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May 8, 2013

USNRC Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Holtec International
Docket Number – PROJ0798

Subject: Submittal of Topical Report on the Quality Assurance Program for Holtec International's 10 CFR Part 50 and Part 52 Projects

This letter transmits Holtec International's Topical Report CD-15-NP, Topical Report on the Quality Assurance Program for Holtec International's10CFR Parts 50 & 52 Projects dated May 7, 2013. This Quality Assurance Program follows the guidance provided in NEI 11-04, Nuclear Generation Quality Assurance Program Description (Final Draft Rev. 0) which is currently under review by the staff. This report does not contain any proprietary information.

Any questions concerning this report may be directed to Mark Soler at 856-797-0900 extension 3619 (email: m.soler@holtec.com) or Tom Marcille at extension 3850 (email: t.marcille@holtec.com).

Holtec looks forward to working with the NRC staff on this crucial part of our design effort and will be happy to meet with the NRC staff to discuss the report as necessary.

Mark Soler
Vice President, Quality
Holtec International

cc: (letter only w/out attachment via email)
Jan Mazza, NRC
Stewart L. Magruder, NRC
Michael E. Mayfield, NRC
Stephanie M. Coffin, NRC

Attachment:

Holtec Report CD-15-NP, "Topical Report on the Quality Assurance Program for Holtec International's 10 CFR Part 50 and Part 52 Projects" (Non-proprietary)

Document ID: 2108005

TO10
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Topical Report On The Quality Assurance Program for Holtec International's 10CFR 50 & 52 Projects

REVISION 0	*DATE OF ADOPTION: May 7, 2013*
Holtec Document ID	*CD-15-NP*

DOCUMENT STATUS: *NON-PROPRIETARY*

REVISION TYPE: *Complete Revision* ☒

Revisions Designated with Bars ☐

This Topical Report incorporates Holtec Quality Assurance Manual which provides the commitments and requirements for conducting safety related design, manufacturing ,licensing, site services and construction activities for nuclear power plants under the rules of 10 CFR part 50 or part 52. In this format, the Topical Report provides mandatory programmatic requirements under each of the eighteen discrete general design criteria arranged in eighteen sections listed in the Table of Contents herein. Additional commitments that are beyond the specific purview of the eighteen criteria but are deemed to be necessary for ensuring comprehensive regulatory compliance are included in this Topical Report.

ABSTRACT

This Topical Report provides the description of Holtec International's Quality Assurance Program (QAP) for all activities, including design, licensing, and construction for nuclear power plants under Holtec's own docket. The QAP may also be employed, if invoked by the Project Plan, to control activities related to design, licensing, procurement, manufacturing, site services and construction of an existing or new nuclear plant under a non-Holtec NRC docket. The QAP has been developed in accordance with quality assurance requirements set forth in 10CFR50 Appendix B and NQA-1; 2008 edition with 2009 addenda and Regulatory Guide 1.28, Revision 4 and per the guidance set forth in NUREG-0800. The Topical Report addresses the QAP through incorporation of Holtec's Quality Assurance Manual (QAM).

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

HOLTEC INTERNATIONAL QUALITY ASSURANCE MANUAL

DOCUMENT	*CD-15*
REVISION 0	*DATE OF ADOPTION: May 7, 2013*

DOCUMENT STATUS: *NON-PROPRIETARY*

REVISION TYPE: *Complete Revision* ☒

Revisions Designated with Bars ☐

This QA manual contains Holtec International's programmatic requirements and commitments for conducting safety related design, manufacturing, licensing, site services and construction activities for nuclear power plants under the rules of 10 CFR Part 50 or Part 52. *The QA Manual provides mandatory programmatic requirements under each of eighteen discrete general criteria arranged in eighteen sections listed in the Table of Contents herein. Additional commitments that are beyond the specific purview of the eighteen criteria but are deemed to be necessary for ensuring comprehensive regulatory compliance are included in this QA Manual.*

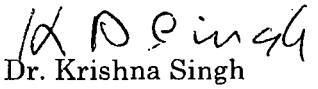
POLICY STATEMENT

Holtec International may perform design and licensing of nuclear power plants under its own NRC docket. Activities may also include procurement, manufacturing, site services and construction related to new nuclear plants. Holtec may also perform design, licensing, procurement, manufacturing, site services and construction of an existing nuclear plant or a new nuclear plant under a non-Holtec NRC docket. These activities shall be controlled and performed in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating License(s) and applicable laws and regulations of the state and local governments.

