



HOLTEC INTERNATIONAL
QUALITY ASSURANCE PROGRAM
TOPICAL REPORT FOR
10CFR71, SUBPART H AND 10CFR72, SUBPART G

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This document conforms to the requirements of the design specification and the applicable sections of the governing codes.

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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 provides field installation and repair services to the industry. For projects involving safety related services and products 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 Quality Assurance Procedure Manual. These manuals meet the applicable portions of 10CFR50, Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, and applicable codes, standards, and regulatory requirements governing the control and monitoring of these products and services.

It is the responsibility of the President, Holtec International, to establish policies, goals, and objectives of the Quality Assurance Program and to assure that the program is being properly implemented.

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

All Holtec personnel shall familiarize themselves with the contents of the Quality Assurance Manual and Quality Assurance Procedure Manual. Persons whose activities are governed by these manuals are directly responsible for implementing the program and the procedures applicable to their activities.

3/10/94

Date

K.P. Singh
President



I. INTRODUCTION

Holtec International is an engineering company that provides miscellaneous services to the nuclear industry such as the design and fabrication of fuel storage racks, spent fuel storage and transport casks, other nuclear plant components, development of computer software, performance of neutron surveillance activities, and the supply of airlock replacement parts. Holtec International's design and analysis capabilities cover a wide variety of areas within the nuclear industry.

All nuclear safety related work performed by Holtec International is done in accordance with Holtec International's quality assurance program which is designed to meet the requirements imposed within 10CFR50 Appendix B, 10CFR71, Subpart H, and 10CFR72, Subpart G. The intent of this document is to provide a summary of Holtec International's quality assurance program so as to show how the program meets the intent of the above referenced regulations.

II. QUALITY ASSURANCE PROGRAM DOCUMENTS

Holtec International's quality assurance program has three levels of controlling documents. The highest level, and overall controlling document, is the quality assurance manual which provides the requirements and commitments that Holtec International must follow during the course of any nuclear safety related project. The manual is organized into eighteen sections, with each section covering a separate criterion in a similar order to that in the above referenced regulations.

The second level of quality assurance program controlling documents is the Holtec International quality procedures. These procedures provide specific details on how Holtec International shall implement the requirements and commitments imposed within the quality assurance manual. A list of the procedures is provided in the quality assurance manual in order to allow for a cross reference with the eighteen criteria addressed in the manual.

Standard and project specific procedures comprise the third level of quality assurance program controlling documents. These procedures are used to control specific project activities and requirements which are not addressed within the Holtec



International quality procedures. Examples of this would be a visual weld examination procedure or a fuel rack cleaning procedure.

III. QUALITY ASSURANCE PROGRAM CONTENT

This section summarizes the requirements and commitments of Holtec International's quality assurance program as detailed in the Holtec International quality assurance manual and corresponding quality procedures (hereafter called quality assurance program documents). Each criterion is summarized separately.

1) Organization

Holtec International's quality assurance program documents define the quality assurance program related responsibilities of all Holtec International personnel, as well as the breakdown of the organizational responsibilities within Holtec International company. The organizational chart shows each element of Holtec International's organization in a hierarchy format so that reporting responsibilities are well-defined and easily determined.

The quality assurance manager reports directly to the Holtec International President so as to provide organizational freedom and independence from cost and schedule. The quality assurance manager is responsible for the maintenance of the overall quality program as well as verifying that conformance to established requirements is being met. He has the authority to stop work due to an unsatisfactory condition or nonconformance and is responsible for verifying implementation of appropriate corrective actions. Qualifications for quality assurance personnel are defined within the quality assurance program documents.

Holtec International's quality assurance program requires that the president of Holtec International review the status of the quality program on an annual basis. Furthermore, as part of Holtec International upper management's commitment to Holtec International's quality assurance program, a statement of policy authored by the president of Holtec International is contained in the quality assurance manual. This policy defines Holtec International's commitment to meeting the requirements of 10CFR50 Appendix B, 10CFR71 Subpart H and 10CFR72 Subpart G as applicable,



on all safety related projects and also delegates overall responsibility of quality program maintenance to the quality assurance manager.

