

NUCLEAR CONTAINERS, INC.
OVERALL QUALITY ASSURANCE MANUAL NO. QA-3
FOR PROTECTIVE SHIPPING PACKAGES

Rev. 1 - March 24, 1993

LOG OF REVISIONS

| MANUAL REV. | PAGE NO. | PAGE REV. DATE |
|----------------|-------------|-------------------|
| 0 | INITIAL | 02/04/81 |
| 1 | ALL | 03/24/93 |

THE MANUAL REVISION NOTED ABOVE IS APPROVED FOR USE.

William M. Arnold 3-24-93
QA MANAGER DATE

William R. Humbelt 3/24/93
PRESIDENT DATE

CONTROLLED COPY NO.: 1

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1.0 QUALITY ASSURANCE ORGANIZATION (71.103)

1.1 PROGRAM RESPONSIBILITY

1.1.1 Nuclear Containers, Inc. (NCI) is a manufacturer of nuclear fuel shipping packages. This Quality Assurance Manual describes the Quality Assurance (QA) Program that is implemented on NCI contracts, or portions thereof, that require compliance with 10CFR71, Subpart H (hereinafter referred to as the Code).

1.1.2 The QA Manager has the overall authority and responsibility for establishing and enforcing this Quality Assurance Program. It is the responsibility of each operating department head to implement the applicable portions of the QA Program within his department.

1.2 ORGANIZATIONAL RESPONSIBILITIES

1.2.1 As shown in Figure 1, the organization of Nuclear Containers, Inc. includes the following departments: Engineering, Operations, QA, Purchasing and Production.

1.2.2 Engineering Department

1.2.2.1 Under the direction of the President, the Engineering Department is responsible for design related activities.

1.2.3 Operations Department

1.2.3.1 Under the overall direction of the Operations Manager, the Operations Department is responsible for the planning and coordination of the activities involved in producing a quality product. Successful implementation of these activities are accomplished through the Production, QA and Purchasing Departments. He is also responsible, through his designated contracting officers, for administration of all contracts, including primary liaison between NCI and the customer.

1.2.4 QA Department

1.2.4.1 Under the direction of the QA Manager, the QA Department is responsible for:

- a. Establishment and enforcement of the measures necessary to implement the Quality Assurance Program in accordance with corporate policies of NCI.
- b. Establishment and implementation of Quality Control (QC) Plans for each product produced at NCI under this QA Program.
- c. Approval of manufacturing plans or outlines.
- d. Preparation and qualification of welding procedures.
- e. Qualification of welders and welding operators.
- f. Establishment of welding materials, processes and procedures to be used for welding operations.
- g. Establishment of equipment, methods, techniques and procedures to be used for nondestructive inspection activities (including calibration of measuring and test equipment).
- h. Qualification of personnel for inspection, nondestructive testing and auditing.
- i. Preparation, review, collection, turnover and/or storage of quality records.
- j. Identification and resolution of quality problems.
- k. Establishment of the equipment, methods, techniques and procedures to be used for any special processes.
- l. Establishment of procedures and schedules for internal audits, vendor survey and selection and for the routine audit of vendors.

1.2.4.2. Personnel performing activities affecting quality are indoctrinated and trained in accordance with a written procedure.

1.2.5 Purchasing Department

1.2.5.1 Under the direction of the Operations Manager, the Purchasing Department is responsible for procurement of all equipment, materials and services, including subcontracted fabrication and services.

1.2.6 Production Department

1.2.6.1 Under the direction of the Production Manager, the Production Department is responsible for fabrication activities such as: receipt and storage of materials, material preparation and processing, welding, assembly, cleaning, painting and shipping. The Production Manager is specifically responsible for establishing and implementing manufacturing plans or outlines for each product produced by NCI under this QA Program.