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

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

Signed,



Dr. Krishna Singh
President- Holtec International

May 7, 2013

GLOSSARY OF TERMS

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

Term	Description
	is to be performed. It may include methods to be employed, equipment or materials to be used, and sequence of operations.
Procurement Documents	Contractually binding documents that identify and define the requirements which items or services must meet in order to be considered acceptable by the purchaser.
Project Plan	Document generated for a project that defines the requirements for the project including, but not limited design basis, scope, QA requirements, etc.
Purchaser	The organization or organizations responsible for issuance and administration of a contract, subcontract, or purchase order.
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
Quality Assurance	All those planned and systematic actions necessary to provide adequate confidence that an item or a facility will perform satisfactorily in service.
Quality Control	Those quality assurance actions that provide means to control and measure the characteristics of an item, process, or facility against established requirements.
Repair	The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item may still not conform to the original requirement.
Rework	The process by which a nonconforming item is made to conform to a prior specified requirement by completion, correction, re-machining, or reassembling.
Safety Related	A class of structure, system, component, or part thereof whose failure could potentially: (a) Compromise the integrity of the reactor coolant pressure boundary; (b) Compromise the capability to shut down the reactor and maintain it in a safe condition; (c) Compromise the

Term	Description
	capability to prevent or mitigate the consequences of accidents which could result in significant potential offsite exposures; (d) Create a loss of safety function to the extent that there is a major reduction in the degree of protection provided to the public health and safety.
Setpoint	The value of a process variable at which an engineered response function (usually a safety function) is actuated.
SSC	Structure, System, or Component
Supplier	Any organization under contract to furnish items or services. It includes the terms Vendor, Contractor, Subcontractor, Fabricator, and subtier levels of these where appropriate.
Testing	The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.
Use-As-Is	A disposition which may be imposed for a nonconformance when it can be established that the discrepancy will result in no unacceptable adverse conditions and that the item under consideration will continue to meet all engineering functional requirements, including performance, maintainability, fit, and safety.
Verification	An act of confirming, substantiating, and assuring that an activity or condition has been implemented in conformance with the specified requirements.

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PART I INTRODUCTION

SECTION 1 GENERAL

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

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

1.1 Scope/Applicability

This QAM contains programmatic requirements that mirror and amplify the provisions of 10CFR50 Appendix B. The QAM has been specifically established to serve as the primary document to control all safety significant activities carried out by the Company for activities listed in Table 1.1 and under the rules of the Codes and standards identified in Table 1.2 under a seamless quality regimen. This manual may also be invoked on a project specific basis to provide goods and services on any applicable project outside of the scope identified in Table 1.1.

It should also be noted that Holtec International maintains several quality manuals in active status for different quality regimes such as ISO-9000 and the various ASME Codes. The jurisdiction of a specific QA manual to a particular project is delineated by the *Project Plan* for the project. It is also possible to apply more than one QA manual conjunctively to a project (such as this manual in conjunction with ISO-9000).

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

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

The policy of Holtec is to assure a high degree of availability and reliability of the nuclear plant(s) and supporting equipment while ensuring the health and safety of all nuclear workers and the general public. To this end, selected elements of the QAM are also applied

to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

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

Table 1.1: QA Manual Applicability

Equipment/Items	Primary Activities
SSCs for nuclear plants under Holtec's own docket; SSCs for new or operating nuclear power plants for other plant owners if invoked by the applicable Project Plan	Design, licensing, procurement, manufacturing, site services and construction

Table 1.2: QA Manual Applicability

(This manual complies with the following Codes and Standards)

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

PART II QAM DETAILS

SECTION 1 ORGANIZATION

1.1 General

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

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

The Vice President of Quality is responsible to size the Quality Assurance staff commensurate with the duties and responsibilities assigned.

