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HF Controls

QUALITY ASSURANCE PROGRAM MANUAL

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Policy Statement

This Quality Assurance Program Manual (QAPM) describes the Quality Assurance Program at HF Controls (HFC). The program is designed to provide administrative measures and procedures necessary for assuring that all HFC hardware and software products as well as any services meet or exceed customer requirements and applicable industry codes and standards. This Quality Program is designed to comply with NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015, "Quality Assurance Requirements for Nuclear Facility Applications," including the exceptions and clarifications identified in USNRC RG 1.28 Revision 5, Section C. In following these industrial standards and regulatory guidance, the HFC Quality Assurance Program complies with 10 CFR 50 Appendix B; "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants", and 10CFR Part 21. The HFC Quality Assurance Program also complies with ISO 9001.

HFC's specific goals and objectives are to provide to our customers: 1) Quality products with no defects or failures, 2) Products delivered on or prior to the promised date. HFC also commits to continually broaden the knowledge base of our employees and services within a safe work environment.

The requirements of this manual shall apply to all activities affecting the quality of products and services provided and performed by HFC, including headquarter, subsidiaries and branch offices worldwide. HFC personnel at every level of the organization are required to fully support HFC's QA Program, achieve a high level of excellence through the application of proven technology in their respective areas of responsibility, and promote an atmosphere of continuous improvement.

Allen Hsu

Allen Hsu
President

Section 1.0 - Organization

HF Controls (HFC) Corporation designs control systems for customers in the form of Projects, provides warranty and non-warranty work on nonfunctioning items, on-site service, and provides spare parts when requested. See Attachment 1 for a flow chart description of the interaction between the processes of the quality management system. HFC has established and is maintaining a Quality Program for products delivered to our customers and services performed for our customers. Although authority for development and execution of the program may, on occasion, be delegated to other parties, such as consultants or contractors, HFC retains overall program responsibility. Internal and external interface responsibilities have been established in implementing procedures.

The HFC QA Manager has the responsibility for establishing the Quality Program and verifying that activities affecting the quality of deliverables are performed in accordance with this program. By reporting directly to the President, HFC, the QA Manager is afforded sufficient authority and organizational freedom, including independence from the cost and schedule impacts of required quality assurance actions; to identify quality problems; to initiate, recommend, or provide solutions to quality problems; and to verify implementation of solutions to quality problems. The QA Manager has the ability to stop work if deemed necessary. All employees share the same responsibility and authority as the QA Manager to identify quality problems; to initiate and provide solutions to quality problems; to verify implementation; and to resolve deficiencies that affect quality.

The QA Manager is the HFC Management Representative and is responsible for ensuring that this quality system is maintained, understood, and implemented at all levels of the organization. The Management Representative is also responsible for reporting on the performance of the Quality System to executive management for review and improvement.

The HFC Quality Policy is affirmed in a statement at the front of this document. All HFC personnel have been made aware of this policy and annually the Policy Statement shall be reviewed by management and disseminated throughout the organization.

The organizational structure, functional responsibilities, level of authority, and lines of communication for activities affecting quality are defined in QPP 1.2 Organizational Responsibilities. In the event that any individual in the organization is absent or otherwise unavailable to perform functions or responsibilities, those functions and responsibilities may be performed by a superior or delegated to a qualified subordinate within the organization.

The President of HFC has assigned trained personnel to manage, perform, and verify activities affecting quality. Personnel assigned these tasks are qualified on the basis of experience and/or training. All employees are responsible for the quality of the products and services under their control and for following procedural requirements during all processes in which they are involved.

A formal management review of the quality system shall be performed annually, at a minimum, to ensure its continuing suitability and effectiveness in satisfying HFC's business policies and objectives. This management review shall evaluate, as a minimum, the results of internal and applicable external audits, corrective and preventive actions status, customer feedback, product nonconformance, Returned Material Authorizations (RMA), follow-up actions from previous meetings, changes that could affect the quality management system, training requirements, recommendation for improvement, and resource needs. Records of the management review meeting and associated completed action items shall be maintained in accordance with documented procedures.

Where more than one organization is involved in execution of the section, the responsibility and authority of each organization shall be clearly established and documented.

HFC management shall ensure that adequate facilities necessary for employees to perform their assigned tasks are provided. Test equipment and software used shall be appropriately certified and identified as appropriate. Services necessary to meet contractual requirements shall be provided.

