holtec International 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.

Regulatory Guides:

Regulatory Guide 1.26, (Revision 6, December 2021) – Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Holtec commits to Regulatory Guide 1.26, Revision 6 for classification of structures, systems and components.

Regulatory Guide 1.28, (Rev. 5, October 2017) – Quality Assurance Program Criteria (Design and Construction)

Holtec commits to Regulatory Guide 1.28, Revision 5 for Quality Assurance Program criteria.

Regulatory Guide 1.29, (Revision 6, July 2021) – Seismic Design Classification

Holtec commits to Regulatory Guide 1.29, Revision 6 for seismic design classification.

Regulatory Guide 1.164, (Revision 0, 2017) – Dedication of Commercial-Grade Items for Use in Nuclear Power Plants

Holtec commits to Regulatory Guide 1.164, Revision 0. Holtec will identify conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in SMR application documents.

Regulatory Guide 1.231, (Revision 0, December 2016) – Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants

Holtec commits to Regulatory Guide 1.231, Revision 0. Holtec will identify conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in SMR application documents.

Regulatory Guide 1.234, (Revision 0, April 2018) – Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21

Holtec commits to Regulatory Guide 1.234, Revision 0. Holtec will identify conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in SMR application documents.

Standards:

ASME NQA-1-2015 – Quality Assurance Requirements for Nuclear Facility Applications

Holtec commits to NQA-1-2015, Parts I and II, as described in Part II of this document with specific identification of exceptions or clarification.

NEI 14-05A, (Revision 1, May 2020) – Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Service

Holtec commits to NEI 14-05A, as endorsed by NRC Final Safety Evaluation ML20322A019.

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

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