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

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

Figure 1.1 provides the Holtec organizational structure.

1.2 Organizational Responsibilities of Key Personnel

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

1.2.1 President

The President of Holtec is responsible for all aspects of design and construction and related activities. The President is also responsible for all technical and administrative support activities provided by Holtec and its contractors. The President directs the Executive Vice President, Vice President of Engineering and Vice President of Operations in fulfillment of their responsibilities.

1.2.2 Executive Vice President (EVP)

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

1.2.3 Vice President of Engineering (VPE)

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

1.2.4 Vice President of Operations (VPO)

The Vice President of Operations (VPO) reports directly to the EVP. The VPO has overall responsibility for projects and project management including oversight of Project Management, Manufacturing, Procurement and Field Services activities.

1.2.5 Vice President of Quality (VPQ)

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

1.2.6 Corporate Quality Assurance Manager and Quality Managers

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

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

The Corporate Quality Assurance Manager and the Division Quality Managers are responsible for assuring that appropriate QA training and qualification activities are completed as applicable to personnel performing quality related activities.

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

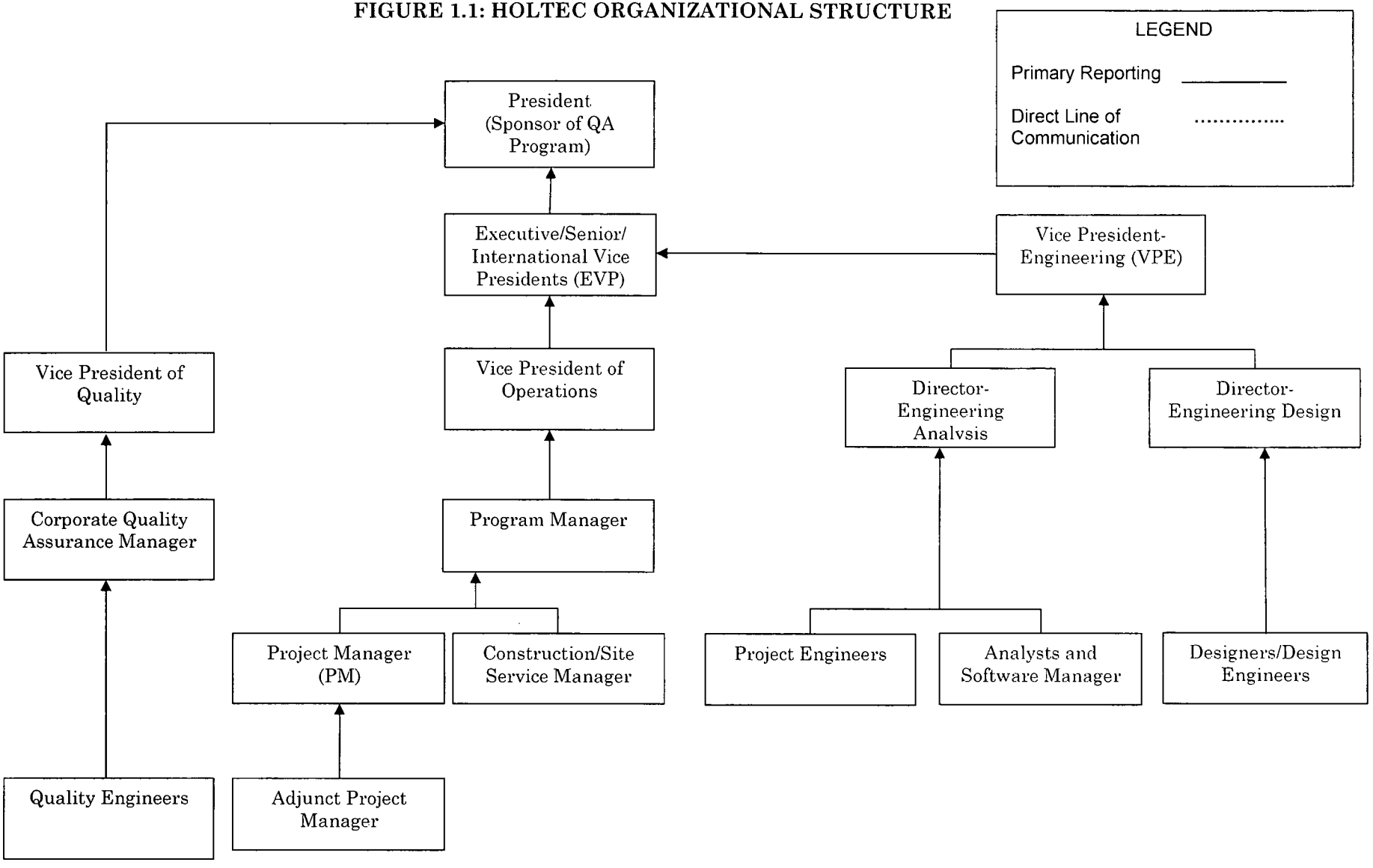
1.3 Quality Assurance Organizational Independence