Implementing Procedures

QPP 1.1, "Management Review"

QPP 1.2, "Organizational Responsibilities"

QPP 17.1, "Quality Records"

Section 2.0 - Quality Assurance Program

Policy statements that define and establish the HFC Quality Assurance Program are in each section of this manual.

The HFC Quality Assurance Program shall apply to all related activities as specifically defined in the applicable Quality Plan (Project or Nuclear Spare Parts). Both plans define the scope and implementation of the HFC Quality Assurance Program to satisfy specific customer requirements.

The HFC Quality Assurance Program is implemented through Quality Procedures, Quality Plans, Process Control Sheets and Work Instructions. Quality Assurance Forms are used to capture objective evidence to demonstrate effective implementation.

The HFC Quality Assurance Program provides assurance that activities affecting quality are documented within controlled systems, and accomplished in accordance with written procedures, instructions, and/or drawings.

The HFC Quality Assurance Program provides for indoctrination, training, and qualification (when required) of personnel who manage, test, perform or verify activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. Methods are in place for the qualification of Inspection and Test and Auditor personnel. Training needs other than those defined herein shall be identified and documented during the annual management review of the quality system. Appropriate records of training shall be maintained as quality records.

The status, adequacy, and effectiveness of this Quality Assurance Program in meeting HFC business and quality objectives, as well as compliance to the aforementioned requirements, shall be audited annually with the results reported to HFC management.

The HFC Quality Assurance Program shall be reviewed annually by the President of HFC, and his staff, and revised as necessary in order to ensure continuing compliance with applicable codes, standards, regulations, and customer requirements. The review should include how to improve the Quality Assurance Program and its influence on organizational effectiveness and efficiency.

Implementing Procedures

QPP 1.1, "Management Review"

QPP 2.1, "Project Quality Plan"

QPP 2.2, "General Indoctrination and Training"

QPP 16.1, "Corrective Action Program"

QPP 16.2, "Customer Feedback"

QPP 17.1, "Quality Records"

QPP 18.1, "Audits"

Section 3.0 - Design Control

HFC shall establish and maintain documented procedures to ensure that applicable regulations, codes, standards, and customer requirements are translated into design documents, procedures, and/or instructions. These documents shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from defined requirements are controlled.

Product Development Plans shall be initiated for each new product design and development activity, and shall describe these activities as well as the responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The Product Development Plan and associated design documents shall be updated as the design evolves.

Organizational and technical interfaces between different groups that input into the design process are defined in the Product Development Plan. All design information necessary to ensure satisfaction of customer requirements shall be documented, transmitted, when applicable, and regularly reviewed.

The design control program is established and implemented to assure that the activities associated with the design of systems, components, structures, and equipment and modifications thereto are executed in a planned, controlled, and orderly manner. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.

Design input requirements, relating to our products, shall be established, documented and their selection reviewed and approved for adequacy. Design input shall take into account the requirements in customer orders. Design requirements shall be objective, quantitative, or capable of unambiguous determination of implementation. Incomplete, ambiguous, or conflicting requirements shall be resolved with those responsible for imposing the requirements. Changes from approved design inputs, including the reasons for the changes, shall be identified, approved, documented, and controlled.

Design output shall be documented and expressed in terms that can be verified against design input requirements and validated. Individuals or groups other than those that performed the original design shall review design output documents. Design output shall contain or make reference to acceptance criteria.

Independent design reviews shall occur at prescribed stages within the design process. Participants at each design review shall include, when necessary,

representatives of all functions concerned with the design stage being reviewed. Records of design reviews shall be maintained.

Design verifications shall include design reviews, alternate calculations, qualification tests, or a combination of methods in accordance with approved procedures. Design verifications shall be performed in accordance with approved procedures, performed prior to release for procurement, manufacturing, or to another organization for use, to ensure that the design output meets the design input requirements. Records of design verifications shall be maintained. In cases where this timing cannot be met, the unverified portion of the design shall be identified and controlled.

Independent design validations shall be performed to ensure that products conform to user needs and/or requirements. Records of design validations shall be maintained.

Design Analyses shall be performed in a planned, controlled, and documented manner. They shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units. Methods such as computer programs and calculations are described and controlled. Qualification testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions.