1.3 REVIEWS AND APPROVALS

1.3.1 All items which affect quality shall be reviewed and approved as follows:

| <u>Item</u> | <u>Approval Required By</u> |
|-------------------------------|--|
| QA Program | QA Manager, Operations Manager and President |
| Plans and Outlines | Production Manager, QA Manager, Engineering and Operations Manager |
| Standard Operating Procedures | Department Head and Operations Manager |
| Drawings | Production or Operations and Engineering |

Organizational Chart

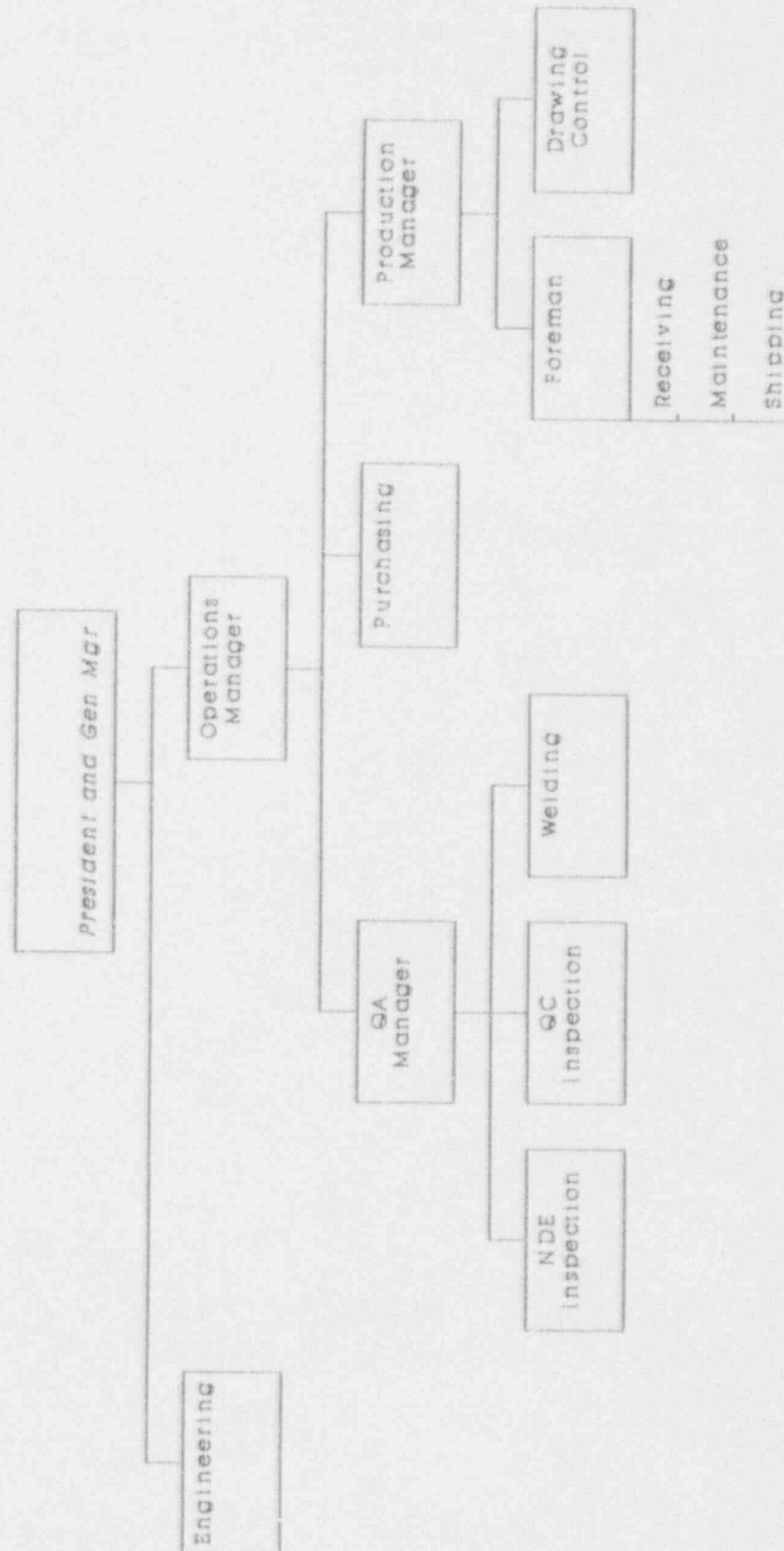



Figure 1

1.4 MANAGEMENT STATEMENT

- 1.4.1 A Quality Assurance Program is hereby established at Nuclear Containers, Inc., Elizabethton, Tennessee, to ensure compliance with the requirements of 10CFR71, Subpart H. The program is described in this Quality Assurance Manual.
- 1.4.2 The Quality Assurance Manager is hereby given the responsibility and authority to organize and maintain the Quality Assurance Program and, through the Quality Assurance Department, assure its implementation and revisions when necessary. The Quality Assurance Manager is given the organizational freedom to identify quality related problems and to initiate action which results in solutions to those problems. The Quality Assurance Manager has the authority to halt the work when necessary to assure compliance with contract requirements and/or the requirements of 10CFR71, Subpart H and this QA Manual.
- 1.4.3 The Department Heads are hereby given the authority and responsibility to establish the necessary organizations to implement the Quality Assurance Program.
- 1.4.4 The Operations Manager is hereby given the authority and responsibility to resolve any conflicts which cannot be resolved by the Quality Assurance Manager and the Department Heads. All resolutions shall comply with the requirements of 10CFR71, Subpart H and this QA Manual.
- 1.4.5 Since NCI is a small company, individuals are sometimes assigned multiple job functions and responsibilities. However, QA functions shall supersede any and all other responsibilities. Product safety, quality and the provisions of this QA Program will not be compromised under any circumstances, including consideration of cost or schedule restrictions. The basic NCI management philosophy, which is impressed upon each NCI employee, is that product quality must never be compromised but must be assured through strict adherence to the applicable drawings, specifications, procedures and plans as required by the QA Program described herein.


