NUCLEAR QUALITY ASSURANCE MANUAL

COLUMBIANA HI TECH
1621 Old Greensboro Road, Kernersville, NC 27284

INTRODUCTION

The Columbiana Hi Tech. Nuclear Quality Assurance Manual for 10 CFR Part 71, Subpart H, and 10 CFR Part 72, Subpart G, has been developed as a means to describe the quality assurance requirements that apply to activities affecting quality associated with the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, repair, and maintenance of items that are classified as important-to-safety and subject to the requirements of 10 CFR Part 71 and/or 10 CFR Part 72 and associated Nuclear Regulatory Commission (NRC) Certificate(s) of Compliance (CoC's).

This manual also satisfies the provisions of 10 CFR Part 50, Appendix B and is applicable to activities affecting quality associated with items and services subject to the requirements of 10 CFR Part 50 that are classified as safety-related.

This manual applies to the following Columbiana Hi Tech locations:

- 1621 Old Greensboro Rd.; Kernersville, NC
- 1802 Fairfax Rd.; Greensboro, NC

The Columbiana Hi Tech Nuclear Quality Assurance Program is comprised of this manual and associated implementing policies and procedures. Columbiana Hi Tech implementing policies and procedures are designed and administered to meet the applicable requirements of 10 CFR Part 71, Subpart H; 10 CFR Part 72, Subpart G; 10 CFR Part 50, Appendix B, and the ASME NQA-1-1994 Edition and the NQA-1-2008 Edition with the NQA-1a-2009 Addenda.

Approved:

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COLUMBIANA HI TECH LLC

Nuclear Manufacturing Excellence

STATEMENT OF POLICY & AUTHORITY

This manual is a description of the Nuclear Quality Assurance Program in effect at Columbiana Hi Tech, LLC facilities. This manual complies with 10 CFR Part 71 Subpart H, 10 CFR Part 72 Subpart G, 10 CFR Part 50 Appendix B, and ASME NQA-1.

The executive management of this company is committed to the support of this program and charge all employees involved in activities affecting the quality of Columbiana Hi Tech products with the responsibility of upholding and abiding by the requirements in this manual.

The Quality Assurance organization is authorized sufficient freedom to identify quality problems, initiate, recommend, or provide solutions, verify implementation of solutions and control further processing or delivery of a nonconforming item, deficiency or unsatisfactory condition until proper disposition has been completed.

In the event of disputes arising between managers of departments regarding the interpretation or fulfillment of the requirements in this manual, this shall be referred to and settled by the undersigned.

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Joseph A. Faldowski
President & COO
Columbiana Hi Tech, LLC

1 - ORGANIZATION

1.1 PURPOSE

To describe the organizational structure, functional responsibilities, levels of authority, and internal and external communications for managing, directing, and executing the Nuclear Quality Assurance Program.

1.2 RESPONSIBILITY & AUTHORITY

1.2.1 The Vice President of EHS & Quality reports directly to the President of Columbiana Hi Tech and is vested with the authority and responsibility to ensure that all elements of the Nuclear Quality Assurance Program are designed, defined, implemented, maintained and assessed in a planned and systematic manner to provide confidence, including evidence, that all items are constructed in accordance with regulatory and contract requirements. The Vice President of EHS & Quality shall report to the President yearly on the overall effectiveness of the Nuclear Quality Assurance Program.

1.2.2 The Vice President of EHS & Quality is vested with the authority and responsibility to assure that all elements of the Nuclear Quality Assurance Program dealing with the control and acceptance functions of inspection, examination and testing described in this manual and associated procedures and instructions are carried out in accordance with this manual and established procedures.

1.2.3 The Quality Assurance Manager and the Quality Control Supervisor report to the Vice President of EHS & Quality and provide support with those respective functions.

1.2.4 The Quality organization is authorized sufficient freedom to

a) identify quality problems;
b) initiate, recommend, or provide solutions;
c) verify implementation of solutions;
d) control further processing or delivery of a nonconforming item, deficiency, or unsatisfactory condition until proper disposition has been completed.

1.2.5 The Vice President of Engineering reports to the President of Columbiana Hi Tech and is responsible for design engineering, manufacturing engineering, manufacturing material control (including production control and purchasing), contract administration and welding engineering. The Vice President of Engineering is supported by Manufacturing and Welding Engineers and other personnel as needed in the performance of these activities.

1.2.6 The Purchasing Manager reports directly to the President and is responsible for the procurement of items and services.

1.2.7 The responsibility for verification of conformance to these quality requirements is that of persons or organizations not having direct responsibility for performing the work. Verifications are the responsibility of the Quality organization. Delegation of verification activities may be assigned to personnel other than those in the quality organization. Such would be the case when a design engineer, other than the one who performed the original calculations, verifies design calculations.

1.2.8 Specified individuals may delegate authority to perform an activity to another individual; however, they retain responsibility for such activities. Use of the term "designee" is implied when a specific title is referenced.

1.2.9 Details of responsibilities and authorities involved in the attainment and verification of the Nuclear Quality Assurance Program are contained in the various policies and procedures and references comprising this manual.

2 - NUCLEAR QUALITY ASSURANCE PROGRAM

2.1 PURPOSE

To describe the Nuclear Quality Assurance Program in effect at Columbiana Hi Tech.

2.2 RESPONSIBILITY

The responsibility for the preparation, review, approval, maintenance and control of this manual is that of the Vice President of EHS & Quality. Controls for the administration, revision, approval, and distribution of this manual are described in subtier procedures.

2.3 SUBTIER PROCEDURES

2.3.1 Quality Assurance implementing procedures (Policy/Procedures) are generated for the various departments of Columbiana Hi Tech. Various procedures are referenced throughout this manual. Each department shall adhere to procedures developed for that particular department.