Design changes, shop changes, modifications, and nonconforming items dispositioned use-as-is or repair, shall be justified and shall be subject to design control measures commensurate with those applied to the original design. Measures have been established to ensure that design changes are reviewed by the same affected group or organization that reviewed and approved the original design.

Design documents, including revisions, shall be reviewed, approved, released, distributed, and controlled in accordance with prescribed procedures and/or instructions.

Procedures have been established to identify critical characteristics, dedicate, and utilize a Commercial Grade Item or Software in nuclear projects.

Implementing Procedures

QPP 3.1, "Design Control"

QPP 3.2, "System Lifecycle and Verification and Validation Program"

QPP 5.1, "Review and Approval of Documents"

QPP 6.1, "Control and Distribution of Documents"

QPP 7.2, "Commercial Grade Item Evaluation"

QPP 7.3, "Commercial Grade Software Evaluation"

QPP 17.1, "Quality Records"

Section 4.0 - Procurement Document Control

HFC shall establish and maintain documented procedures to ensure that purchased products and services conform to specified requirements.

Applicable technical, regulatory, administrative, reporting, and quality requirements (e.g., specifications, codes, standards, tests, inspections, special processes, and 10CFR Part 21) are invoked for procurement of items and services, as applicable.

Review of procurement document requirements has been specified in procedures. Responsible organizations shall review the procurement documents to ensure conformance and inclusion of applicable technical and quality requirements prior to release.

The Quality Assurance Program includes provision for ensuring that documented evidence of an item's conformance to procurement requirements is available before the item is placed in service or used, unless otherwise specified in procedures.

The Quality Assurance Program ensures that changes to procurement documents receive the same level of control as the original document.

The Quality Assurance Program ensures that procurement documents provide for defining the scope of work, technical requirements, quality assurance program requirements required by the supplier, the right to access a supplier's facility and their records for the purpose of inspection and audits by HFControls, HFC's customers, or a designated representative, documentation to be submitted, reporting and approving a nonconformance, and identification of spare parts.

When contractually specified, HFC customers, or their agents, shall be afforded the right to verify, at HFC's facility or HFC's suppliers facilities, that subcontracted product conforms to specified requirements.

HFC shall not use customer verification as a means of assuring supplier conformance to procurement requirements, nor shall it absolve our responsibility to provide acceptable product to our customers.

Implementing Procedures

QPP 4.1, "Review, Approval, and Issuance of Purchase Orders"

QPP 10.1, "Receipt, In-process, and Final Inspections"

QPP 17.1, "Quality Records"

QPP 10.2, "Counterfeit, Fraudulent, and Suspect Items Evaluation"

Section 5.0 - Instructions, Procedures, and Drawings

HFC shall establish and maintain a quality system that assures activities that affect quality are prescribed by documented procedures, instructions, and drawings, and shall be accomplished in accordance with these procedures, instructions, and drawings.

Procedures, instructions, and drawings shall include, as appropriate, quantitative or qualitative acceptance criteria for determining that activities affecting quality have been satisfactorily accomplished.

Procedures, instructions, and drawings shall be reviewed and approved for adequacy by authorized personnel prior to use. Changes to these documents shall be reviewed and approved by the same organization that performed the original review and approval. The designated organization shall have access to pertinent background information upon which to base their review and approval.

Changes to quality documents shall be identified in the document or the appropriate attachments.

Implementing Procedures

QPP 5.1, "Review and Approval of Documents"

QPP 5.2, "Preparation of Procedures"

Section 6.0 - Document Control

Procedures are established by HFC to control the issuance of documents, such as instructions, procedures, drawings, and data, including changes thereto, which prescribe activities affecting quality.

These procedures are established to identify documents and data, including changes that are to be controlled along with their specified distribution, the identification of assignment of responsibility for preparing, reviewing, approving and issuing of these documents and data, and for the review of these documents and data for adequacy, completeness, and correctness prior to approval and issuance.

Measures are established requiring the same organizations that performed the original review and approval to review and approve changes to documents unless another responsible organization is designated.

New and revised controlled documents are distributed in accordance with approved procedures. Superseded documents are removed from the work area. Any obsolete documents retained for legal and/or knowledge-preservation shall be suitably identified.

Methods have been established to ensure that the current revision status of documents is identified and readily available to preclude the use of invalid and/or obsolete documents.

Documents of external origin, such as standards and customer documents, shall be controlled.