2) Quality Assurance Program

The Holtec International quality assurance program requires that all activities important to safety involving design, procurement, fabrication, inspection and testing are performed in accordance with written procedures. An index of quality assurance procedures is maintained in the quality assurance manual. The index lists the eighteen criteria of Holtec International's quality assurance manual along with its corresponding quality assurance procedures. Additional project specific procedures are written as needed when specific project requirements are not covered by quality procedures.

All Holtec International personnel performing safety related activities must be indoctrinated into Holtec International's quality assurance program prior to performing safety related work. Additionally, a training session is held each year for Holtec International personnel in order to review specific quality assurance requirements.

Holtec International personnel performing inspection, testing or auditing activities are qualified in accordance with written procedures using guidelines established by the American Society for Nondestructive Testing, American Society of Mechanical Engineers, American National Standards Institute, or other recognized authority, as applicable. These procedures define education, training, experience and examination requirements for qualifying personnel to perform inspection, testing or auditing. Qualification records are maintained by the quality assurance manager and include certification records, bases for qualification, qualification time period, experience and training records and examination scores as applicable.

Contractors used by Holtec International to perform safety related work shall either have their own quality assurance program which meets or exceeds Holtec International's, or shall perform the work under Holtec International's quality assurance program.

A project plan is written for each safety related project prior to the start of work. This project plan defines the design bases for the project and lists the applicable quality and standard



procedures to be used on the job. Additionally, the project plan lists all Holtec International personnel who may perform work on the project.

Maintenance of the quality assurance program is the responsibility of the quality assurance manager. While he is responsible for assuring that all applicable facets of Holtec International's quality program are implemented on each safety related project, all Holtec International personnel are responsible for following the requirements imposed within the quality assurance program.

3) Design Control

Holtec International's quality assurance program documents establish measures necessary to assure the control of the design process, from input through verification. A design basis is defined at the start of each project so that appropriate codes, standards and other relevant documents are used during the course of the design process. Design parameters, as well as miscellaneous design requirements, such as maintenance, repair and storage, are defined within Holtec design documents as applicable.

Drawings, procedures and design reports are the three main documents produced by Holtec International through its design process. Holtec International quality program requirements for procedures and drawings are defined in criterion 5 of this report.

Holtec International's quality assurance program documents require that all design reports include, as applicable, a defined purpose, assumptions, references, inputs, outputs and results. Design reports are signed by the author and are reviewed by the quality assurance manager and the project manager. Additionally, the design report is verified by an individual or group of individuals other than the author of the report. Verification may be made either by qualification testing, design review or alternative calculations. When qualification testing is used, the prototype should be subjected to the most adverse design conditions.

Holtec International quality assurance program documents require that design verification, if other than by prototype or lead production quality testing, must be satisfactorily completed prior to release for fabrication unless the timing cannot be met. In this case, written justification must be provided to the quality



assurance manager and unverified portions of the design must be identified and controlled.

Changes to a Holtec International design report must be reviewed and approved in a similar manner to the original. Changes in design for items regulated under 10CFR71 or 10CFR72 and that may result in conditions differing from those prescribed on the certificate of compliance must be approved by the NRC prior to implementation.

4) Procurement Document Control

Holtec International's quality assurance program establishes measures to control the preparation, review, approval and issuance of all purchase orders.

Measures are established within Holtec International's quality assurance program to ensure that all procurement documents contain the following information, as applicable:

- a) A statement of the scope of work to be performed by the vendor.
- b) The design basis technical requirements including codes and standards, specifications etc.
- c) Quality assurance requirements including compliance by the vendor with the requirements of 10CFR50, Appendix B, 10CFR71 Subpart H, or 10CFR72, Subpart G.
- d) Permission to gain access to the supplier's or sub-tier supplier's plant facilities and records.
- e) Identification of documentation required to be supplied by the vendor.
- f) Requirements for reporting and approving disposition of nonconformances.
- g) Record retainage and control requirements.

