HOLTEC INTERNATIONAL

QUALITY ASSURANCE MANUAL

REVISION 13	DATE OF ADOPTION:

DOCUMENT STATUS:

REVISION TYPE:	Complete Revision	☐
	Revisions Designated with Bars	☒

The Holtec Quality Assurance Manual (HQAM) is the supreme controlling document in all spheres of the company's "safety-significant" activities pursuant to the provisions of 10CFR50 Appendix B, 10CFR72 Subpart G, and 10CFR71, Subpart H. "Read-only and print enabled" text of this document is maintained in the company's network under the directory n:\public\qainfo\hqam\ for immediate access to all Holtec personnel. The QA Manual provides mandatory programmatic requirements under eighteen discrete criteria arranged in eighteen sections listed in the Table of Contents that follows this cover page. The last page of this document is so identified.

Hardcopies of this manual are not maintained or controlled within the Company, except for copies held by the QA Manager or his designee.

This document is also provided to selected external organizations that maintain a QA interface with Holtec International. The record of all external distributions of this document is documented and controlled through a database on the company's network.

The external recipient of this document must accept full responsibility for its confidentiality, and for ensuring that the latest revision issued by Holtec International is utilized in the recipient organization's work.

FS2

TABLE OF CONTENTS

Statement of Management Policy 1
Preface 2
Corporate Charter and Activity 4
Definitions 5

1.0 Organization 12

2.0 Quality Assurance Organization 14

3.0 Design Control 17

4.0 Procurement Document Control 20

5.0 Instructions, Procedures, and Drawings 23

6.0 Document Control 25

7.0 Control of Purchased Materials, Equipment, and Services 27

8.0 Identification and Control of Materials 30

9.0 Control of Special Processes 32

10.0 Inspections 33

11.0 Test Control 35

12.0 Control of Measuring and Test Equipment 37

13.0 Handling, Storage, and Shipping 39

14.0 Inspection, Operating, and Test Status 40

15.0 Nonconforming Materials, Parts, or Components 41

16.0 Corrective Action 43

17.0 Quality Assurance Records 45

18.0 Quality Assurance Audits 47

STATEMENT OF MANAGEMENT POLICY

Holtec International provides engineering design, analysis and consulting services to the power and process industries. The company also supplies fabricated equipment/components and site construction services to a wide variety of industrial sectors including nuclear power plants. For projects involving *safety-significant* (*safety-related* and *important-to-safety)* goods and services for nuclear plants, it is the policy of Holtec International to perform project activities in accordance with quality assurance practices described in the Holtec Quality Assurance Manual and its daughter documents. This manual meets the applicable provisions of 10CFR50 Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, and applicable codes, standards, and regulatory requirements governing the execution, control, and monitoring of all activities designated as *safety-related* or *important-to-safety.*

It is the responsibility of the President of Holtec International to establish policies, goals, and objectives of the Quality Assurance Program and to establish the necessary quality organization to assure that the company's program is being properly implemented in accordance with the stipulation of this Quality Assurance Manual.

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

All Holtec personnel authorized to work under the company's QA program must be familiar with the contents of this manual. Personnel whose activities are governed by this manual are directly responsible for implementing the program and the procedures applicable to their activities.

PREFACE

The Holtec Quality Assurance Manual (HQAM) is the premier document which delineates quality related requirements in all aspects of a Holtec contract, such as interface of Holtec personnel with the customer, development of Holtec operating procedures, management review of the quality program for evaluation of effectiveness, self-assessment, root cause evaluation, implementation of corrective action program, procurement document control, internal audit program, indoctrination of personnel and personnel certification, and reporting requirements for defects and non-conformances under Federal laws (10CFR21).

The central goal of this Quality Assurance Manual may be broken down into three discrete items, namely:

(1) To provide a clear and comprehensive description of the quality assurance commitments of the Holtec organization, in keeping with 10CFR50 Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, the Statement of Management Policy, and generally recognized industry codes and standards.

(2) To provide the framework from which Holtec Quality Procedures (HQPs) can be evolved to control the day-to-day QA related functioning of company personnel.

(3) To provide a clear portrayal of the organizational layout and corporate activities to enable an autonomous audit team to obtain a complete understanding of the company's corporate profile and quality practices so as to enable the team to conduct an effective audit.

This manual does not seek to provide detailed, specific requirements for implementation of 10CFR50 Appendix B, 10CFR71 Subpart H, and 10CFR72 Subpart G. Rather, this manual only discusses the upper-tier, general requirements of the Quality Assurance Program. The details of implementation are left to the Holtec Quality Procedures and other types of procedures permitted by the Holtec Quality Assurance Program.

This main text of this manual is organized into eighteen (18) sections. These sections mirror the eighteen criteria of 10CFR50 Appendix B, 10CFR71 Subpart H, and 10CFR72 Subpart G. Each of the eighteen sections are divided into five (5) subsections as follows:

1.0 Purpose-This sub-section defines the objective of the Quality Assurance Program element.

2.0 Applicability-This sub-section discusses the types of activities that the Quality Assurance Program element seeks to control.

3.0 Policy-This sub-section documents the main programmatic requirements of the Quality Assurance Program element described in sub-section 1.0.

4.0 Responsibilities-This sub-section defines, as applicable, key responsibilities of corporate positions within the Holtec organizational structure as they relate to the Quality Assurance Program element.

5.0 Implementation-This sub-section states that procedures shall be used to implement the programmatic requirements documented in sub-section 3.0, and the specific requirements the procedures must control, if applicable.

Every effort is made to use clear and consistent terminology throughout this manual. Terminology that is commonly used throughout the manual is defined, as applicable, in the Definitions section. Usage of the term "*Safety-Significant*" throughout this manual refers to items, systems, or structures that are "*safety-related*" within the purview of 10CFR50 and "*Important-to-Safety*" under 10CFR72. The notion of graded approach to *Important-to-Safety* (ITS) components, structures, and systems is an integral part of the quality implementation under the provisions of 10CFR72 envisaged in this manual.

This manual is supplemented by a series of Quality Procedures labeled as HQP-1.0, 2.0, 2.1, etc. where the first digit indicates the corresponding section of this manual.