2.3.2 Policy/Procedures shall be prepared, reviewed, approved and controlled in accordance with established procedure(s).

2.4 QUALIFICATION OF PERSONNEL

2.4.1 The training of all applicable personnel in the understanding and use of the Code, other standards and this manual is the responsibility of the Vice President of EHS & Quality.

2.4.2 Management training is a continuing function of Columbiana Hi Tech managers. They are kept current on regulatory requirements, ASME Codes and standards and other industry standards, bulletins, and controversial matters by the Quality Department. Records of these indoctrinations and training are maintained on file by the Quality Assurance Department.

2.4.3 The indoctrination and training of Columbiana Hi Tech personnel prior to performing or supervising activities affecting quality is a recognized and practiced precept by all operating department managers.

2.4.4 The various department managers are responsible for assuring that the company policies and procedures covering the activities in their areas are treated in detail by bulletins and/or special instructions, and that their personnel are familiar with and proficient in these policies and procedures.

2.4.5 New employees are familiarized with Columbiana Hi Tech work, equipment, policies, procedures and standards by supervision of their assigned department. The evaluation of their competence and continued performance to required levels of quality and efficiency are, equally, the responsibility of the department managers and supervisors.

2.4.6 The training, examination, qualification and certification of nondestructive examination personnel is defined and controlled by established procedure(s), under the control of the Level III, which is in accordance with the written practice based on the American Society of Nondestructive Testing standard SNT-TC-1A.

2.4.7 Principal QA/QC management personnel qualifications shall be in accordance with established procedure(s).

2.5 TRAINING

2.5.1 Training shall be performed in accordance with established procedure requirements. The procedure shall as a minimum, make provisions for:

a) Minimum QA training requirements by job function.
b) Retention of training records.
c) Identification of applicable personnel.
d) Follow up training to be conducted when QA system is changed.
e) Training of personnel prior to performing or supervising work affecting quality.

2.6 GENERAL

2.6.1 Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, such as, adequate cleanliness, and assurance that all prerequisites have been satisfied. Consideration shall be given for the need for special controls, processes, test equipment, tools, and skills to attain the required quality by inspection and test. Procedures shall be written for any identified controlled conditions beyond normal manufacturing parameters. Procedures shall also be developed as required that identify special controls, processes, test equipment, tools, and skills needed to attain the required quality by inspection and test.

2.6.2 The Vice President of EHS & Quality shall oversee an effective industry experience and lessons learned program to ensure Columbiana Hi Tech's practices are consistent with current industry standards and expectations. This program is described in established procedure(s). This procedure shall, as a minimum, make provisions for:

a) Required evaluation of notices sent to Columbiana Hi Tech for necessary actions.
b) Defining the type of information to be evaluated for potential impact on Columbiana Hi Tech.
c) Defining the method for documenting the necessary actions
d) Defining the criteria for determining if a notice is applicable to Columbiana Hi Tech
e) Required documentation of all evaluations performed

3 - DESIGN CONTROL

3.1 PURPOSE

To describe the established measures to assure the correct translation of the applicable certified design specification into drawings, procedures, specifications, and instructions.

3.2 RESPONSIBILITY & AUTHORITY

3.2.1 The Vice President of EHS & Quality is responsible for the surveillance and audit of all sub-contracted design work to ensure the requirements of contract, regulatory, code, specification and this procedure are satisfied. Audits shall be conducted and documented per Columbiana Hi Tech Nuclear Quality Assurance Program requirements.

3.2.2 Columbiana Hi Tech may subcontract design work to qualified engineering sources. The engineering source shall be audited and approved by Quality Assurance as applicable.

3.2.3 The Vice President of Engineering is responsible for defining, controlling, and verifying the design application.

3.3 GENERAL

3.3.1 The CHT design application is defined, controlled, and checked or verified. Design inputs are translated into design documents and design interfaces are identified and controlled. Design reviews are performed by persons other than those who designed the item, but who may be from the same organization. Design changes are governed by control measures commensurate with those applied to the original design.

3.3.2 Design control measures will apply to such items as:

- Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyzes;
- Compatibility of materials;
- Accessibility for in-service inspection, maintenance, and repair;
- Features to facilitate decontamination; and
- Delineation of acceptance criteria for inspections and tests.

3.3.3 The completed design, including regulatory requirements, will be translated into specifications, drawings, operating procedures, and work instructions.

3.4 DESIGN REQUIREMENTS

3.4.1 Design Inputs

If Columbiana Hi Tech personnel are to perform design activities, procedures will be established to identify, document, review, and approve design inputs. The procedures will assure that appropriate quality standards are included in the design, and that deviations from those standards are controlled.

3.4.2 Design Analyses

a) Design analyses are performed in a planned, controlled, and documented manner, and include:
   - Definition of the objective of the analyzes
   - Definition of design inputs and their sources
   - Identification of assumptions
   - Identification of computer calculations
   - Review and approval

b) Design analyses will also assure the suitability of materials, parts, equipment, and processes to the safety-related function of the product.

3.4.3 Design Verification

If Columbiana Hi Tech personnel are to perform design activities, design control measures will be applied to verify the adequacy of the design, and include:

a) The extent of design verification based on the importance to safety, complexity, degree of standardization, state of the art, and similarity with previously proven designs.

b) The method for checking or verifying the design to include one or more of the following: design reviews, alternate calculations, and qualification testing.

c) If testing is used to verify a specific design feature in lieu of other verifying or checking processes, the qualification testing will be conducted under the most adverse design conditions.