The Holtec International quality assurance program requires that all purchase orders for safety related items and services be reviewed and approved by the project manager and quality assurance



manager. Changes to purchase orders are required to be reviewed and approved in a similar manner to the original.

5) Instructions, Procedures and Drawings

Holtec International quality assurance program documents require that all activities that are important to safety must be prescribed and accomplished in accordance with written instructions, procedures or drawings. Methods for complying with the eighteen criteria set forth within 10CFR50 Appendix B, 10CFR71, Subpart H, and 10CFR72, Subpart G, are also required to be described within defined procedures.

Instructions, procedures and drawings are required by the Holtec International quality assurance program to include qualitative and quantitative acceptance criteria in order to verify that activities important to safety have been satisfactorily accomplished.

Measures are established through Holtec International quality assurance program documents in order to assure that all instructions, procedures and drawings are reviewed and approved by a cognizant engineer other than the author. Additionally, instructions, procedures and drawings must be reviewed and approved by the quality assurance manager. Revisions to instructions, procedures and drawings are required to be reviewed and approved in a similar manner to the original revision.

6) Document Control

Holtec International's quality assurance program documents define the methods to be employed in the transmittal and control of project records requiring controlled distribution. All records under the control of the Holtec International quality assurance program must be maintained to reflect current status. These records include, but are not limited, to design documents, design changes, computer program software, procurement documents, quality program manuals, procedures, nonconformance reports and drawings. An index of all quality records is maintained by the Holtec quality assurance manager. Current revisions of documents are required to be maintained and controlled so that obsolete or superseded documents are not used.



Holtec International's quality assurance program documents establish review and approval requirements for all quality records. Individuals responsible for review and approvals of documents are identified within quality assurance program documents. Changes to quality records are required to be reviewed and approved in a similar manner to the original revision of the document. Changes to quality records must be performed in accordance with applicable quality assurance program document commitments.

7) Control of Purchased Material, Equipment and Services

Holtec International's quality assurance program documents define measures to ensure that materials, equipment and services conform to procurement documents. Procedures are established to define requirements for procurement document control, supplier evaluation and selection, supplier surveillance and receipt inspection in order to assure purchased items are properly controlled from the procurement phase through item receipt.

Holtec International quality assurance program documents define requirements for the processing of procurement documents. Responsible individuals are defined within these procedures. Purchase order content shall include hold point requirements as applicable in order to assure Holtec International maintains adequate control over the processing of an item by the subcontractor.

Holtec International's quality assurance program documents require that Holtec International personnel evaluate all Holtec International subcontractors prior to contract award. A supplier shall be evaluated to determine its technical capability as well as its production capability. Those suppliers found to have satisfactory technical and production capabilities are submitted to the quality assurance department for a quality assurance evaluation. The quality assurance evaluation shall assess past performance and also determine the capabilities of the supplier to comply with required codes through audit, survey or other means. Unacceptable conditions discovered by Holtec International quality assurance are addressed through nonconformances and audit findings as applicable. Holtec International may impose its own quality assurance program on suppliers which are determined not to have an adequate quality assurance program.



All suppliers of safety related materials, equipment and services must be placed on Holtec International's approved vendors list prior to contract issuance. Specific requirements for placing vendors on the approved vendor list are defined within Holtec International quality assurance program documents.

Measures for performing supplier surveillances are defined within Holtec International quality assurance program documents. Source surveillance is used to determine that in-process work by the supplier is being performed in accordance with purchase order requirements. The project manager, in conjunction with the quality assurance manager, must determine the extent of source surveillance required for a particular job or supplier. Holtec International quality assurance program documents define types of surveillance activities that may be performed including hold point verification. Surveillance reports are required to be written for all surveillances performed.