The original issue of this manual was adopted in December 1986. In the subsequent years, revisions have been issued to incorporate the lessons learned from continued operations as well as from the experience of our clients and our suppliers. These revisions have continued to enhance the reach and effectiveness of the company's QA practices. Revisions to this manual will be issued in the future, as they have been in the past, at periodic intervals to enhance this document. The past and future revisions are in keeping with our company's belief that quality assurance is a journey, not a destination.

CORPORATE CHARTER AND ACTIVITY

Holtec International provides turnkey services to the nuclear power industry that includes design conceptualization, detailed design, analysis, material acquisition, manufactured equipment acquisition, and site construction services. Engineering analysis services are typically confined to thermal, mechanical, hydraulic, nuclear, criticality, shielding, structural, and radiological disciplines.

Engineered products and equipment and field installation/repair services are generally supplied through subcontracted manufacturing organizations and directly contracted field labor personnel that are qualified in accordance with Holtec Quality Assurance Manual (HQAM) and Holtec Quality Assurance Procedures (HQAP). Engineering analysis, design and consulting services are generally performed by personnel who are directly and continuously employed by Holtec International.

The company is also engaged in the development and licensing of *safety-significant* systems for use in the nuclear power industries, such as HI-STAR™ and HI-STORM™ Systems for long-term storage in an inert environment and off-site transport of spent nuclear fuel.

DEFINITIONS

Approval:	An act of endorsing, or adding positive authorization, or both.
Appurtenance:	A part that is attached to a component which has been completed.
As-Built Data:	Documented data that describe the condition actually achieved in a product.
ASME:	American Society of Mechanical Engineers
Assembly:	A combination of subassemblies or components, or both, fitted together to form a unit.
Audit:	A planned and documented activity to determine through investigation or evaluation of objective evidence, the adequacy of, and adherence to, established procedures, instructions, specifications, codes, and other applicable contractual and licensing requirements, and the effectiveness of implementation.
AVL:	Approved Vendor List, documenting vendors qualified by Holtec to provide applicable *safety-related* or *important-to-safety* products or services.
Certification of Compliance:	A written statement, signed by a qualified party, attesting that the items or services are in accordance with specified requirements and accompanied by additional information to substantiate the statement.
Certificate of Conformance:	A written statement, signed by a qualified party, certifying that items or services comply with specific requirements.
Certified Test Report:	A written document, approved by a qualified party, that contains sufficient data and information to verify the actual properties of items and the actual results of all required tests.

Certification:	The act of determining, verifying, and attesting to, in writing, the qualifications of personnel or material.
Characteristic:	Any property or attribute of an item, process, or service that is distinct, describable, and measurable, as conforming or nonconforming to, specified quality requirements. Quality characteristics are generally identified in specifications and drawings that describe the item, process, or service.
Checks:	The tests, measurements, verifications, or controls placed on an activity, by means of investigations, comparisons, or examinations, to determine satisfactory condition, accuracy, safety, or performance.
Client:	A corporate entity which establishes a contract with Holtec International to procure goods and/or services from the company.
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.
Customer:	See "Client".
Defective Material:	A material or component that has one or more characteristics that do not comply with specified requirements.
Deviation:	Written authorization to depart from a particular requirement.
Documentation:	Any written or pictorial information in paper or electronic form describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
Examination:	An element of inspection consisting of investigation of materials, components, supplies, or services to determine conformance to those specified requirements that can be determined by such investigation. Examination is usually nondestructive and includes simple physical and manipulation, gauging, and measurement.

Handling:	An act of physically moving material by hand or mechanical means, but not including transport modes.
Important-to-Safety (ITS):	A class of structure, system, or component whose function is: (a) To maintain the conditions required to store spent fuel or high-level radioactive waste safely; (b) To prevent damage to the spent fuel or the high-level radioactive waste container during handling and storage, or (c) To provide reasonable assurance that spent fuel or high-level radioactive waste can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.
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).
Manufacturer:	One who constructs any class of component, part, or appurtenance to meet prescribed design requirements.
Material:	A substance of combination of substances forming components, parts, pieces, equipment, or items (intended to include machinery, casting, liquids, formed steel shapes, aggregates, cement, etc.).
Modification:	A planned change in plant design or operation, accomplished in accordance with the requirements and limitations of applicable codes, standards, specifications, licenses, and predetermined safety restrictions.

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.
Objective Evidence:	Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements, or tests which can be verified.
Package:	A wrapping or container in which material or equipment has been enclosed.
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 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:	The execution phase of a contract established with a Client in which work is performed or produced.
Project Team:	All of the Holtec personnel and its contractors that are qualified and assigned to perform work on a Project under the direction of the Project Manager.
Purchaser:	The organization or organizations responsible for issuance and administration of a contract, subcontract, or purchase order.

Qualification (Personnel):	The characteristics are abilities gained through training or experience, or both, that enable an individual to perform a required function.
Qualified Party:	An organization authorized as knowledgeable and competent to perform certain functions.
Qualified Procedure:	A procedure which incorporates all applicable codes and standards, manufacturer's parameters, and engineering specifications, and has been proven adequate for its intended purpose.
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.
Receiving:	Taking delivery of an item at a designated location.
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.
Report:	Something (document) that gives information for record, narration and exposition purposes.
Rework:	The process by which a nonconforming item is made to conform to a prior specified requirement by completion, correction, remachining, 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 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.

Safety-Significant: A generic term to denote both *safety-related* and *important-to-safety* structures, systems, and components.

Source Surveillance: A review, observation, or inspection for the purpose of verifying that an action has been accomplished as specified at the location of material procurement or manufacture.

Specification: A concise statement of a set of requirements to be satisfied by a product, material, or process indicating, whenever appropriate, the procedure by which it may be determined whether the requirements given are satisfied.

Standard: The result of a particular standardization effort approved by a recognized authority.

Subsystem: A group of assemblies or components, or both, combined to perform a single function.

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.

System: A group of subsystems united by some interaction or interdependence, performing many duties but functioning as a single unit.

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 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.