Implementing Procedures

QPP 5.1, "Review and Approval of Documents"

QPP 6.1, "Control and Distribution of Documents"

Section 7.0 - Control of Purchased Items and Services

HFC shall establish and maintain documented procedures and processes to ensure that the purchased product conforms to procurement document requirements. A product may include a service, hardware, spare parts, software, or a combination thereof.

The quality assurance programs of NQA-1 vendors shall be evaluated by audit. Audits are performed in accordance with approved procedures. ISO 9000 vendors may be evaluated by obtaining a copy of their ISO Certificate. Vendors providing commercial grade products/services used in safety-related applications shall be evaluated, when applicable, in accordance with approved procedures. Vendors listed on the HFC Qualified Suppliers List (QSL) shall be evaluated at intervals consistent with the importance and complexity of the product. The use of customer-approved vendors is allowable. Documented evidence of customer-designated use shall be maintained in accordance with approved procedures.

Procedures have been established noting the requirements for procurement, inspection, and acceptance of commercial grade products that may be used by HFC.

Procedures have been established to define the processes for accepting product through source verification. Source verification arrangements and the method of product release shall be defined in procurement documents.

Methods have been established and documented for the disposition of item(s) that do not conform to the procurement document.

For products provided directly to HFC, implementing procedures shall define requirements for receipt inspection to assure that purchased items or services conform to procurement documents. Drop shipment from HFC's vendor directly to HFC's customer must be evaluated and authorized by the HFC QA Manager/Designee.

Procedures have been established to perform bid evaluations to determine the extent of conformance to the procurement document.

Measures have been established to ensure that supplier generated documents are controlled, handled, and approved.

Methods have been established for the acceptance of services such as third party inspection, engineering and consulting services, etc. These methods include a) technical verification of data produced, b) surveillance or audit of the

activity, c) review of objective evidence for conformance to the procurement document requirements.

Measures have been established to control changes to procurement documents.

When required by procurement documents, HFC, or a designated agent, shall verify the purchased product at the vendor's facility.

Records of acceptable suppliers shall be maintained as quality records.

HFC has established documented methods with applicable suppliers for the disposition of items and services that do not conform to procurement documentation requirements.

Implementing Procedures

QPP 4.1, "Review, Approval and Issuance of Purchase Orders"

QPP 7.1, "Supplier Selection, Qualification and Re-Evaluation"

QPP 7.2, "Commercial Grade Item Evaluation"

QPP 7.3, "Commercial Grade Software Evaluation"

QPP 17.1, "Quality Records"

QPP 10.2, "Counterfeit, Fraudulent, and Suspect Items Evaluation"

Section 8.0 - Identification and Control of Items

HFC shall establish and maintain documented procedures to ensure that materials, parts, and components used in quality-affecting activities, including those items supplied by HFC customers or returned for rework, are properly identified and controlled.

These procedures shall ensure that applicable materials, parts, and components, including partially fabricated assemblies, maintain their identification from initial receipt and fabrication up to installation and use. Materials, parts, and components are controlled to prevent loss, damage, or deterioration, and to prevent the inadvertent use of incorrect or defective materials, parts, and components.

Physical marking shall be utilized to the maximum extent possible; however if it is not practical, then physical separation, procedural controls or other appropriate means shall be employed. When specified, identification and traceability requirements will be controlled. All products procured or assembled by HFC shall have their identification and traceability documented. Records of this activity shall be maintained as quality records.

Markings used for identification are clear and legible when utilized and do not detrimentally effect the function of the material, part, and component. If required, markings shall be transferred to each part of the identified material, part, and component when subdivided. The identification shall be readable upon surface treatment or coating unless other means of identification are substituted.

Material or equipment purchased by HFC shall be inspected per applicable procedures or instructions. Inspection results are documented and acceptable material is appropriately marked.

Items having limited shelf life are controlled to prevent their inadvertent use or installation.

Methods have been established to control material, parts, and components consistent with planned duration and conditions of storage. These methods shall ensure that material, parts, and components are replaced if damaged, deteriorated, aged or mishandled.

Implementing Procedures

QPP 8.1, "Identification and Control of Materials, Parts, and Components"

QPP 16.1, "Corrective Action Program"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 9.0 - Control of Processes

HFC shall establish and maintain documented procedures to ensure processes that directly affect quality are carried out under controlled conditions.