Measures for performing receipt inspection activities are defined within Holtec International quality assurance program documents. Receipt inspection is performed in order to verify received items meet all requirements of the purchase order. The extent of receipt inspection to be performed on supplier furnished items in order to assure items are properly identified and conform to purchase order requirements is established through Holtec International quality and project procedures. When item acceptance is contingent on post-installation testing or inspection, the acceptance criteria must be defined with suppliers through procurement documents prior to item use.

Measures have been established through Holtec International quality assurance program documents to control items discovered during receipt inspection to have a nonconforming condition. These measures include segregation of items, evaluation of the nonconforming items and disposition with justification as required.

Holtec International quality assurance program documents establish measures to assure that a supplier provides all documentation for a received part as required by the purchase order. These documents include, but are not limited to, material test reports, certificates of conformance and nonconformance reports.



8) Identification and Control of Materials, Parts and Components

Holtec International quality assurance program documents establish measures to ensure that materials, parts and components, including partially fabricated assemblies, are adequately identified in order to preclude the use of incorrect or nonconforming items. Measures are established by Holtec International through its quality documents to ensure that limited life items are controlled in order to preclude their use once the shelf life of these items has expired.

Measures are established by Holtec International through quality assurance program documents in order to provide means for material, part or component identification so that items maintain traceability to appropriate documentation such as drawings and test reports throughout fabrication, installation and use.

9) Control of Special Processes

Holtec International quality assurance program documents establish measures to ensure that special processes such as welding and NDE examination are controlled. Procedures, equipment, and personnel used to perform special processes are required to be qualified in accordance with applicable codes, standards and specifications. Special process operations must be performed by appropriately qualified personnel. Special process operations are required to be documented and verified. All special process records including procedure, equipment and personnel qualifications, as well as special process operation results are required to be maintained as quality records.

10) Inspection Control

Holtec International's quality assurance program documents establish measures to ensure that inspection procedures, instructions, or checklists include identification of characteristics and activities to be inspected, acceptance and/or rejection criteria as applicable, identification of the individuals or groups responsible for performing the inspection operation, recording of inspection results, identification of hold and witness points, approval requirements for inspection data and inspection prerequisites such as personnel qualifications. Inspections through sampling shall use known standards as applicable for the basis of acceptance.



Measures are established within Holtec International's quality assurance program documents to ensure that all items important to safety are, upon receipt, inspected to verify that the item meets purchase order requirements. Controls of materials, both before and after receipt inspection, are defined for both accepted and nonconforming material within Holtec International quality assurance program documents.

Measures for in-process controls are established through Holtec International quality assurance program documents for situations when direct inspection would be impractical. In-process controls when required, may include, but are not limited to, monitoring of processing methods, equipment and personnel, as well as review of in-process documentation.

Holtec quality assurance program documents establish measures to ensure that all nonconformances identified during the course of fabrication are resolved during final inspection; that all items which are inspected must be identifiable and traceable to specific records; and that all inspection records must be reviewed by the Holtec International QA manager to verify the inspection requirements have been satisfied.

Holtec International quality assurance program documents require that all inspectors must be qualified in accordance with applicable codes and standards and shall be properly trained. All inspector qualification records are maintained within the quality assurance files and are required to be kept current. Measures are defined within Holtec International's quality assurance program to ensure that inspection personnel are independent from personnel performing the activity being inspected.

11) Test Control

Holtec International quality assurance program documents establish measures to ensure that applicable test programs (i.e., load tests, production tests etc.) are performed in accordance with written procedures. Holtec International quality assurance program documents require that modifications, repairs and replacements to items with required testing programs must be tested to the original design and testing requirements except as altered by other applicable project documents (i.e., revised procedures, nonconformance reports).