SECTION 1.0: ORGANIZATION

1.0 PURPOSE

To establish the Holtec International organizational structure, and the authority and duties of personnel performing activities that bear upon the quality of *safety-significant* functions of structures, systems, and components.

2.0 APPLICABILITY

This section applies to all *safety-significant* activities. These activities include performing the functions associated with attaining quality objectives and quality assurance functions. The quality assurance functions are:

A. Assuring that an appropriate quality assurance program is established and effectively executed;

B. Verifying by procedure(s) such as checking, auditing, monitoring, and inspection that activities affecting the *safety-significant* functions have been performed correctly.

3.0 POLICY

3.1 A Corporate Organization shall be established to implement the Quality Assurance Program, to ensure that the implementation is carried out faithfully and diligently, to maintain an open and questioning environment, to eliminate conditions that may lead to detraction from quality, and to facilitate a continuous enhancement of quality.

3.2 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.

3.3 The person(s) responsible for overall implementation of the Quality Assurance Program shall have a direct line of communication to the sponsor of the quality program (Holtec President) such that the required authority and organizational freedom (including sufficient independence from cost and schedule) to insure the primacy of quality considerations are present.

4.0 RESPONSIBILITIES

4.1 The quality assurance responsibilities of key personnel shall be defined in the implementing procedure(s).

4.2 Irrespective of specific responsibilities defined, functions may be delegated to other qualified personnel within the organization provided that:

i. individual is determined to be qualified to perform the function by the company's executive management
ii. delegating individual retains full responsibility for the work performed

4.3 Regardless of the organizational structure, the person(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform the required functions without hindrance.

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies in Subsection 3.0 and shall define the corporate and quality assurance organizational structure of Holtec International; an organization chart shall be included in the implementing procedure(s).

5.2 Documentation of activities performed by the company's personnel may be carried out in the electronic form, or in paper form. Required duration for maintaining retrieval capability of all types of documentation generated by the company and other parties on a *safety-significant* project are spelled out in the applicable Holtec quality procedure.

SECTION 2.0: QUALITY ASSURANCE PROGRAM

1.0 PURPOSE

To establish the requirements for planning, managing, and implementing the Holtec Quality Assurance Program. This section also establishes the requirements for control of this Manual and training of personnel responsible for performing and verifying activities that bear upon quality.

2.0 APPLICABILITY

The Quality Assurance Program applies to all activities affecting the *safety-significant* functions of those structures, systems, and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

3.0 POLICY

3.1 This program shall be in conformance with the applicable requirements of 10CFR50 Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, 10CFR21, and NQA-1.

3.2 The Quality Assurance Program, as described in this manual, delineates the measures established by Holtec to assure that activities that affect the quality of *safety-significant* structures, systems, components, and services are performed in a controlled manner and are sufficiently documented to provide objective evidence of compliance with established requirements. Control over activities that bear upon the quality of items, services, or components shall be to an extent consistent with their importance to safety and as necessary to assure performance to specified requirements. The applicable requirements of the program are also imposed upon suppliers and consultants.

3.3 Because the quality assurance requirements of 10CFR50, Appendix B, 10CFR71 Subpart H, and 10CFR72 Subpart G are considered by Holtec management to be mandatory elements of a total quality assurance program, the Holtec Quality Assurance Program is structured directly to fulfill and comply with these requirements on all *safety-significant* projects.

3.4 Indoctrination and training shall be completed prior to performing any activities that may bear upon quality. Indoctrination and training may be achieved by formal presentation, required reading, on the job training, e-mail instructions, reading of company Administrative Memorandums, Position Papers, and Standard Procedures or any combination thereof. Indoctrination and training shall be documented in paper or electronic form.

3.5 Distribution of the Quality Assurance Manual shall be controlled by a database that uniquely identifies the name and affiliation of the recipient.

A. All hardcopies of the Quality Assurance Manual shall be considered uncontrolled, except for the copy(ies) in the custody of the company's QA Manager. The QA Manager's hard copy shall bear his signature on the cover page to indicate that the copy is controlled and that it is the latest revision.

B. An up-to-date copy of the QA Manual shall be maintained in the company's computer network system, in N:\Public\QAInfo\HQAM.

C. The QA Manager may provide his controlled copy to any of the company's personnel on a temporary basis to allow the person to work at a location where the electronic copy is not accessible.

D. Earlier revisions of the Quality Assurance Manual shall not be maintained in general and/or public work areas of Holtec; these shall be destroyed, except that one copy of the preceding revision shall be maintained in electronic or hardcopy storage.

3.6 Graded requirements applicable to the class of a *safety-significant* item or service (namely, (i) safety related (ii) ITS Category A, (iii) ITS Category B, and (iv) ITS Category C) under Sections 1 through 18 of this QA Manual shall be set down in implementing procedure(s). The implementing procedures shall conform to 10CFR50 Appendix B for *safety-related* items and services, and 10CFR72 Subpart G and 10CFR71 Subpart H for *important-to-safety* items and services.

4.0 RESPONSIBILITIES

4.1 The Holtec Quality Assurance Manager has the direct responsibility for:

A. Ensuring that this Quality Assurance Program is implemented and that it provides for control of all activities that bear upon quality on *safety-significant* projects; also responsible for ensuring that the program is modified and updated as standards, regulations, results, and experience dictate.

B. Conducting periodic indoctrination of Holtec personnel in person or through e-mail who are actively involved in nuclear *safety-significant* work. The indoctrination effort will be aimed to foster a clear understanding of the intent and objectives and procedures of the QA program. All new company employees must be subject to QA indoctrination to the extent judged appropriate by the QA Manager.

C. Ensuring that personnel who perform, verify, or manage activities that bear upon quality, receive indoctrination and/or training. The extent of the indoctrination or training shall be commensurate with the scope, complexity, and nature of the activity and the education, experience, and proficiency of the person.

4.2 The President of Holtec is responsible to maintain a constant vigil on the effectiveness of the Holtec QA Program and to effectuate a formal internal and site self-assessment at approximately annual intervals.

4.3 Additional responsibilities for the above and other personnel shall be defined in implementing procedures.

5.0 IMPLEMENTATION

5.1 The Holtec Quality Assurance Program is described by this QA Manual, and implemented through Holtec Quality Procedures, Holtec Project Procedures, Holtec Standard Procedures, and other procedures as needed.