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

1.4 NQA-1 Commitment

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

FIGURE 1.1: HOLTEC ORGANIZATIONAL STRUCTURE



SECTION 2 QUALITY ASSURANCE PROGRAM

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

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

As described in Part III of the QAM, specific program controls are applied to nonsafety-related SSCs that are significant contributors to plant safety, for which the Codes listed in Table 1.1 are not applicable. The specific program controls, consistent with applicable sections of the QAM, are applied to those items in a select manner, targeted at those characteristics or critical attributes that qualifies the SSC as a significant contributor to plant safety.

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

Where Holtec is responsible for construction activities, detailed engineering specifications and construction procedures would be developed as necessary to implement the QAM prior to commencement of construction activities.

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

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.1 Responsibilities

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

2.2 Delegation of Work

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

2.3 Site-Specific Safety-Related Design Basis Activities

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

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. In this case, the activity is understood to be a general process such as design or construction.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAM will be in accordance with 10 CFR 50.55(f). Changes to the QAM are evaluated by the Vice President of Quality to ensure that such changes do not degrade safety for previously approved quality assurance controls specified in the QAM. New revisions to the document will be reviewed, at a minimum, by the Vice President of Quality and approved by the President.

2.6 Personnel Training and Qualifications

Personnel assigned to implement elements of the QAM shall be capable of performing their

assigned tasks. To this end, Holtec establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the QAM to achieve initial proficiency, maintain proficiency, and adapt to technology changes, method, or job responsibilities. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include or address the following, as appropriate:

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

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

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

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

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

2.7 NQA-1 Commitment / Exceptions

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

- Section 302, Inspection and Test

  - *NQA-1-2008,* Requirement 2 includes use of Appendix 2A-1 guidance as if it were part of the Requirement. As an option to being certified as Level I, II, or III in accordance with NQA-1-2008, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel. For specific test activities (with the exception of NDE as covered by ASNT-TC-1A), an individual may be qualified via training and a capability examination for the specific testing activity being performed.

- Holtec follows Section 301 for qualification of nondestructive examination personnel, except that Holtec will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at construction sites for the scope of activities governed by these cited standards.

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

SECTION 3 DESIGN CONTROL

Holtec has established and implements a process to control the design and design changes of items that are subject to the provisions of the QAM. The design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within Holtec and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection and test, as required. Design change processes and the division of responsibilities for design-related activities are detailed in Holtec and supplier procedures. Changes to design inputs, final designs and field changes to operating facilities are justified and subject to design control measures commensurate with those applied to the original design. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the Holtec design organization or by other organizations so authorized by Holtec as appropriate.