The Project Quality Plan (PQP) is the mechanism in which all quality-affecting project activities or nuclear spare parts orders are described and controlled. The PQP defines the quality assurance program controls applicable to the project work scope, and identifies the project team, deliverables, applicable quality records that are created by the project, and QA and customer witness and hold points. The PQP is reviewed, approved, and controlled in accordance with approved procedures.

HFC does not use or maintain any quality-affecting equipment that requires periodic preventive maintenance, nor does HFC perform special processes such as welding and heat-treating, etc., that requires qualified personnel.

A Shop Floor Order or Process Control Sheet shall be utilized for any internal assembly activities or work scope activities outsourced under the direct control of the HFC QA Program Manual. The Shop Floor Order or the Process Control Sheet is utilized to approve processes and equipment, as appropriate.

Records of qualification shall be maintained, as appropriate.

Implementing Procedures

QPP 2.1, "Project Quality Plan"

QPP 9.1, "Control of Processes"

QPP 17.1, "Quality Records"

Section 10.0 - Inspection

HFC shall establish and maintain documented procedures for inspection activities in order to verify that the specified requirements in the Project Quality Plan, or implementing procedures, are met. The PQP, or implementing procedures, shall define the inspections required and the inspection records to be established.

Receipt inspection shall be performed as described in implementing procedures. HFC shall ensure that incoming items are not used or processed until they have been inspected or otherwise verified as conforming to procurement documents. Items that have not been subject to receipt inspection shall not be released for use.

The PQP, or implementing procedures, shall define all in-process and/or final inspection attributes. Witness and hold points applied in the project documents shall be verified, and accepted, by personnel qualified in accordance with approved procedures. Final inspection shall verify that the finished item conforms to requirements, all nonconformances are resolved, and that all previous defined inspections have been carried out. No item may be released until all inspections that have been defined in the PQP, or implementing procedures, have been satisfactorily completed and the data, documentation, and records associated with these inspections are available and completed. Product failing inspection shall be subject to controls defined in the Corrective Action Program.

In-process inspections shall be identified in the Shop Floor Order for items where the quality cannot be verified once completely assembled or manufactured.

Modifications, repairs, or replacements of items performed subsequent to Final Inspections shall require re-inspection and retest as appropriate to verify acceptability.

Inspection personnel report directly to the QA Manager and are independent of the work being inspected. Personnel performing inspections shall be trained and/or qualified in accordance with approved procedures.

Records of inspection activities shall be maintained in accordance with approved procedures. Records shall identify the inspection authority responsible for release of inspected items, the item inspected, inspection date, inspector, type of observation, results, and disposition.

Related to Counterfeit, Fraudulent, and Suspect Items (CSFI), HFC demands all its suppliers to ensure no such items are used in the products delivered to HFC. In addition, HFC QA/QC department quality control inspection team shall evaluate all receiving items to ensure no CSFI are received or used in HFC products.

Implementing Procedures

QPP 2.2, "General Indoctrination and Training"

QPP 2.5, "Qualification of Inspection Personnel"

QPP 10.1, "Receipt, In-Process, and Final Inspection"

QPP 10.2, "Counterfeit, Fraudulent, and Suspect Items Evaluation"

QPP 15.1, "Nonconformance Control Program"

QPP 16.1, "Corrective Action Program"

QPP 17.1, "Quality Records"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 11.0 - Test Control

HFC shall establish and maintain documented procedures for acceptance test activities in order to ensure requirements specified in approved test procedures are met. Test procedures shall define the required tests and the test records to be established.

Test procedures shall have provisions for assuring that test prerequisites have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Assigned witness and hold points shall be verified, and accepted, by trained and/or qualified personnel in accordance with approved procedures.

Test results shall be documented and evaluated by responsible individuals to assure that acceptance test requirements have been satisfied. Test activities failing established acceptance criteria shall be subject to the controls defined in the Corrective Action Program. Records shall identify the item tested, date of test, personnel performing the test, test results, actions taken in connection with deviations, and the personnel evaluating the test results. Records of test activities shall be maintained in accordance with approved procedures.

Tests required to collect data, such as for design input, shall be planned, executed, documented, and evaluated.

Procedures are in place for developing test requirements and acceptance criteria for computer programs and associated computer systems. Test requirements and acceptance criteria for verification and in-use tests are provided and approved. Procedures contain applicable requirements, and applicable results shall be documented.