William R. Housholder, President

3/24/93
DATE

- 2.0 QUALITY ASSURANCE PROGRAM (71.105)
- 2.1 SCOPE OF MANUAL
- 2.1.1 This Quality Assurance Manual describes the Quality Assurance Program that is implemented on NCI contracts, or portions thereof, that require compliance 10CFR71, Subpart H.
- 2.1.2 This Manual describes the Quality Assurance Program for controlling the identification of material and components covered by this QA Program and for controlling the quality of work performed under the Code at the facilities of Nuclear Containers, Inc. in Elizabethton, Tennessee.
- 2.1.3 This Manual is supplemented by Standard Operating Procedures where necessary to describe the details by which the controls outlined herein are achieved.
- 2.1.4 The Manual establishes the authority and responsibilities of those personnel in charge of planning, managing, conducting and documenting the Quality Assurance Program and the methods of control of those functions.
- 2.1.5 Special contractual requirements which are beyond the scope of the Code are not included. Such requirements may supplement this Quality Assurance Manual provided they do not conflict with nor negate any rules of the Code nor degrade the quality levels specified in the Code.
- 2.1.6 The Quality Assurance Manager shall regularly review the status and adequacy of the QA Program and is responsible for effecting written revisions thereto. All revisions to this Manual must be approved by the President and the Nuclear Regulatory Commission (NRC) prior to implementation.

3.0 PACKAGE DESIGN CONTROL (71.107)

3.1 RESPONSIBILITIES

3.1.1 Designs of new shipping packages for the transportation of radioactive nuclear fuels is the responsibility of the Engineering Department under the direction of the President. All designs must receive final approval of the President before requesting approval of the NRC. The President is thus responsible for assuring that the design meets all regulatory requirements as specified in 10CFR71.