3.4.4 Change Control

a) Changes to final design, field changes, modifications to existing products and nonconforming items dispositioned use-as-is or repair, will be justified and subject to design control measures commensurate with original design.

b) Changes in the conditions specified in the package approval for 10 CFR 71/10 CFR 72 that require NRC approval, will receive NRC approval.

3.4.5 Interface Control

Design interfaces will be identified and controlled, and will include assignment of responsibility and the establishment of procedures for the review, approval, release, distribution, and revision of documents involving design interfaces.

3.4.6 Documentation and Records

Design documentation and records that provide evidence that the design and verification processes were appropriately performed will be retained in accordance with Columbiana Hi Tech QA Program requirements.

3.4.7 Additional Requirements

If the sub-tier documents related to product lines or projects contain additional requirements for design control, they will be met in addition to the requirements stated herein.

4 - PROCUREMENT DOCUMENT CONTROL

4.1 PURPOSE

To describe the measures established to assure that applicable regulatory requirements, specification, drawing and contract requirements which are necessary to assure adequate quality requirements are included or referenced in the CHT Purchase Order for materials, items or service.

4.2 RESPONSIBILITY & AUTHORITY

4.2.1 It is the responsibility of the Manufacturing Engineer to translate customer contract, drawings, specifications and standards into the requirements of the Columbiana Hi Tech Purchase Order and purchase order changes for materials, items or services including those associated with weld filler materials.

4.2.2 It is the responsibility of the Vice President of Engineering and the Vice President of EHS & Quality to verify completeness, accuracy and to approve Columbiana Hi Tech Purchase Orders and purchase order changes. Additionally, Quality Assurance is responsible for the quality evaluation of sources, the determination of need for inspection, examination or test at the source and/or upon receipt and the conduct of necessary source audits, according to this procedure and its references.

4.2.3 It is the responsibility of the Purchasing Manager to seek approved sources, as required and place the purchase orders and changes.

4.3 PROCEDURE

4.3.1 Materials, items or services shall be procured as described in established procedure(s). This procedure(s) shall, as a minimum, make provisions for:

a) Preparation, review, approval, and changes to Columbiana Hi Tech Purchase Orders.
b) Qualification and selection of suppliers of materials, items and services.
c) Identification of quality assurance requirements and the elements of the program applicable to the items or services procured.
d) Inclusion of basic technical requirements in Columbiana Hi Tech Purchase Orders.
e) Source inspection and audit.
f) Documentation requirements.
g) Lower tier procurements.

5 - INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 PURPOSE

To delineate the use of instructions, procedures and drawings.

5.2 RESPONSIBILITY & AUTHORITY

5.2.1 It is the responsibility of the Vice President of Engineering to prepare and control all working instructions, specifications, sketches, procedures and standards except those for nondestructive examination.

5.2.2 Nondestructive Examination procedures are prepared, maintained and controlled by the Vice President of EHS & Quality. Nondestructive Examination procedures shall be approved by an NDE Level III.

5.2.3 The verification responsibility for instructions, specifications, sketches, procedures and standards is that of the Quality Assurance Department.

5.3 GENERAL

5.3.1 Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances, and shall be accomplished in accordance with the instructions, procedures, or drawings. Instructions, procedures or drawings shall contain appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

5.3.2 The basic document, used by Columbiana Hi Tech, to assure the accomplishment of all manufacturing and quality activities is the Traveler. This document, its attachments, lists and sketches contain the details and sequence of all operations, inspections, examinations or tests, or provides the reference to procedures, specifications or standards and their revisions, which are necessary to complete the products involved. The proper completion of this document and its references demands a full review and understanding of the contract, its references, its drawings, equipment/design specifications, Code provisions and standards associated with the order. Development of Traveler's shall be per established procedure(s).

6 - DOCUMENT CONTROL

6.1 PURPOSE

To describe the established measures for controlling the review, approval, issuance and recall of documents which prescribe activities affecting quality.

6.2 RESPONSIBILITY & AUTHORITY

6.2.1 It is the responsibility of the Vice President of Engineering to control the distribution of instructions, specifications, sketches, process procedures and standards.

6.2.2 The Vice President of EHS & Quality is responsible for the control of Nuclear Quality Assurance Program policies and procedures including this program manual.

6.3 GENERAL

6.3.1 Established procedure(s) controls the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe activities affecting quality. These measures assure that documents, including changes are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.

6.3.2 The reviewing organizations shall have access to pertinent background information upon which to base its approval and shall have adequate understanding of the requirements and intent of the original document.

6.3.3 Established procedure(s) controls the issuance, preparation, review and approval of Policy/Procedures.

6.3.4 Document Control measures provide for:

a) Identification of individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto;
b) Identifying the proper documents to be used in performing the activity;
c) Coordination and control of interface documents;
d) Ascertaining that proper documents are being used;
e) Establishing current and updated distribution lists.

7 - CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 PURPOSE

To describe the established measures for assuring purchased material, items and services conform to procurement documents.

7.2 RESPONSIBLITY & AUTHORITY

7.2.1 The Vice President of Engineering is responsible for translating the Customer contract and associated Code, regulations, specifications and standards into the requirements of the Purchase Order for materials, items or services.

7.2.2 The Vice President of EHS & Quality is responsible for reviewing and approving content and accuracy of Purchase Orders according to established procedure(s). Additionally, Quality Assurance is responsible for the quality evaluation of sources, the determination of need for inspection examination or test at the source and/or upon receipt and the conduct of necessary source audits, according to this procedure and its references.

7.2.3 The Purchasing Manager is responsible for the selection and use of sources permitted according to established procedure(s), this procedure and references of both.

7.2.4 The Quality Control Manager is responsible to inspect, examine and test purchased material, items and services at the source or upon receipt as directed by the Purchase Order.