5.2 A Project Plan is developed for each *safety-significant* project to assure a controlled execution of the project in accordance with the provisions of this manual.

5.3 The latest revision of this Manual and *all* Holtec quality procedures (HQPs) that a project team can utilize in the execution of a project shall be maintained in the company's electronic network and shall be made accessible to all Holtec project team personnel for ready reference.

SECTION 3.0: DESIGN CONTROL

1.0 PURPOSE

To establish measures to assure that applicable regulatory requirements and design bases for *safety-significant* structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions. This section also establishes the methods to assure that design activities are prepared, reviewed, approved, and made available in a controlled manner.

2.0 APPLICABILITY

2.1 This policy applies to Holtec activities associated with the control of the design and design documents for *safety-significant* items and services.

2.2 The applicability of these procedures shall include: design considerations and design review requirements; internal and external interface control consideration; and design document review, approval, distribution, control, and revision requirements.

3.0 POLICY

3.1 Design considerations include, as appropriate, physics, stress, materials, thermal, hydraulic, radiation, accident and other multi-disciplinary analyses; appropriate design bases, codes, standards, and regulations; and acceptance/rejection criteria.

3.2 *Safety-significant* design documents shall be subject to review for compliance to Holtec quality standards.

3.3 *Safety-significant* design documents shall be issued and maintained in accordance with document control and quality assurance records provisions of this Quality Assurance Program.

3.4 Design analyses (including engineering calculations, quantitative studies and assessments) shall be performed in a planned, controlled, and correct manner. Analyses shall be legible and in a form suitable for reproduction, filing, and retrieving. Analyses shall be sufficiently detailed as to purpose, method, assumptions, design input, identification of any computer programs used, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the results without recourse to a discussion with the originator. Documented analyses shall be identifiable by subject,

customer (job or contract), system or component. Design analyses shall be documented in a uniquely numbered document that can be located in hardcopy or in the company's electronic database by project team personnel.

3.5 Design and review functions maybe performed by technically competent individuals that are not full time employees of Holtec International; these activities must be in accordance with Holtec's QA procedures and only when qualifications of such individuals are reviewed and approved according to the company's personnel certification program.

3.6 Completed design documents may be submitted to the customer for approval, or for information, as specified in the contract documents. However, Holtec continues to bear full responsibility for meeting the requirements of the company's Quality Assurance Program.

3.7 Design verification encompasses the process of checking the adequacy of a design. Checking shall be performed by competent individuals or groups other than those who performed the original design, but who may be from the same organization. However, if an element of the design is checked by someone other than the overall verifier, the verifier is not required to recheck the element. Verification involves checking the adequacy of the overall design process.

3.8 The extent of design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with this Quality Assurance Program, the verification process need not be duplicated for identical designs. A design verification shall be performed to account for changes to design inputs, however, to confirm the applicability of previously proven designs.

3.9 Acceptable methods of performing design verification include any one or a combination of the following:

i. Design Reviews: This method shall be performed in accordance with a checklist(s) containing sufficient criteria necessary to verify the adequacy of those design elements checked under this method.

ii. Alternate Calculations or Simplified Calculations: These are calculations or analyses that are made with alternate or simplified methods to verify correctness of the original calculations or analyses.

iii. Qualification Tests: A test program used to verify the adequacy of design. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Where a test program is used to verify the adequacy of a specific design feature in lieu of other

verifying or checking processes, suitable qualification testing of a prototype or sample unit under the most adverse design conditions (or a simulation of those conditions) shall be performed.

3.10 The record of the design verification conducted on a document shall be available in the company's network or in hardcopy, as appropriate.

4.0 RESPONSIBILITIES

4.1 Responsibilities for design control activities for *safety-significant* projects shall be assigned in Holtec implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedures shall be prepared to implement the policies in Subsection 3.0 and shall incorporate appropriate design control practices, checks, and reviews.

5.2 Procedures shall be established to ensure that design inputs (such as design bases, regulatory requirements, and codes and standards) are identified and documented and to the level of detail necessary to permit the design activity to be carried out in a correct manner

5.3 The design bases are specified in whole or in part by the customer's procurement documents that delineate technical and quality requirements. When deemed appropriate by the company Project Manager, Holtec shall develop a stand-alone "design specification" or "design criteria" document.

5.4 Design activities shall be documented in accordance with procedures that meet the requirements of industry standards and codes. The design activities shall be conducted in a manner that permit reviewing, checking, verifying, and auditing by competent personnel, such that the final design can be related to the source of the design input.

5.5 Procedures shall be established for the preparation and control of drawings.

5.6 Procedures shall be established for the preparation and control of other design documents such as Specifications, Technical Reports, and Calculation Packages.

5.7 Procedures shall be established for the control of design interfaces and for managing the flow of design information between Holtec, the customer, participating design organizations and qualified individuals contracted by Holtec International.

SECTION 4.0: PROCUREMENT DOCUMENT CONTROL

1.0 PURPOSE

To establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipments, and services whether purchased by Holtec or by its contractors and subcontractors.

2.0 APPLICABILITY

This policy applies to all Holtec activities associated with the preparation, review, approval and control of procurement documents, including changes, which contain the necessary information for supplier compliance with the purchase order and applicable regulatory, code, and industry standard requirements. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with 10CFR50 Appendix B, 10CFR71 Subpart H, and 10CFR72 Subpart G, as applicable. The procurement documents shall also specify, when applicable, that the provisions of 10CFR21 apply.

3.0 POLICY

3.1 Purchase orders shall be prepared by personnel on the Project Team for the procurement of materials, parts, components, or services. The person initiating a purchase order shall ensure that all applicable items indicated above are included in the procurement document(s). All *safety-significant* purchase requisitions shall be subject to at least one independent review concurrence. The Quality Assurance department shall conduct required surveillances to ensure that *safety-significant* purchase orders are being issued in accordance with this QA Manual and its implementing procedures.