Implementing Procedures

QPP 2.2, "General Indoctrination and Training"

QPP 2.5, "Qualification of Inspection Personnel"

QPP 11.1, "Test Control"

QPP 11.2, "Product Development Test Control"

QPP 17.1, "Quality Records"

Section 12.0 - Control of Measuring and Test Equipment

HFC shall establish and maintain documented procedures to ensure that measuring and test equipment (M&TE) and inspection hardware (e.g., templates, test fixtures, etc.) used in quality affecting activities are properly identified, calibrated, and controlled.

M&TE shall be marked or labeled such that the current status of each instrument is readily discernible. As described in implementing procedures, a master list or database is maintained to identify each piece of measuring and test equipment, their location, manufacturer, model number, calibration date, serial number, accuracy and tolerance ranges, calibration due date, and calibration intervals.

M&TE shall be calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated. If this is not possible, the standard used and its measurement uncertainty shall ensure that the equipment being calibrated is consistent with its measurement capability. M&TE shall be calibrated using reference standards traceable to national standards (e.g., National Institute of Standards and Technology, "NIST"), where such standards exist. If no national standards exist, the basis for calibration shall be documented.

M&TE calibration intervals shall be identified or the measuring and test equipment shall be calibrated prior to each use.

M&TE which are not calibrated to full capability or which have limitations on their use shall be labeled or otherwise identified as to their limitations.

Environmental conditions (e.g., temperature, humidity, static electricity) in which M&TE are calibrated shall be controlled and shall be appropriate for the calibration being performed. As required, M&TE and test software shall be guarded against adjustments that would invalidate the calibration or test results.

Handling, preservation and storage of M&TE shall be prescribed in approved procedures.

M&TE found to be beyond calibration limits at the time of re-calibration shall be identified and evaluated on a Condition Report and a use history review conducted to ascertain the identity of components inspected with the M&TE since their last calibration.

Commercial measuring devices (rulers, tape measures, levels, etc.) will not be required to be calibrated if such commercial equipment provides adequate accuracy for the tests or inspections indicated.

Calibration service providers employed to calibrate M&TE for activities affecting quality shall be selected and qualified in accordance with approved procedures.

Records of calibration activities shall be maintained in accordance with approved procedures.

Test software shall be reviewed, approved, and controlled in accordance with approved procedures.

When contractually required, technical data pertaining to the M&TE shall be made available to our customers, or their agents, to enable them to verify the functionality and adequacy of the M&TE.

Implementing Procedures

QPP 12.1, "Control of Measuring and Test Equipment"

QPP 16.1, "Corrective Action Program"

QPP 17.1, "Quality Records"

Section 13.0 - Handling, Shipping, Storage and Preservation of Items

HFC shall establish and maintain documented procedures for ensuring that the handling, packaging, shipping, storage, and preservation of items affecting quality satisfy requirements specified in the customer procurement document.

Items shall be handled in a manner not to cause them excessive vibration or damage. Carts may be used to move items around the HFC facility. Lighter items can be hand carried to points of destination.

Special handling requirements, when required, shall be defined in the Project Quality Plan (PQP) or approved procedure.

Equipment is staged on shelves, carts, or on the floor in the original container until receipt inspection is completed. In-process items shall be staged on pallets or shelves in a manner not to cause damage or deterioration. Items shall be stored in a manner to prevent damage, deterioration, and loss. Appropriate methods for authorizing receipt to and dispatch from these areas have been defined in implementing procedures. As defined in implementing procedures, the condition of product in stock is assessed at least annually to detect deterioration. Documentation of these checks is maintained.

Methods have been established when required for particular items, special equipment (such as containers, shock absorbers, and accelerometers), and special protective environment including atmosphere, moisture, and temperature parameters shall be established, as applicable, and verified.

Packaging shall be performed using standard commercial practices in a manner that prevents damage or deterioration to the item shipped or packaged as specified by the customer. For critical, sensitive, perishable, or high-value articles, specific procedure for handling, storage, packaging, shipping, and preservation shall be used. Special handling tools and equipment are typically out-sourced.

Delivery shall be performed using commercial carriers or customer designated carriers. Delivery of product is not considered a critical attribute to product quality unless contractually specified. Commercial carriers do not require approval for placement on the Qualified Suppliers List.

Controls have been established to ensure that unauthorized personnel have limited access to HFC facilities.

Items are marked and/or labeled during packaging, handling, and storage to ensure that the integrity of the units is preserved (e.g., carts, tables, shelves, etc.).