7.3 GENERAL

7.3.1 All sources of materials, items and services are evaluated for quality performance by one or more of the following methods.

a) Inspection, surveillance, examination or test at the source of supply, as specified by Quality Assurance in the Purchase Order & performed by Quality Control.

b) Inspection, examination or test of materials or services upon receipt at Columbiana Hi Tech, as specified by Quality Assurance in the Purchase Order and performed and reported by Quality Control in accordance with established procedure(s).

c) Evaluation by Quality Assurance on a scheduled basis, of the quality performance history developed from either a) or b) or both.

d) Planned & scheduled on-site audits of intended & existing sources by Quality Assurance or designees.

7.4 PROCEDURE

7.4.1 The Purchasing Manager prepares the Purchase Order or changes.

7.4.2 The Manufacturing Engineer and Quality Assurance Manager reviews and approves the Purchase Order or changes.

7.4.3 Purchasing processes the Purchase Order according to established procedure(s) and notifies the Columbiana Hi Tech Vice President of EHS & Quality, or designee, by written notice, of any intended source requiring qualification by audit.

7.4.4 The Vice President of EHS & Quality upon receipt of written notice on intent to use a new source requiring audit:

a) Verifies the intended source is not shown on the current Qualified Vendor List (QVL) or is approved, awaiting inclusion on the list.

b) Verifies that the intended use of the source, and the product or services to be ordered, require audit under the conditions outlined in established procedure(s).

c) Arranges for an audit of the source by qualified personnel within Columbiana Hi Tech.

d) Conducts or has conducted an audit according to prepared checklists or to specifications, standards or procedures applicable to the work being ordered.

e) Evaluates audit results and, upon finding them satisfactory, approves the source for addition to the Qualified Vendor List. The list is maintained by Columbiana Hi Tech Quality Assurance and is issued each calendar quarter, unless no changes occur, and is distributed to Receiving Inspection, Purchasing and Manufacturing Engineering Departments, as a minimum.

7.4.5 Upon receipt inspection, the Inspector verifies evidence of Columbiana Hi Tech inspection at the source when the Purchase Order so indicates. Results of each receipt inspection are recorded in the Supplier Quality History Record. The Receiving Inspector forwards written notice of goods or services received from sources requiring approval but who do not appear on the Qualified Vendor List, and withholds them until disposition by Quality Assurance.

7.4.6 Received material shall be inspected by Quality Control to ensure supplier compliance to purchase order requirements.

7.4.7 Quality Assurance takes action on reported receipts of material or services from sources requiring approval but who are not approved. This action may range from audit of the source to return of the material or items to the source.

7.4.8 Quality Assurance, on a semi-annual basis, evaluates the Supplier Quality History as described in applicable sub tier procedures.

7.4.9 Quality Assurance routinely evaluates corrective action replies. In the course of this evaluation (and approval, if replies are adequate) high evidence of repetitive discrepancies, poor response content, or lack of timely or any response are added causes for special written requests for action by Purchasing to improve source performance.

7.4.10 An unsatisfactory source for quality reasons, is reported in letter form to the applicable departments by the Quality Assurance Department to stop quote, procurement and Columbiana Hi Tech receipt inspection and release activities. This status can only be reversed by the Vice President of EHS & Quality or President of Columbiana Hi Tech.

7.4.11 Commercial grade items shall be procured and controlled per established procedure(s).

7.5 USE OF COMMERCIAL GRADE CALIBRATION OR TEST LABORATORIES

7.5.1 In lieu of an audit or commercial-grade survey, Columbiana Hi Tech may choose to approve calibration or testing services from a supplier based on accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). Procurement of calibration or testing services from these accredited suppliers is allowed provided each of the following conditions are met:

(a) A documented review of the supplier's accreditation shall be performed and will include verification of the following:

(1) The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

(2) For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

(3) For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainties.

(b) The procurement documents shall include the following:

(1) The service must be provided in accordance with their accredited ISO/IEC 17025:2005 program and scope of accreditation.

(2) As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance.

(3) The equipment/standards used to perform the calibration must be identified in the certificate of calibration.

(4) Columbiana Hi Tech must be notified of any condition that adversely impacts the supplier's ability maintain the scope of accreditation.

(5) Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

(c) It shall be validated at receipt inspection that the supplier's documentation certifies that:

(1) The contracted calibration or test service has been performed in accordance with the supplier's ISO/IEC-17025:2005 program, has been performed within their scope of accreditation, and

(2) The requirements of the purchase order have been met.

8 - IDENTIFICATION & CONTROL OF ITEMS

8.1 PURPOSE

To delineate the requirements for identification and control of material, parts, and components.

8.2 GENERAL

8.2.1 Established procedures provide the working instructions used for the identification and control of materials, parts, and components including partially fabricated subassemblies. By virtue of this procedure, measures are established for assuring that only correct and accepted items are used, and installed, and relating an item of production at any stage, from initial receipt through fabrication, installation, repair, or modification to an applicable drawing, specification, or other pertinent technical document.

8.2.2 Physical identification shall be used to the maximum extent possible. Where physical identification is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification may be either on the item or on records traceable to the item, as appropriate.

8.2.3 Where identification marking is employed, the marking shall be clear, unambiguous, and indelible, and shall be applied in such a manner as not to affect the function of an item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identifications are substituted.

8.2.4 Any special identification requirements shall be stated in travelers.

8.2.5 Material requiring shelf life controls shall also meet the requirements of established procedure(s).

9 - CONTROL OF SPECIAL PROCESSES

9.1 PURPOSE

To describe the established measures for ensuring that special processes, such as welding, cleaning, nondestructive examination, coating and heat treatment; and tests, such as hydrostatic and pneumatic are accomplished under controlled conditions, in accordance with applicable Codes, Standards, Specifications, and other special requirements, using only qualified personnel and procedures.