3.2 The independent review of the procurement documents will include checks to verify that proper codes, regulatory requirements, material specifications (ASME, ASTM, AWS, etc.) are invoked, that appropriate acceptance or rejection criteria are incorporated, and that Quality Assurance Manual requirements are incorporated. Purchase orders for the procurement of materials, parts, components, or services for *safety-significant* projects shall be subject to approval by the Project Manager or his designee.

3.3 Purchase orders shall be issued only after they have received the required approvals and concurrences described above. Changes to purchase orders shall be subject to the same review and approval process as the original purchase order.

4.0 RESPONSIBILITIES

4.1 The Project Manager shall be responsible for delegating appropriate personnel to write and review purchase orders on his (her) project.

4.2 The QA Manager is responsible, through periodic surveillances or review to ensure that the quality provisions in purchase orders for *safety-significant* projects are consistent with this QA Manual and its implementation procedures.

5.0 IMPLEMENTATION

5.1 Procedures shall be established to delineate the sequence of actions to be accomplished to control the preparation, review, approval and issuance of procurement documents for *safety-significant* items and services.

5.2 The procedures shall require that all *safety-significant* procurement documents include provisions for the following, as applicable:

A. A statement of the scope of work to be performed by the supplier.

B. Identification of the design basis technical requirements by reference to specific drawings, specifications, codes, regulations, industry standards, or other documents that describe the items or services to be furnished.

C. Identification of test, inspection, and acceptance requirements, and any special instructions and requirements for such activities as design, fabrication, identification, cleaning, erecting, packaging, handling, shipping, and extended storage.

D. Identification of the Quality Assurance requirements that must be met by the supplier.

E. Clear delineation of the applicability of 10CFR21 for *safety-significant* systems, components, and structures.

F. Identification of the documentation (such as drawings, specifications, procedures, fabrications and inspection plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results) to be prepared and maintained by the supplier and requirements for submittal to Holtec for review and approval.

G. Holtec's right of access to the supplier's facilities and records to facilitate inspection and audits, as deemed necessary.

H. Extension of applicable requirements to lower tier suppliers, including Holtec's and customer's right of access to facilities and records.

I. Reporting and approving "use-as-is" or "repair" dispositions of nonconformances.

SECTION 5.0: INSTRUCTIONS, PROCEDURES, AND DRAWINGS

1.0 PURPOSE

To establish requirements to assure that activities that bear upon quality are prescribed by documented instructions, procedures, and drawings.

2.0 APPLICABILITY

This policy is applicable for all *safety-significant* activities and prescribes the requirements for developing instructions, procedures, and drawings for quality-related activities as required by this manual.

3.0 POLICY

3.1 Measures shall be established and documented to assure that activities affecting the quality of *safety-significant* items and services are appropriately prescribed in controlled instructions, procedures, and drawings and are accomplished in accordance with these documents.

3.2 Instructions, procedures, and drawings shall be prepared, reviewed, approved, and distributed prior to the start of the activity. The content and extent of detail contained in the instructions, procedures, and drawings shall be based on the complexity of the work to be performed and the understanding, skill, and knowledge of the user.

3.3 Instructions, procedures and drawings shall include appropriate quantitative and qualitative acceptance criteria for verifying that important activities have been satisfactorily accomplished.

3.4 Holtec procedures shall be designed to provide those detailed written instructions necessary to ensure compliance with 10CFR50, Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, 10CFR21, and ASME NQA-1, as applicable, and this Quality Assurance Manual.

4.0 RESPONSIBILITIES

4.1 The Quality Assurance Manager shall be responsible for issuance of Holtec Quality Procedures.

4.2 All Holtec Quality Procedures are subject to approval by the company's executive management.

4.3 The appropriate Project Manager is responsible to ensure that project-specific procedures and drawings are prepared, when necessary, and implemented in accordance with this Quality Assurance Manual.

4.4 Additional responsibilities of the above personnel and other personnel shall be defined in the implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedures shall be established to implement the policies in Subsection 3.0 and which define the responsibilities and delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, drawings, and associated changes or revisions.

SECTION 6.0: DOCUMENT CONTROL

1.0 PURPOSE

This section establishes the requirements for the control, identification, and distribution of quality-related documents.

2.0 APPLICABILITY

This policy applies to all documents affecting the quality of *safety-significant* services.

3.0 POLICY

3.1 Documents required to perform a specific activity shall be available at the location where the activity is to be performed during the work activity. Obsolete or superseded documents shall be controlled to prevent their inadvertent use.

3.2 Document review and control measures shall provide for the following:

A. Documents such as reports, procedures, specifications, drawings, etc., shall be prepared, reviewed, and approved by qualified personnel.

B. Each document shall have a unique identifying number.

C. Each document shall have means for identifying the revision status and approval or effective date of each revision.

D. Maintaining controlled documents current to the latest revision at appropriate locations.

3.3 Document changes shall be reviewed and approved in the same manner as the original document. The individuals or groups performing the review shall have access to pertinent background information and shall be competent to evaluate the intent and requirements of the original document.

3.4 Types of documents that are controlled to various degrees include, but are not limited to, Quality Assurance manuals, procedures, specifications, drawings, inspection and test results, procurement documents, and nonconformance and corrective action reports.

4.0 RESPONSIBILITIES

4.1 The Quality Assurance Manager is responsible for maintaining an effective document control system.

4.2 Additional description of responsibilities shall be defined in the implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedures shall be established to implement the policies in Subsection 3.0 and to provide for the control of documents, including changes thereto, which prescribe the activities that bear upon quality or safety, or which relate to quality.

SECTION 7.0: CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

1.0 PURPOSE

To establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement requirements consistent with the *safety-significant* designation of the acquisition.

2.0 APPLICABILITY

The requirements of this policy apply to all *safety-significant* material, equipment, and services (hereinafter referred to as the acquisition) procured. The requirements of this section applies to provisions, as appropriate, for source evaluation (audit, surveillance, source inspection) and receiving inspection.

3.0 POLICY

3.1 Quality requirements applicable to *safety-significant* acquisitions shall be clearly delineated in the appropriate Holtec quality procedure(s). The requirements set forth in the implementing procedure(s) shall be tailored to the *safety-significant* class (i.e., Safety-Related, *Important-to-Safety* Category A, B, or C) of the acquisition.