Design documents are reviewed by individuals knowledgeable in the QAM to ensure the documents contain the necessary QAM requirements. QA personnel are included in the review process for quality related procedures associated with design.

3.1 Design Verification

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

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

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

identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.

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

3.2 Design Records

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

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

3.3 Computer Application and Digital Equipment Software

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

3.4 Setpoint Control

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

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

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

3.5 NQA-1 Commitment

In establishing its program for design control and verification, Holtec commits to compliance with NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3. In addition, Holtec commits to NQA-1 Subpart 2.7 for computer software, NQA-1 Subpart 2.14 for Quality Assurance requirements for commercial grade items and services and, as applicable for construction activities, and NQA-1, Subpart 2.20 for subsurface investigation requirements.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

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

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

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

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1 NQA-1 Commitment / Exceptions

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

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

- Section 300 and 400 of Requirement 4 require the review of technical and Quality Assurance Program requirements of procurement documents prior to award of a contract and for procurement document changes. Holtec may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and quality assurance requirements of the procurement.

- Procurement documents for Commercial Grade Items that will be procured by Holtec for use as safety-related items shall contain technical and quality requirements as applicable, such that the procured item can be appropriately dedicated in accordance with the Holtec QAM, Section 7, "Control of Purchased Material, Equipment and Services."

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Holtec has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAM. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff, instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

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

5.2 Procedure Content

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

5.3 NQA-1 Commitment

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

SECTION 6 DOCUMENT CONTROL

Holtec has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are conducted to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

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

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

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

6.1 Review and Approval of Documents

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

Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

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

6.3 NQA-1 Commitment

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

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

7.1 Acceptance of Item or Service

Holtec establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item or service importance to safety, complexity, quantity, and the frequency of procurement. Verification actions may include testing, as appropriate, during design, manufacturing or construction activities. Verifications occur at the appropriate phases of the procurement process, and may include, as necessary, verification of activities of suppliers below the first tier.

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

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

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

7.2 NQA-1 Commitment / Exceptions

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

- Holtec considers that other 10 CFR Parts 50 and 52 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to Holtec are not required to be evaluated or audited.
- When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

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

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

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

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

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

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

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

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

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

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

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

Holtec has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication and construction as applicable so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1 NQA-1 Commitment

In establishing provisions for identification and control of items, Holtec commits to compliance with NQA-1-2008, Requirement 8.

SECTION 9 CONTROL OF SPECIAL PROCESSES

Holtec has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include, as applicable, assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Records are maintained, as appropriate for the currently qualified personnel, processes and equipment for each special process. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1 NQA-1 Commitment

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

SECTION 10 INSPECTION

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

10.1 Inspection Program

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

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

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as rejection, acceptance, and re-inspection results, and the person(s) performing the inspection.

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

10.2 Inspector Qualification

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

10.3 NQA-1 Commitment / Exceptions

In establishing inspection requirements, Holtec commits to compliance with NQA-1-2008, Requirement 10. For new plant construction activities, as applicable, Holtec also commits to Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements. Procedures to incorporate applicable elements of Subparts 2.4, 2.5 and 2.8 shall be established prior to implementation of applicable construction activities.

The following clarifications apply:

- Subpart 2.4 commits Holtec to IEEE 336-1985, which refers to IEEE 498-1985. Both IEEE 336-1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. Holtec commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.

- An additional exception to Subpart 2.4 is addressed in Part II, Section 12 of the QAM.

SECTION 11 TEST CONTROL

Holtec has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAM will perform satisfactorily in service. Test programs include criteria for determining when testing is required in order to demonstrate that performance of equipment and plant systems is in accordance with design. Testing programs also include provisions to establish and adjust test schedules, and to maintain status for periodic or recurring tests when applicable. Tests are performed according to applicable procedures that include, as applicable and consistent with the effect on safety: (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, (4) mandatory verification points as necessary to confirm satisfactory test completion, (5) any special qualification requirements for personnel and (6) any special environmental conditions. Test results are documented and evaluated by the organization performing the tests. Test records are traceable to the item(s) tested. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

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

11.1 NQA-1 Commitment for Computer Program Testing

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

11.2 NQA-1 Commitment

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

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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

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

12.1 NQA-1 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, Holtec commits to compliance with NQA-1-2008, Requirement 12 with the following clarification and exception:

- For applicable Holtec construction activities, NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, Holtec will implement the QA requirements of NQA-1-2008, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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

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.