9.2 RESPONSIBILITY & AUTHORITY

9.2.1 The Welding Engineer is responsible for:

a) Preparation and initiation of tests of all Welding Procedure Specifications (WPS), supporting Procedure Qualification Records (PQR), and Manufacturer's Record of Welder or Welding Operator Qualification Tests, in accordance with the requirements of established procedure(s).
b) Ordering of testing of welding materials and/or welder qualification test plates in accordance with applicable sections of this manual.

9.2.2 The Manufacturing Engineer is responsible for the preparation of:

a) Procedures for testing, cleaning, coating, handling, heat treatment, etc., or
b) Contract for the services including procedures, as necessary via purchase orders from qualified vendors.

9.2.3 The NDE Level III is responsible for the approval of nondestructive examination procedures. Additionally, the NDE Level III is responsible for qualification and certification of NDE personnel in accordance with the requirements of established procedure(s).

9.2.4 The Quality Assurance Manager is responsible for the review and approval of procedures and acceptance standards.

9.2.5 Manufacturing, Material Control and Quality Control personnel are responsible to ensure the work is immediately discontinued on jobs where the traveler is required to be removed from the work areas for up-grading, revision, Nonconformance Report processing or any other reason. Material Control is responsible to advise Quality Control and Manufacturing of such removal.

9.3 GENERAL

9.3.1 Qualification of personnel, procedures, and equipment shall comply with the requirements of applicable codes and standards.

9.3.2 Documentation shall be maintained for currently qualified personnel, processes, or equipment in accordance with the requirements of pertinent codes and standards.

9.3.3 For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures or equipment shall be defined.

9.4 PROCEDURE

9.4.1 Special processes and tests shall be controlled as described in established procedure(s). This procedure(s) shall provide for:

a) Welding procedure specification, preparation and qualification.
b) Weld joint identification and traceability to welder, weld filler material, and inspector, as required.
c) Weld wire receipt, control and issuance.
d) Preparation and control of other special processes and tests. (i.e. cleaning, heat treatment, coating, etc.)
e) Control of Nondestructive Examination Procedures to include preparation and approval.
f) Control of subcontracted examinations.

10 - INSPECTION

10.1 PURPOSE

To describe the measures established for inspection of activities affecting quality including the activity of verifying conformance to documented instructions, procedures, and drawings.

10.2 RESPONSIBILITY & AUTHORITY

10.2.1 Columbiana Hi Tech personnel who perform inspections, examinations, tests and surveillance of activities affecting quality report directly to the Quality Control Manager who is responsible for quality control functions and who in turn reports to the Vice President of EHS & Quality.

10.2.2 The Manufacturing Engineer or Welding Engineer is responsible for the complete description of purchased materials, items, and services, as well as the preparation and control of the Traveler and referenced procedures for the fabrication of contracted end- items. These Purchase Orders, Travelers, and Procedures form the basis of instructions and individually are inspection checklists for the activity covered.

10.2.3 The Quality Assurance Manager is responsible for ensuring that all design and Code characteristics, including dimensions, processes, examinations, tests, etc. are described or referenced in the combination of Purchase Orders and Travelers.

10.2.4 Manufacturing and Material Control personnel are responsible to ensure that Purchase Orders, Travelers, referenced procedures and special instructions which specify inspection, examination, hold, test, or other verification operations/requirements are fully honored and never by-passed, without written authority of the Vice President of EHS & Quality.

10.2.5 Columbiana Hi Tech personnel who perform inspections, examinations, tests and surveillance of activities affecting quality shall be qualified in accordance with established procedure(s).

10.2.6 Quality Control personnel are responsible for performing inspection, tests, examination, etc. in accordance with the approved procedures contained in this manual and those specified in Quality Assurance approved Purchase Orders, Travelers and special inspection procedures. Quality Control personnel have both the authority and responsibility to stop work on operations found to depart from procedure or specification.

10.2.7 Established procedure(s) shall be used in conjunction with this procedure for implementation.

10.3 GENERAL

10.3.1 Inspection and test records shall, as a minimum, identify the date of inspection or test, the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted.

10.3.2 Examinations, measurements, or tests of items processed shall be performed for each work operation where necessary to assure quality. The Traveler shall be used to designate such operations.

10.3.3 Unless otherwise provided for in Customer contract, purchase order, or specification, a 100% inspection of all items manufactured by and/or for Columbiana Hi Tech shall be imposed.

10.3.4 Where a sample is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices and shall provide adequate justification for the sample size and selection process.

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

10.3.6 If mandatory inspection hold points, which require witnessing or inspecting by the Purchaser's designated representative and beyond which work shall not proceed without the consent of the purchaser's designated representative, are required, the specific hold points shall be indicated on travelers. Such consent shall be documented prior to the continuation of work beyond the designated hold point.

11 - TEST CONTROL

11.1 PURPOSE

To delineate the procedure established to ensure that all testing required to demonstrate that the item will perform satisfactorily in service is identified and documented, and that the testing is performed in accordance with written test procedures which incorporate or reference the requirements and acceptance limits contained in applicable design documents.

11.2 RESPONSIBILITY & AUTHORITY

11.2.1 The Manufacturing Engineer is responsible to ensure that all testing requirements are extracted from Customer specifications, codes, and standards and develop any necessary procedures.

11.2.2 Quality Control and Manufacturing personnel are responsible to assure that only properly controlled, calibrated, adjusted and identified tools, gages, instruments and equipment are used in the conduct of activities affecting quality.