3.2 Measures shall be established, implemented, and documented to assure that purchased material, equipment, and services (whether procured directly or through suppliers) conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the supplier, quality surveillance and inspection and audit at the source, and inspection of products on delivery.

3.3 Documentary evidence that material and equipment conform to the procurement specifications shall be available prior to final installation or final use of the material or equipment at the client's facility.

If required by the *safety-significant* category of the acquisition, measures shall be implemented for performing a procurement source evaluation.

3.4 Source evaluation(s) shall include one or more of the following methods, appropriate to the "*Safety-Significant*" category of the acquisition.

A. An evaluation of the supplier's quality capability by review of the supplier's history of providing an identical or similar product that performs satisfactorily in use; the supplier's history shall reflect current capability

B. A review of the supplier's quality capability as determined by a review of the quality assurance program and a direct evaluation of the supplier's facilities and personnel and implementation of his quality assurance program.

C. A review of the supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated.

3.5 If required by the *Safety-Significant* designation of the acquisition, measures shall be established for the acceptance of an item or service procured from a supplier. Methods of acceptance shall include one or more of the following:

A. Certificate of Conformance: from an approved supplier, which shall document:

i. The purchased material or equipment and/or the purchase order number

ii. The specific procurement requirements met by the purchased material or equipment, such as codes, standards, and specifications

iii. Documentation that identifies procurement requirements which have not been met. This documentation shall include those nonconformances dispositioned as "accept-as-is" or "repair".

iv. Certification statement signed or otherwise authenticated by an authorized representative of the supplier

Where only the supplier certificates of conformance are used to verify the requirements met by the item, the validity of the supplier certificates of conformance shall be periodically evaluated by audits of the supplier's QA program or independent inspections or tests of procured items to assure that they are valid.

B. Source Surveillance or Inspection shall be performed at intervals appropriate to the importance and complexity of the item or service.

C. Receiving Inspection shall be performed in accordance with documented procedures to verify conformance with the requirements of the procurement documents. The type and degree of inspection to be performed to assure compliance with the purchase order and its included criteria and requirements is dependent upon the particular supplier, product, and degree of source verification (inspection, audit, or surveillance) performed. Receiving Inspections shall be documented.

3.6 Holtec shall maintain an Approved Vendor List (AVL) on the company's network which will list the class(es) of *Safety-Significant* acquisitions for which a vendor is qualified. Suppliers of *safety-significant* materials, equipment, and services must be on the AVL prior to commencement of work on *safety-significant* projects for Holtec, or a suitable restriction must be placed on the purchase order that the order may be cancelled if the vendor fails to meet certain quality requirements

3.7 The depth of the evaluation of a supplier being considered for the Approved Vendor List shall vary, depending on the complexity and *safety-significant* classification of the items the supplier furnishes.

3.8 Products and services may be procured from suppliers under direct control of Holtec's QA program in accordance with Holtec's QA procedures, if deemed necessary by Holtec's executive management.

4.0 RESPONSIBILITIES

4.1 The Quality Assurance Manager is responsible for quality assurance evaluation of the products and services supplied by vendors and qualification of prospective vendors for the AVL; the Quality Assurance Manager is also responsible for maintaining the AVL on the company's network.

4.2 Other responsibilities shall be defined in the implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedures shall be established to implement the policies described in Subsection 3.0.

SECTION 8.0: IDENTIFICATION AND CONTROL OF MATERIALS

1.0 PURPOSE

To establish measures for the identification and control of materials.

2.0 APPLICABILITY

The provisions of this section applies to the control of *safety-significant* material from receipt through manufacturing of items, components and equipment.

3.0 POLICY

3.1 Measures shall be established to ensure that no unidentified material is introduced in the manufacturing of a *Safety-Significant* system, structure, or component.

3.2 Measures shall be established to maintain material traceability and identification during the manufacturing cycle commensurate with the *Safety-Significant* designation of the item.

3.3 Controls shall be established to prevent the use, or submittal to clients, of incorrect or defective items, or of items that have not received the required reviews, inspections, or tests

3.4 Methods of marking materials and item(s) shall not detrimentally affect the function or service life of those items.

3.5 Materials and components fabricated for, or purchased by, Holtec shall have their identity uniquely established either on the item or by tags or records traceable to the item. Items that are subdivided shall retain their identification through a transfer of markings, tags, or traceable records.

3.6 Where required, inspections and test certifications shall be traceable to the item or material.

4.0 RESPONSIBILITIES

4.1 Responsibilities of applicable personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies in Subsection 3.0.

5.2 Suppliers shall be required to establish and use material identification and control procedures in accordance with applicable quality and procurement document requirements consistent with those set forth in this manual and its implementing procedures.

SECTION 9.0: CONTROL OF SPECIAL PROCESSES

1.0 PURPOSE

To establish measures to control special processes on Holtec *safety-significant* projects

2.0 APPLICABILITY

This policy applies to all Holtec activities pertaining to performing or securing services involving special processes, including welding, heat treating, and nondestructive testing.

3.0 POLICY

3.1 Measures shall be established to ensure that special processes are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, criteria, and other special requirements.

3.2 Suppliers shall be required to control special processes in accordance with applicable codes, standards, criteria, design specifications, and other special requirements.

3.3 The qualification records of personnel conducting the special processes shall be in accordance with the applicable codes, standards, criteria, specifications, and other special requirements. Where an appropriate national or recognized qualification and certification standards is not available, the qualification and certification requirements shall be established by the Holtec project team with assistance from the company's corporate engineering staff.

4.0 RESPONSIBILITIES

4.1 Specific responsibilities of applicable personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Holtec, as well as its suppliers, shall perform special processes in accordance with written procedures. The suppliers shall submit special process procedures, when required by the Purchase Order, to Holtec for review and approval.

5.2 Holtec may impose its own special process procedures on its supplier.

SECTION 10.0: INSPECTIONS

1.0 PURPOSE

To establish measures to perform inspections of materials, components and equipment, and examination/monitoring of activities that bear upon quality to assure that items designed, manufactured, and shipped adhere to applicable requirements.