Personnel performing activities affecting quality shall be trained in accordance with approved procedures.

Implementing Procedures

QPP 2.2, "General Indoctrination and Training"

QPP 2.3, "Lead Auditor Qualification"

QPP 2.4, "Auditor Qualification"

QPP 2.5, "Qualification of Test Personnel"

QPP 13.1, "Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components"

QPP 17.1, "Quality Records"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 14.0 - Inspection, Test and Operating Status

HFC shall establish and maintain documented procedures to indicate, by the use of markings, such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items.

Measures shall be established to provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Unsatisfactory inspection or test results are processed in accordance with Section 15.0.

Measures shall be established for indicating the operating status of structures, systems, and components to prevent inadvertent use or operation.

The identification of inspection and test status shall be maintained throughout fabrication, assembly, installation, and testing.

The authority for application and removal of tags, markings, labels and stamps shall be specified.

Implementing Procedures

QPP 8.1, "Identification and Control of Materials, Parts, and Components"

QPP 10.1, "Receipt, In-Process, and Final Inspections"

QPP 11.1, "Test Control"

QPP 13.1, "Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components"

QPP 14.1, "Inspection and Test Status"

QPP 17.1, "Quality Records"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 15.0 - Control of Nonconforming Items

HFC shall establish and maintain documented procedures to ensure that materials, parts, or components that do not conform to requirements are prevented from use or installation. Identification of any of these items not conforming to requirements will require generation of a Condition Report. The responsibility for review and authority for the disposition of nonconforming items shall be defined.

Procedures for nonconforming items shall address identification, documentation, evaluation, segregation, disposition, and notification to affected organizations, including the customer, when required.

Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked, in accordance with documented procedures. Disposition and or cause of the nonconforming items shall be documented on the Condition Report.

The description of repairs and of any nonconformity that has been accepted under authorized concession shall be recorded to denote the actual condition. Repaired, reworked, and replacement items shall be re-inspected in accordance with documented procedures.

Measures have been established to ensure that personnel performing evaluations to determine a disposition have demonstrated competence in the specific area. The engineering department shall provide a technical justification for repair and use-as-is dispositions. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.

Implementing Procedures

QPP 15.1, "Nonconformance Control Program"

QPP 16.1, "Corrective Action Program"

QPP 17.1, "Quality Records"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 16.0 - Corrective Action

HFC shall establish and maintain documented procedures to ensure that conditions adverse to quality such as inadequate processes, procedures, adverse quality trends, audit findings, deviations from the quality system and/or project requirements, and customer feedback are promptly identified and resolved.

Procedures for corrective action shall require identification of the root cause, the actions taken to resolve significant conditions adverse to quality, to prevent recurrence of the adverse condition, and for the evaluation and documentation of the effectiveness of the corrective actions taken to eliminate the significant conditions adverse to quality.

The investigation, corrective and preventive actions shall be documented on the Condition Report and shall be commensurate with the severity of the condition adverse to quality. Relevant information regarding corrective and preventive conditions shall be reported to, and evaluated by, HFC management during the annual management review of the quality system. HFC shall implement and record any changes to documented procedures resulting from corrective and preventive actions.

Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant trends are reported to, and evaluated by, HFC management during the annual management review of the quality system.

A process for identifying, documenting, and resolving customer feedback shall be established.

Significant conditions (10CFR Part 21) adverse to quality shall be documented in accordance with established procedures.

Preventive Actions resulting for data analysis and Management review shall be identified and reported in the Corrective Action Program.

Deficiencies in quality which can cost significant financial impact to the operating plants shall be reported as early as possible to the customers for appropriate actions.

Implementing Procedures

QPP 1.1, "Management Review"

QPP 16.1, "Corrective Action Program"

QPP 16.2, "Customer Feedback"

QPP 16.3, "10CFR Part 21 Reporting"

QPP 16.4, "Significant Deficiency Reporting"

QPP 17.1, "Quality Records"

Section 17.0 - Quality Assurance Records

Sufficient records are maintained by HFC to demonstrate conformance to specified requirements and the effective operation of the quality system.

Procedures are established for classification and identification, collecting, indexing, accessing, filing, storage, maintenance, and disposition of quality records. Records shall be protected against damage, deterioration, or loss. Records shall be bound or placed in folders for storage in steel file cabinets or in containers on shelving. Electronic media shall be stored in appropriate containers.