Measures are established through Holtec International quality assurance program documents to ensure that test prerequisites as defined in design documents are properly transferred into test procedures. Prerequisites may include, but are not limited to, instrument calibration, environmental conditions, documentation requirements and acceptance criteria.

Measures are established within Holtec International quality assurance program documents to ensure that test results are documented and evaluated and that their acceptability is determined by qualified personnel.

12) Control of Measuring and Test Equipment

Holtec International quality assurance program documents establish measures to ensure that measurement and test equipment shall be calibrated, adjusted and maintained at prescribed intervals or prior to use. Measuring and test equipment is required to be labelled or tagged in order to indicate the planned date of the next calibration. Measuring and test equipment is required to be traceable to calibration records.

Measures are established within Holtec International quality assurance program documents to ensure that all calibrations of measuring and test equipment are performed using calibration standards that are both traceable and have known valid relationships to nationally recognized standards. When no known recognized standard exists, the basis for the calibration is required to be defined and documented.

Measures are established within Holtec International quality assurance program documents to control measuring and test equipment which is found to be out of calibration. These controls include validation of all previous inspection and test results from the time the item was found to be out of calibration back to the time of the previous acceptable calibration of the same item. Any measuring or test equipment found to be out of calibration is required by Holtec International quality assurance program documents to be repaired or replaced.



13) Handling, Storage and Shipping

Holtec International quality assurance program documents establish measures to ensure that cleaning, handling, storage and shipping of items are accomplished in accordance with design requirements to preclude damage or deterioration by environmental conditions. Measures for establishing provisions for the use of special handling, lifting or storage equipment in order to adequately identify and preserve items, components or assemblies are provided within Holtec International quality assurance program documents.

Measures are established within Holtec International quality assurance program documents to ensure that a review of packaging be performed prior to item shipment in order to assure packaging meets approved drawings, specifications and codes. Additionally, verification of completion of all documentation including procedures, manuals and inspection and test results is required to be performed prior to shipment. Physical identification of the item shall be verified prior to shipment.

14) Inspection, Test and Operating Status

Holtec International quality assurance program documents establish measures to ensure that the identification of the inspection, test and operating status of items is known by organizations responsible for quality assurance.

Measures are established by Holtec International through its quality assurance program documents to control the application and removal of status indicators such as markers and tags. Additionally, Holtec International quality assurance program documents establish measures to ensure that if required operations such as tests or inspections are bypassed, such action is taken through controlled procedures and under cognizance of the quality assurance department.

15) Control of Nonconforming Materials, Parts or Components

Measures are established within Holtec International quality assurance program documents to require nonconformances to be identified through deviation reports and corresponding corrective actions. Individuals responsible for review and disposition of nonconforming items are identified within Holtec International quality assurance program documents.



Measures are established through Holtec International quality assurance program documents to ensure that nonconforming items are segregated and controlled until proper disposition is completed.

Holtec International quality assurance program documents establish measures to ensure that the acceptability of nonconforming items is verified by inspecting or testing the nonconforming item against original requirements after designated repair or rework. Final disposition of nonconforming items must be defined and documented.

Holtec International quality assurance program documents require that nonconformances be assessed by the quality assurance manager on a defined basis to determine any quality trends.

16) Corrective Action

Holtec International quality assurance program documents establish measures to ensure that causes of conditions detrimental to quality are promptly identified and reported to upper management through deviation reports and corrective action reports. Measures are also established to ensure: that corrective actions are performed by suppliers with identified nonconforming conditions or items; and that follow-ups are performed and documented as applicable to verify implementation and effectiveness of the corrective action.

Measures are established within Holtec International quality assurance program documents to ensure that corrective actions have been correctly implemented so as to minimize the possibility of recurrence of the nonconforming condition. Individuals responsible for verifying and documenting corrective action are identified within Holtec International quality assurance program documents.