2.0 APPLICABILITY

In general, Holtec does not directly engage in manufacturing and thus the provisions of this section typically apply to Holtec's suppliers who manufacture equipment under a *safety-significant* contract from Holtec. However, the provisions of this section shall apply to Holtec in those cases where the quality assurance responsibilities in a manufacturing process are directly assumed by the company.

3.0 POLICY

3.1 Measures shall be established to surveil and/or inspect activities that bear upon quality by or for the organization performing the activity, to verify conformance with documented instructions, procedures, and drawings for accomplishing the activity.

3.2 If direct inspection of processed material or products is not performed, then indirect control by monitoring of processing methods, equipment and personnel shall be provided in accordance with a written project procedure or surveillance plan.

3.3 Inspections shall be performed by individuals determined to be qualified to conduct the specific type of inspection by Holtec's QA Department. Inspections must be performed by individuals other than those who performed the activity being inspected.

3.4 Inspection holdpoints and witness points shall be indicated in the appropriate manufacturing documents. Work shall not proceed beyond holdpoints without the documented consent of the individual(s) responsible for accomplishing the inspection.

3.2 Inspection records shall, as appropriate, indicate the following:

A. Inspector or data recorder.
B. Type of observation.
C. Results.
D. Acceptability status.
E. Action taken in connection with any deficiencies noted.

4.0 RESPONSIBILITIES

4.1 Holtec's Quality Assurance Department shall be responsible for qualification of Holtec inspection personnel.

4.2 Additional responsibilities of personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Inspections of materials, components and equipment shall be performed in accordance with Holtec quality and project inspection procedures. A supplier's inspection procedure that meet the criteria of this section and Holtec's overall QA program may be used upon Holtec 's approval of the supplier's procedures or QA program, as appropriate.

SECTION 11.0: TEST CONTROL

1.0 PURPOSE

To establish measures to provide for testing of materials, computer codes, components, systems, etc. (hereafter referred to as the "item").

2.0 APPLICABILITY

The commitments of this section will apply to Holtec's supplier or Holtec, depending on the type and scope of the project where testing is required, to demonstrate that the item will perform satisfactorily in service.

3.0 POLICY

3.1 When testing is required to demonstrate that an item will perform satisfactorily in service, measures shall be established to control such testing.

3.2 Tests shall be documented and evaluated; test records shall include the following, as appropriate.

A. The tester or data recorder.
B. Type of observation.
C. Results.
D. Status of acceptability.
E. Action taken in connection with any deficiencies noted.

4.0 RESPONSIBILITIES

4.1 The Project Team is responsible for developing, for their review of and the adoption of, appropriate test procedures.

4.2 The Quality Assurance Department is responsible for conducting periodic surveillance to ensure that the provisions of this section and the associated implementing procedures are followed by the Project Teams.

4.3 Additional responsibilities of personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Unless the specific testing is a physically trivial activity, Holtec or its supplier shall use written procedures or instructions or plans for testing. These procedures or plans shall include, as applicable, acceptance criteria, provisions for meeting prerequisites, stipulation of appropriate test equipment, and performance of test under suitable environmental conditions.

SECTION 12.0: CONTROL OF MEASURING AND TEST EQUIPMENT

1.0 PURPOSE

To establish measures for control of measuring and test equipment used in *safety-significant* items.

2.0 APPLICABILITY

In the event a Holtec project requires the use of measuring and test equipment, the commitments of this section will be invoked.

3.0 POLICY

3.1 Measuring and Test Equipment (M&TE) shall be calibrated against certified equipment having known valid relationship to nationally recognized standards. Where no nationally recognized standards exist, the bases for calibration shall be documented.

3.2 M&TE shall be traceable to calibration records and shall be identified by unique serial or control number(s).

3.3 Approved suppliers may calibrate and inspect their own measuring and testing equipment, or they may use the services of an approved standards laboratory.

4.0 RESPONSIBILITIES

4.1 Specific responsibilities for applicable personnel shall be defined in the implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to assure that tools, gauges, instruments, and other measuring and testing devices used in activities that bear upon quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

SECTION 13.0: HANDLING, STORAGE, AND SHIPPING

1.0 PURPOSE

To establish measures for controlling, handling, storage, shipping, cleaning, and preservation of materials, equipment, or items in order to preclude damage and deterioration.

2.0 APPLICABILITY

The policy provisions of this section govern handling, storage and shipping and preservation of all *safety-significant* materials and items.

3.0 POLICY

3.1 Measures shall be established for the preservation, handling, storage, packaging, and shipping of materials, items, and components by such methods as required to prevent deterioration or damage.

3.2 When necessary for particular products, special protective environments, such as moisture content, temperature, and inert gaseous environments, must be specified in applicable procedures and the necessary environment provided.

3.3 The handling, storage, preservation, packaging, and shipping requirements above shall be met by Holtec, either directly or through imposition of applicable requirements on the suppliers.

4.0 RESPONSIBILITIES

4.1 Specific responsibilities of applicable personnel shall be defined in implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedures shall be prepared for the preservation, cleaning, handling, storage, and shipping of project materials to prevent damage or deterioration of all project items and components.

SECTION 14.0: INSPECTION, OPERATING, AND TEST STATUS

1.0 PURPOSE

To establish measures to indicate by suitable means, the status of inspection and test or quality status of materials, items, and components.

2.0 APPLICABILITY

The provisions of this section apply to identifying the status of items and components manufactured for Holtec.

3.0 POLICY

3.1 Measures shall be used to ensure, as applicable, that suitable marking methods such as tags, stamps, labels, or routing cards are used to identify the test or inspection status of an item. Status may also be indicated by physical location, such as a QA Hold Area.

3.2 Measures shall provide for identifying those item(s) that have satisfactorily passed required tests or inspections, where necessary to preclude inadvertent bypassing of such inspections and tests.

3.3 Measures shall be established to identify the operating status of components, such as tagging valves and switches, to prevent inadvertent operation.

4.0 RESPONSIBILITIES

4.1 Specific responsibilities of applicable personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies in Subsection 3.0, and shall include appropriate details dealing with the authority and execution of application/removal of tags, labels, stamps, etc.