11.2.3 Quality Control personnel are responsible to provide the control activities, in keeping with this procedure, to assure that tools, gages, instruments and equipment used for measuring and testing are calibrated, adjusted, as required, identified and recorded at the established frequencies.

11.2.4 The Quality Control Supervisor is responsible to identify the need, during work planning processes, for special tools, gages, instruments or test equipment for measuring and testing, beyond the known capability of existing Columbiana Hi Tech measuring and test equipment inventories. Should such need appear, procurement or fabrication actions will be initiated to provide them for Quality Control.

11.3 PROCEDURE

11.3.1 Test procedures shall include provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, and that necessary monitoring is performed. Prerequisites include such items as calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. Test results shall be documented and evaluated by Quality Control to assure that test requirements have been satisfied.

11.3.2 Test requirements and acceptance criteria shall be provided by the organization responsible for the design of the item under test unless otherwise designated.

11.3.3 Manufacturing Engineering shall interpret Customer specifications and applicable codes and standards and formulate necessary procedures that comply with paragraph 11.3.1 and 11.3.2.

11.3.4 Quality Assurance shall review each procedure to ensure compliance to Customer specifications, codes, and standards and this procedure.

11.3.5 Quality Assurance shall review test results and records to assure that test requirements have been satisfied.

11.3.6 Quality Control shall perform test(s) in accordance with established procedures and document results per the requirements of same.

11.3.7 Quality Control shall document test results. These test records shall, as a minimum, identify the following:

a) Item Tested
b) Date of Test
c) Tester or Data Recorder
d) Type of Observation
e) Results or Acceptability
f) Action taken in connection with any deviations noted
g) Person Evaluating Test Results

12 - CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 PURPOSE

12.1.1 To describe the established measures to assure that tools, gages, instruments and other inspection, measuring and testing equipment are:

a) of the proper range, type and accuracy to verify conformance to established requirements, and
b) controlled, calibrated, adjusted and maintained at prescribed intervals, or prior to use, against certified equipment having valid traceability to nationally recognized standards, where such standards exist. When such standards do not exist, the basis for calibration shall be documented.

12.1.2 This requirement is not intended to imply a need for special calibration and control measures on rulers, tape measures, levels, and such other devices if normal commercial practices provide adequate accuracy.

12.2 RESPONSIBILITY & AUTHORITY

12.2.1 Quality Control and Manufacturing personnel are responsible to assure that only properly controlled, calibrated, adjusted and identified tools, gages, instruments and equipment are used in the conduct of activities affecting quality.

12.2.2 The Quality Control Manager is responsible to provide:

a) The control activities, in keeping with this procedure, to assure that tools, gages, instruments and equipment used for measuring and testing are calibrated, adjusted, identified and recorded at the established frequencies.
b) For the suitable storage and protection of company owned inspection equipment.

12.2.3 The Quality Control Manager is responsible to identify the need, during work planning processes, for special tools, gages, instruments or test equipment for measuring and testing, beyond the known capability of existing Columbiana Hi Tech measuring and test equipment inventories. Should such need appear, procurement or fabrication actions will be initiated to provide them for Quality Control.

12.2.4 The Quality Assurance Manager shall ensure that calibration service providers are audited and approved.

12.3 PROCEDURE

12.3.1 Control of measuring and test equipment shall be accomplished as described in established procedure(s). This procedure(s), as a minimum, shall provide for:

a) Assurance that tools, gages, instruments, and other inspection, measuring and test equipment used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements.
b) Identification of inspection equipment, tools, gages.
c) Calibration and adjustment of inspection tools, instruments, and gages to include: established methods and intervals of calibration against nationally recognized standards.
d) Documented evaluation of validity of previous inspections/test, when inspection/test equipment is found to be suspect or out of calibration.
e) Records documenting results and/or calibration history/status of measuring and test equipment.

12.3.2 The control of measuring and testing equipment for field applications shall be accomplished as described in established procedure(s). This procedure(s), as a minimum, shall provide for:

a) The definition of field application measuring and test equipment.
b) The recall of field application measuring and test equipment.
c) The notification of effected organizations when measuring and test equipment is found out of tolerance.

13 - HANDLING, STORAGE, AND SHIPPING

13.1 PURPOSE

To describe the established measures to control handling, storage, shipping, cleaning, packaging and preservation of material and items.

13.2 RESPONSIBILITY & AUTHORITY

13.2.1 The Manufacturing Engineer is responsible for recognizing the need for, and prescribing the procedure, equipment, and controls necessary for special conditions, handling, storage, cleaning, preservation, packaging, packing and shipping in the Travelers, procedures or instructions referenced therein.

13.2.2 The Quality Assurance Manager is responsible to assure that procedures and instructions are adequate for the situation and are provided when necessary.

13.2.3 Manufacturing and Material Control personnel are responsible for abiding by the procedures and instructions in the Travelers or referenced documents.

13.2.4 Quality Control personnel are responsible to verify procedures and instructions prescribed are properly abided by, and verified at Traveler operations involved.

13.3 GENERAL

The implementation of measures for the control of handling, storage, and shipping has been delegated to the appropriate Columbiana Hi Tech departments for their respective scope of work. Procedures, practices, and instructions are established and documented as necessary to provide control of handling, storage, cleaning, packaging, preservation, shipping release, and shipping of material and equipment to prevent damage, deterioration or loss during manufacture and shipment as required by the Customer specification.

13.4 PROCEDURE

13.4.1 When necessary for a particular item to have special identifications, coverings, handling, storage, special equipment, or special environmental conditions, such as inert gas atmosphere, specific moisture content levels, and temperature levels, etc. they are specified by Manufacturing Engineering in the Traveler and/or procedure, are reviewed by Quality Assurance, performed by Manufacturing and Material Control and are verified by Quality Control.