17) Quality Assurance Records

Holtec International quality assurance program documents require that evidence of activities affecting quality shall be documented and shall provide sufficient information to permit identification of the record with the items or activities to which it applies. Quality assurance records include, but are not limited to design, procurement, manufacturing, and installation records, audits, nonconformance reports, inspection and test results,



drawings and specifications, analysis reports, personnel qualifications and training records, procedures, calibration records and corrective action reports.

Holtec International quality assurance program documents require that inspection and test records shall, as required, contain observations, evidence of inspection or test performance, results of inspections or tests, adverse conditions, names of inspectors or testers, and equipment identification.

Holtec International quality assurance program documents establish measures to ensure that documents defined as quality assurance records are legible and that they reflect the total of work performed.

All quality assurance records are defined as "lifetime" or "nonpermanent". Holtec International quality assurance program documents define which quality assurance records are "lifetime" and which are "nonpermanent". "Lifetime" records are those records that pertain to the design, fabrication and installation of a particular item such that the records can demonstrate the capability of the item and provide evidence of all activities supporting the acceptability of the item. Examples of "lifetime" records include design reports, drawings, procedures and inspection reports. "Nonpermanent" records are those records that show evidence of an activity being performed but do not meet the criteria for "lifetime" records. "Nonpermanent" records include audit reports, training records and calibration records. "Nonpermanent" record retention times are defined within Holtec International quality assurance program documents.

Holtec International quality assurance program documents establish measures to ensure quality assurance records are properly controlled from receipt through long term storage. Responsibilities for receipt, storage, retrieval and disposal of quality assurance records are provided within Holtec International quality assurance program documents. Records are required to be indexed so that they are retrievable.

Holtec International quality assurance program documents define storage requirements in order to assure quality assurance records are not damaged or destroyed. Quality assurance records are required to be stored in boxes, cabinets or shelves and shall be protected from such conditions as water, fire etc. Dual facilities are typically used by Holtec International and are sufficiently



separated from each other so as to ensure that the integrity of records is maintained and that no single event can destroy all quality assurance records. Measures are established through Holtec International quality assurance documents to ensure records requiring special storage requirements are stored properly. Quality assurance record storage areas are required by Holtec International quality assurance program documents to have controlled access. In the case where a quality assurance record is damaged or lost, it is required to be replaced immediately in a controlled manner by responsible personnel.

18) Audits

Holtec International quality assurance program documents define a comprehensive audit program including organizational independence of the auditors, audit schedule requirements, identification of auditors and their required qualifications, access provisions for audit personnel, documentation requirements, methods for reporting audit findings and methods for corrective actions and follow-ups.

Holtec International quality assurance program documents require that schedules be defined for internal and external audits. Audit plans are required to be written for each audit and shall define the key activities or areas to be audited.

Holtec International internal audits are required to be performed annually and shall review all aspects of Holtec International's quality assurance program in order to determine the effectiveness of the program. External audits are required to be performed on a triennial basis for all safety related suppliers and shall evaluate all applicable and Holtec International relevant portions of the supplier's quality assurance program.

Holtec International quality assurance program documents establish qualification requirements for auditors including lead auditors. Additionally, responsibilities of audit personnel regarding the performance of the audit as well as the follow-up documentation (i.e., audit report, findings etc.) are defined within the same documents.

The Holtec International quality assurance program documents establish requirements for the performance of the pre- and post-audit conference. The pre-audit conference is used to define the scope of the audit as well as the specific areas to be audited, and



define a schedule and agenda for the audit. The post-audit conference is used to discuss the results of the audit with the audited party.

Holtec International quality assurance program documents establish measures for writing of audit reports and provide instructions for the processing of findings and their corresponding corrective actions. Corrective action responses are required to clearly state the corrective action taken to correct the nonconforming condition and date of implementation.

Holtec International quality assurance program documents require that the audit team verify that corrective action responses are made in a timely manner, that the corrective action responses are adequate, and that corrective actions have been properly implemented.