Records are established and maintained that provide evidence that the product has been inspected and/or tested. These records identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Pertinent quality records from subcontractors are included.

Requirements concerning record retention including duration, location, transmittal, and assigned responsibility are established.

Records shall be made accessible to the Purchaser or his designated alternate, e.g. the Owner, for an agreed-to period of time.

Provisions have been established to ensure that records are stored in facilities or locations constructed and maintained which minimizes the risk of damage or destruction. Nuclear quality records shall be stored in 2-hour fire rated Class B containers meeting NFPA 232-2007 or at a dual storage approved facility.

Implementing Procedures

QPP 17.1, "Quality Records"

Section 18.0 – Audits

HFC shall establish and maintain documented procedures to ensure that a comprehensive system of planned and periodic audits is established and effectively implemented.

Audits shall be scheduled on the basis of the status and importance of the activity to be audited, performed in accordance with written procedures or checklists, and shall be carried out by qualified personnel independent of those having direct responsibility for the activity being audited. Each section of the manual shall be audited annually.

Measures are established to ensure that audits plans are developed and documented, reported, authenticated, and contain appropriate information.

Results of audits shall be documented and brought to the attention of the personnel having responsibility in the area audited. Management personnel for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

Relevant results of the audits shall be reported and provided to HFC Management for review during the annual management review of the quality system. Adverse findings shall be investigated and actions taken to correct the finding including measures to prevent recurrence.

Audit records shall include audit plans/checklists, audit reports, written replies, and record of corrective action completion.

Auditor shall audit Counterfeit, Fraudulent, and Suspect Items (CFSI) procedure regularly to ensure no CSFI issues.

Implementing Procedures

QPP 1.1, "Management Review"

QPP 2.3, "Lead Auditor Qualification"

QPP 2.4, "Auditor Qualification"

QPP 16.1, "Corrective Action Program"

QPP 17.1, "Quality Records"

QPP 18.1, "Audits"

Section 19.0 - Contract Review

HFC shall establish and maintain documented procedures to ensure that customer orders are reviewed and accepted prior to order release to engineering or production.

Implementing procedures shall assure that customer requirements are reviewed and accepted by authorized HFC personnel to ensure that HFC has the capability to perform the stated scope of work. HFC normally receives customer requirements in the form of purchase orders and contracts.

Differences between HFC proposals and customer authorizing documents shall be reconciled prior to acceptance of the order. Verbal authorizations are not accepted by HFC.

Amendments to customer authorizing documents must be reviewed and accepted in the same manner as the original document.

Records of contract review shall be maintained.

Implementing Procedures

QPP 17.1, "Quality Records"

QPP 19.1, "Contract Review"

Section 20.0 – Servicing and Customer Supplied Products

Servicing activities may include: warranty issues, service contract activities, RMAs, training, application engineering and/or field design changes.

Procedures are developed to process Customer Supplied Products in the form of Returned Material Authorizations.

HFC shall establish and maintain documented procedures to ensure that trained and/or qualified personnel perform, verify, and report these functions under controlled conditions. For service activities covered by an open project, the Quality Plan shall define the scope of HFC field services required by the customer.

Methods have been established for performing, verifying, and reporting to ensure HFC field service operations meet defined requirements when contractually specified.

Implementing Procedures

QPP 2.1, "Project Quality Plans"

QPP 8.1, "Identification and Control of Materials, Parts, and Components"

QPP 10.1, "Receipt, In-Process, and Final Inspection"

QPP 13.1, "Handling, Shipping, Storage, and Preservation of Materials, Parts, and Components"

QPP 15.1, "Nonconformance Control Program"

QPP 17.1, "Quality Records"

QPP 20.1, "Servicing and Customer-Supplied Products"

Section 21.0 - Statistical Techniques

Current statistical data, process data, variations, supplier issues, and trends are identified for management review. Graphical techniques such as bar charts, tables, etc., are used as necessary to depict trends. Applicable managers control their areas for the use of statistical techniques.

The areas that are targeted for data analysis and used for process improvement are, as a minimum, the following:

- Customer satisfaction
- Conformance to product and service requirements
- Trends
- Opportunities for preventive actions
- Suppliers

Implementing Procedures

QPP 21.1, "Statistical Techniques"

DOOSAN HF Controls

ATTACHMENT 1 "Quality Management Process for Projects"