13.4.2 Inspection shall verify compliance to packaging, preservation, shipping and identification requirements in accordance with Section 10 of this manual, per Customer and specification requirements referenced.

14 - INSPECTION, TEST, AND OPERATING STATUS

14.1 PURPOSE

To describe the measures established to identify inspection and test status of items throughout the manufacturing process, up to and including, final inspection and shipment.

14.2 RESPONSIBLITY & AUTHORITY

14.2.1 The Manufacturing Engineer is responsible for preparation of shop travelers, which document manufacturing operations, inspections, and test to be performed.

14.2.2 It is the responsibility of Material Control personnel to:

a) Maintain stores or bond area.
b) Place items with Travelers into work.
c) Move items with travelers through the various stages of manufacturing and inspection.
d) Assure that only accepted items which have passed required inspections are placed into work.

14.2.3 It is the responsibility of Manufacturing personnel to:

a) Fabricate items per Travelers, procedures and drawings.
b) Notify Quality Control of inspection points which are ready for inspection.
c) Notify inspection of any dimensional errors which arise during fabrication.
d) Assure that work is performed in the sequence and manner prescribed by Travelers, and discontinue such work when a Traveler is removed from the work area.
e) Assure that only accepted items that have passed required inspections are placed into work.

14.2.4 The Quality Assurance Manager is responsible to review and verify that Travelers provide for performance of all required inspections and test and documentation of same.

14.2.5 It is the responsibility of Quality Control personnel to:

a) Verify that only accepted items which have passed required inspections are placed into work.
b) Verify that items are manufactured per Travelers and perform various inspections (dimensional, NDE functional, etc.) as required, per Traveler, specification and drawing requirements.

c) Notify applicable personnel or organizations of Hold and/or Witness Points.
d) Attach or remove status indicator (tags) as required.
e) Identify items, and issue nonconformance reports (NCR's) per Section 15, for items found to be nonconforming.

14.3 PROCEDURE

14.3.1 Identification of inspection and test status of items shall be accomplished as described in established procedure(s). This procedure(s), as a minimum, shall provide for:

a) Assurance that required inspections and test are performed and that the acceptability of items with regard to inspections and test performed is known throughout manufacturing and inspection processes.
b) Use and processing of status indicators such as, travelers, tags, markings, stamps, and inspection records. Additionally, measures shall include procedures for control of status indicators including the authority for application and removal of tags, markings, labels and stamps.
c) Identification of nonconforming items.

15 - CONTROL OF NONCONFORMING ITEMS

15.1 PURPOSE

To delineate the measures established to control items, services, or activities which do not conform to requirements.

15.2 RESPONSIBILITY & AUTHORITY

15.2.1 It is the responsibility of the Quality Control Manager to:

a) Identify nonconforming items and services and prevent further processing, delivery, or installation pending final disposition.
b) Report nonconforming conditions on a Nonconformance Report (NCR), and identify responsibility, i.e. Columbiana Hi Tech, vendor or Customer.
c) Withhold the item in bond or in place until disposition is made on the NCR. Place a Withhold Tag on the item.
d) When the disposition of the discrepant item is completed, remove the item from bond or withhold status and verify the disposition is being carried out, as designated, and clear Nonconformance Report numbers on Traveler and/or P.O. Receiving Log, as applicable.
e) Apply and remove Withheld Tags.

15.2.2 It is the responsibility of designated Manufacturing personnel to:

a) Verify the discrepancy as noted on the NCR.
b) Complete the cause and corrective action blocks of the NCR when required.
c) Carry out the disposition as required by the NCR.

15.2.3 It is the responsibility of the Manufacturing Engineer to:

a) Review NCR reported discrepancies against the Code, contract and drawing requirements.
b) Contact the Customer and vendor as required for additional information and recommendations.
c) Complete the disposition and, if required, complete the rework traveler.
d) Forward reported deficiencies for Customer acceptance, as required.

15.2.4 It is the responsibility of the Quality Assurance Manager to:

a) Review and approve the completed NCR for completeness, signatures, accuracy and conformity to Code, contract and drawing requirements.
b) Maintain a log of all Nonconformance Reports generated.
c) Forward documents to Manufacturing Engineering for transmittal to Customers.

15.2.5 It is the responsibility of Purchasing Manager to coordinate the return of materials to the vendors for replacement or rework.

15.3 GENERAL

15.3.1 Nonconforming items and services shall be processed as described in established procedure(s). This procedure(s) as a minimum shall provide for:

a) Identification, documentation, segregation, disposition, and notification to affected organizations as required.
b) The review and acceptance, rejection, rework, or repair of nonconforming items and services in accordance with documented procedures.
c) Review and evaluation of 10 CFR Part 21 applicability.

15.3.2 Reporting of defects and noncompliance in compliance with 10 CFR Part 21 (as applicable) shall be accomplished in accordance with established procedure(s).

16 - CORRECTIVE ACTION

16.1 PURPOSE

To delineate the measures established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected as soon as practical.

16.2 RESPONSIBILITY & AUTHORITY

16.2.1 The Quality Assurance Manager is responsible for determining and assigning responsibility for a condition reported on a Nonconformance Report and deciding the need for determination of cause and establishment of corrective action to preclude recurrence.

16.2.2 It is the responsibility of applicable department personnel to investigate and determine cause and corrective action taken for conditions found and reported as Columbiana Hi Tech responsibility.

16.2.3 It is the responsibility and final authority of the Vice President of EHS & Quality to evaluate statements of cause and corrective action to determine their adequacy and to assure completeness.