SECTION 15.0: NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

1.0 PURPOSE

To establish measures to control materials, parts, components, items, services, or documentation which do not conform to requirements set forth in the governing project documents in order to prevent their inadvertent use or installation.

2.0 APPLICABILITY

This policy applies to all Holtec activities associated with the identification and control of *safety-significant* items, services, or activities which do not conform to technical or quality requirements.

3.0 POLICY

3.1 Measures shall be established to control material, parts, or components, which do not conform to specified requirements in order to prevent their inadvertent use or installation.

3.2 Measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations

3.3 Measures which control further processing, delivering, or installation of a nonconforming or defective item pending a decision on its disposition shall be established and maintained.

3.4 Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

3.5 Nonconformance evaluation and documentation processes shall include the provision to evaluate the nonconformance for potential reportability under 10CFR21.

4.0 RESPONSIBILITIES

4.1 It is the responsibility of any personnel functioning under the rubric of Holtec's QA Program who detects a nonconformance to report it in accordance with the applicable nonconformance procedure(s).

4.2 The Quality Assurance Department is responsible for ensuring that nonconformances, which are identified by means of quality assurance inspections or audits, are resolved in accordance with nonconformance and audit procedures. The Quality Assurance Department is also responsible to maintain nonconformance reports on file.

4.3 Additional responsibilities of personnel shall be defined in implementing procedure(s).

5.0 IMPLEMENTATION

5.1 Procedures shall be established to implement the policies in Subsection 3.0.

5.2 Procedure(s) shall be prepared for evaluating and reporting of defect(s) and noncompliances in accordance with 10CFR21 when applicable.

SECTION 16.0: CORRECTIVE ACTION

1.0 PURPOSE

To establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and repeated nonconformances are promptly identified and corrected.

2.0 APPLICABILITY

This policy applies to all functions performed by Holtec and its subcontractors associated with the identification and correction of conditions adverse to quality for *safety-significant* items, services, or activities.

3.0 POLICY

3.1 Measures shall be established to identify conditions adverse to Quality. These conditions may be item related, programmatic, and/or indicative of an adverse trend (i.e., multiple nonconformances in a single area within a short time).

3.2 Measures and implementing procedures to segregate non-conformances into those that have an insignificant effect on quality and those that may be characterized as materially adverse to quality.

3.3 In the case of conditions adverse to quality, measures must provide for determination of the cause (root cause or apparent cause, as applicable) of the condition and corrective action(s) required to preclude recurrence.

3.4 Appropriate documentation on the condition adverse to quality, the cause of the conditions, and the corrective actions taken to rectify the condition(s), shall be prepared and maintained in the company's quality files.

3.5 Measures shall be established to ensure that adverse condition(s), cause(s), and correction action(s) are reported to the appropriate levels of management in the company.

4.0 RESPONSIBILITIES

4.1 All Holtec personnel (and subcontractors working under the Holtec QA program) who perform nuclear *safety-significant* work are responsible for reporting conditions adverse to Quality, either item-related or programmatic, to the Quality Assurance Manager for evaluation.

4.2 The Quality Assurance Department shall be responsible for reviewing all corrective action reports and for performing an evaluation to determine whether a Root Cause assessment is warranted.

4.3 Additional responsibilities of personnel shall be defined in implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies described in Subsection 3.0.

SECTION 17.0: QUALITY ASSURANCE RECORDS

1.0 PURPOSE

To provide requirements for the maintenance of appropriate records to maintain evidence of activities that are of material consequence to quality.

2.0 APPLICABILITY

This policy applies to the generation, control, and maintenance of quality assurance records for *safety-significant* items and services.

3.0 POLICY

3.1 Quality assurance records shall be legible, identifiable, reproducible, complete and accurate. Quality Assurance records, to the extent practicable, shall be prepared and maintained in electronic form.

3.2 Applicable organizations shall prepare sufficient records as their work is performed to provide documentary evidence of activities that bear upon quality.

3.3 Quality assurance records shall include, but are not limited to, instructions and procedures which prescribe quality assurance activities (including those which establish a records retention program), design records (such as specifications, calculation packages, drawings, procurement documents); inspections and test reports, audits, qualification records, nonconformance and corrective action reports, and 10CFR21 evaluations. The records shall also include closely related data, such as qualifications of personnel, procedures, and equipment.

3.4 Requirements concerning record retention, such as duration, location, and assigned responsibility shall be established and documented in the implementing procedure(s).

4.0 RESPONSIBILITIES

4.1 The Quality Assurance Department shall be responsible for the long-term retention of Quality Assurance Records.

4.2 Additional responsibilities of personnel shall be defined in implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies described in Subsection 3.0.

SECTION 18.0: QUALITY ASSURANCE AUDITS

1.0 PURPOSE

To establish the requirements for conducting audits to ensure that Holtec International's Quality Assurance program is being implemented in a faithful and effective manner. This section also sets down the requirements to ensure that the organizations rendering *safety-significant* activities to Holtec International's projects maintain the quality requirements consistent with their authorized scope of supply.

2.0 APPLICABILITY

This policy applies to both Holtec internal audits and audits of Holtec suppliers and potential suppliers.

3.0 POLICY

3.1 Measures shall be established to carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the auditee's Quality Assurance Program and to determine the effectiveness of the program.

3.2 Audits shall be performed by qualified personnel not having direct responsibilities in the areas being audited, and shall be performed in accordance with written procedures or checklists.

3.3 Qualification requirements for auditors shall be established and documented, and records of auditor qualifications shall be maintained.

3.4 Audit results, including deficiencies identified, shall be documented and reviewed by the company's executive management for consistency and adherence to the company's written procedures.

3.5 Follow-up action, including re-audit of deficient areas, shall be carried out, where indicated, to ensure that the deficiencies have been rooted out.

4.0 RESPONSIBILITIES

4.1 Specific responsibilities of applicable personnel shall be defined in implementing procedures.

5.0 IMPLEMENTATION

5.1 Procedure(s) shall be established to implement the policies described in Subsection 3.0.

— LAST PAGE —