13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components within the plant. This includes as applicable, control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment. Housekeeping practices help assure that only proper materials, equipment, processes, and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions are developed and used as appropriate.

13.2 NQA-1 Commitment / Exceptions

In establishing provisions for handling, storage, and shipping, Holtec commits to compliance with NQA-1-2008, Requirement 13. Holtec also commits during applicable manufacturing and construction activities, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1 and Subpart 2.2. Holtec also commits to Subpart 2.3 for applicable construction activities only. The following clarifications and exceptions apply:

- Subpart 2.1, Section 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, Holtec may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. Holtec establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness.

- Subpart 2.2, Section 202 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the manufacturing activities, Holtec may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage.

- Subpart 2.2, Section 606, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, Holtec documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel when applicable. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

Holtec has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAM in order to maintain personnel and plant safety and avoid inadvertent use/operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In the case where temporary modifications are incorporated during construction activities, the modifications shall be controlled in accordance with written instructions

Administrative controls are implemented when altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations as appropriate.

14.1 NQA-1 Commitment

In establishing measures for control of inspection, test and operating status, Holtec commits to compliance with NQA-1-2008, Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Holtec has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Nonconformances are corrected or resolved prior to operation of 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. Nonconformance dispositions are reviewed for adequacy. Analysis of quality trends related to nonconforming conditions are performed periodically and reported to management. Significant trends are reported to management in accordance with Holtec procedures, regulatory requirements, and industry standards.

15.1 Interface with the Reporting Program

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

15.2 NQA-1 Commitment

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

SECTION 16 CORRECTIVE ACTION

Holtec has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Holtec procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Holtec procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, Holtec documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

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

16.1 Interface with the Reporting Program

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

16.2 NQA-1 Commitment

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

SECTION 17 QUALITY ASSURANCE RECORDS

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

17.1 Record Retention

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

17.2 Electronic Records

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

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

17.3 NQA-1 Commitment / Exceptions

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

SECTION 18 AUDITS

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

18.1 Performance of Audits

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

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

The audits are scheduled on a formal preplanned audit schedule and in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity and to assure that each applicable element of Holtec's QAP is audited at least once each year. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Corporate Quality Assurance Manager.

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

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

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

18.2 NQA-1 Commitment

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

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

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

Specific program controls are applied to nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

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

1.1 Organization

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

1.2 QA Program

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

1.3 Design Control

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

1.4 Procurement Document Control

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

1.5 Instructions, Procedures, and Drawings

Holtec provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, 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 functional performance of

the SSC.

1.6 Document Control

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

1.7 Control of Purchased Items and Services

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

1.8 Identification and Control of Purchased Items

Holtec 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 employs process and procedure controls for special processes, including, but not limited to welding and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

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

1.11 Test Control

Holtec employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

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

1.16 Corrective Action

Holtec employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17 Records

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

1.18 Audits

If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and 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 1.18).

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

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

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

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

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

PART IV REGULATORY COMMITMENTS

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

NRC Regulatory Guides and Quality Assurance Standards

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

Regulatory Guides:

Regulatory Guide 1.8, (Rev. 3, May 2000), Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

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

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

Regulatory Guide 1.26 defines classification of systems and components.

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

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

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

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

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

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

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

Regulatory Guide 1.37, (Revision 1, March 2007) – Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

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

Regulatory Guide 1.54, (Revision 2, October 2010) - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

For applicability of RG 1.54 and any clarifications or alternatives, FSAR Chapter 1 and/or 6 should be consulted.

Standards:

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

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

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

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