16.2.4 The Purchasing Manager is responsible for follow-up assistance to Quality Assurance in seeking and gaining effective cause and corrective action from Columbiana Hi Tech vendors of material, items and services.

16.3 GENERAL

16.3.1 For conditions adverse to quality found during manufacturing processes and or audits, documentation as a minimum shall:

a) Contain the cause of the condition.
b) Delineate corrective action taken to preclude recurrence.
c) Report conditions adverse to quality to appropriate level of management.

16.3.2 Corrective Action measures shall be accomplished as described in established procedure(s).

17 - QUALITY ASSURANCE RECORDS

17.1 PURPOSE

17.1.1 To describe the established measures, which assure that sufficient records are maintained to furnish evidence of activities affecting quality.

17.2.2 Records developed shall be consistent with the regulatory codes (lifetime and nonpermanent), standards, specifications and contract requirements.

17.2 RESPONSIBILITY & AUTHORITY

17.2.1 The Manufacturing Engineer is responsible to ensure the contract, Code, specification or standard, relating to records are recognized, interpreted and provided for in Travelers, referenced procedures and/or instructions.

17.2.2 The Quality Assurance Manager is responsible to ensure the Traveler and references comply with contract, Code, and specifications requirements.

17.2.3 The Quality Control, Manufacturing and Material Control personnel are responsible to ensure those sequential operations of the Traveler, referenced procedures, instructions and Purchase Order requirements are properly completed, examined, acceptance stamped/initialed and dated.

17.3 GENERAL

17.3.1 Inspection and test records shall contain the following where applicable:

a) A description of the type of observation.
b) The date of the inspection or test.
c) Information related to conditions adverse to quality.
d) Inspector or Data Recorder identification.
e) Evidence as to the acceptability of the results.
f) Action taken to resolve any discrepancies noted.

17.3.2 Records shall be legible, identifiable, and retrievable.

17.3.3 The Quality Assurance Manager is responsible for preparation of a Certificate of Conformance, when required, per established procedure(s).

17.4 PROCEDURE

17.4.1 Manufacturing Engineering, in the course of review of the Customer contract and associated specifications, Code and standards shall determine and specify required reporting documents (including the Traveler itself) which constitute records of work performance and verification. This may be accomplished through preparation of Travelers, inspection and test procedures, etc.

17.4.2 Quality Assurance shall ensure records are maintained as specified throughout manufacturing and storage.

17.4.3 The Quality Department shall assure that all required documents and data released and specified are properly completed, identified and approved prior to final assembly of data packages and reproduction of required copies. A facsimile package to that used for presentation and shipment shall be maintained for the period required by the specifications.

17.4.4 The retention period for the records is as follows:

a) Transportation Packaging – Life of the packaging plus three years, or three years after termination of NRC QA Program Approval (if applicable), whichever is longer;
b) Spent Fuel Storage Packaging – Shall be maintained by or under the control of the licensee until the commission (NRC) terminates the license.

Additionally, records of use for all transport packages shall be maintained for a period of three years after the shipment.

17.4.5 Records deemed necessary by Columbiana Hi Tech or Customers shall be retained for periods as specified and shall be indexed, filed, and maintained in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.

17.4.6 Storage and maintenance of quality records shall be accomplished as described in established procedure(s).

18 - AUDITS

18.1 PURPOSE

To describe the method and controls employed in planning, scheduling, conducting and documenting the results of audits used to verify compliance with significant aspects of the Nuclear Quality Assurance Program.

18.2 RESPONSIBILITY & AUTHORITY

18.2.1 The Vice President of EHS & Quality is responsible for defining the plan, sequence, content and reporting of results of Nuclear Quality Assurance Program audits. To this objective, the President or Vice President of EHS & Quality, is authorized to select and assign personnel qualified per established procedure(s) but not having responsibilities in the areas being audited.

18.2.2 Audit results shall be documented by auditing personnel and shall be reviewed by management having responsibility in the area audited. Responsible management shall take necessary action to correct the deficiencies revealed by the audit.

18.2.3 Personnel performing audits shall be qualified in accordance with established procedure(s).

18.3 GENERAL

18.3.1 Audits shall be performed in accordance with established procedure(s). This procedure(s) shall as a minimum provide for:

a) An objective evaluation of compliance with established requirements, methods, and procedures:
b) Assessment of progress in assigned tasks:
c) Determining adequacy of Nuclear Quality Assurance Program performance; and
d) Verifying implementation of recommended corrective action.

18.3.2 Deficiencies shall be documented (as applicable) and follow up performed to verify that corrections have been accomplished.

18.3.3 Audits shall be conducted periodically or on a random, unscheduled basis or both. It is desirable to conduct audits when one or more of the following conditions exist:

a) When it is necessary to determine the capability of a Vendor’s Nuclear Quality Assurance Program prior to awarding contract or purchase order.

b) When significant changes are made in functional areas of the Nuclear Quality Assurance Program, including significant reorganizations and/or procedure revisions.
c) When it is suspected that safety, performance, or reliability of the item is in jeopardy due to deficiencies and nonconformances in the Nuclear Quality Assurance Program.
d) When a systematic, independent assessment of program effectiveness or item quality or both is considered necessary.
e) When it is considered necessary to verify implementation of required corrective actions.

18.3.4 The President shall regularly review the status and adequacy of this program by examination of audit results received from the Vice President of EHS & Quality, by personal assessment of various program elements, by audit and documentation of same; by review of Columbiana Hi Tech Customer audits/reports. Results of the above shall be discussed with the Vice President of EHS & Quality, and documented by letter, memo, etc. on an annual basis.