3.2 COORDINATION WITH OUTSIDE ORGANIZATIONS

3.2.1 Most new package designs at NCI evolve from a specific need by one or more customers of NCI. Often NCI works in conjunction with its customer(s) in developing a package design, in evaluating a package design for compliance with 10CFR71 requirements, in verifying such compliance and in the preparation and/or submittal of Safety Analysis Reports and requests for NRC approvals.

3.2.2 Where NCI is contracted by its customer for package design work, it is the responsibility of the President to administer the contract and provide liaison with the customer.

3.2.3 All outside services procured by NCI in conjunction with package design and evaluation shall be authorized and fully described by the Purchase Orders of NCI. Such services may include computer analyses, drop tests, fire tests, material tests, etc.

3.2.4 Whenever NCI has responsibility for the safety analysis of a package design, the President shall assure that all regulatory requirements as stipulated in 10CFR71 are met as described herein. Written procedures must be established to provide for the review, approval, release, distribution and revision of documents involving design interfaces among the participating design groups. Such procedures must also comply with the QA Programs of the organizations concerned.

3.3 DESIGN EVALUATION PROCEDURE

3.3.1 Design Concept

3.3.1.1 Each package design concept shall be evaluated to assure that appropriate quality standards are included in design drawings and specifications and that deviations from such standards are controlled. Also, each design concept shall be reviewed as to the suitability of application of materials, parts, equipment and processes that are essential to the safety related functions of the materials, parts and components of the packaging. Valid industry standards such as "Cask Designer's Guide" are used in such evaluations. Materials, parts and equipment which are standard, commercial (off the shelf) or which have been previously approved for a similar application are reviewed for suitability prior to selection.

3.3.2 Safety-Related Items

3.3.2.1 Each design concept shall be evaluated to assure proper identification of all safety-related functions, including: criticality physics, radiation shielding, stress, thermal, hydraulic and accident analyses, 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 Design Review

3.3.3.1 Each design concept shall be reviewed in conjunction with NRC Regulatory Guide 7.9 to assure that the safety-related functions as described in Section 3.3.2 are fully evaluated regarding the regulatory requirements per 10CFR71.

3.3.4 Verification Procedures

3.3.4.1 Designs are reviewed to assure that (1) design characteristics can be controlled, inspected and tested and (2) inspection and test criteria are identified.

3.3.4.2 Methods of verifying the adequacy of each design shall be established; these methods may be by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of suitable testing. Where a test program is used to verify the adequacy of a specific design or design feature in lieu of other verifying processes, it shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. Worst case conditions shall be defined or the method(s) for determining worst case conditions shall be established.

3.3.5 Design Changes

3.3.5.1 The President is responsible for assuring that design changes are documented in the design drawings and specifications and for the submitting of the revised drawings for NRC approval. All design changes must be fully evaluated for their effects on safety-related functions and are subject to the same design controls and approvals that were applicable to the original design unless the applicant designates another qualified responsible organization. If a design already has NRC approval, design changes cannot be implemented without the approval of the NRC.

3.3.6 Maintenance and Operating Procedures

3.3.6.1 Maintenance and operating procedures shall be established as required to assure continued adequacy of all safety-related functions of the package design.

3.3.7 Corrective Action

3.3.7.1 The Engineering Department is responsible for documentation of errors and deficiencies in the design, including the design process, that could adversely affect safety-related structures, systems and components, and to assure that corrective action is taken to preclude repetition.

3.4 DRAWINGS & SPECIFICATIONS

- 3.4.1 The Engineering Department is responsible for assuring that the package design, materials and components are correctly described in drawings and specifications. All applicable regulatory requirements as well as requirements for materials, parts, components, special processes, qualifications, inspections, tests and tolerances shall be included in the drawings and specifications.

3.5 QA PLANS

- 3.5.1 A QA Plan shall be established, as required, for the fabrication of prototypes or test models. Each QA Plan shall comply with the requirements of the QA Program as described herein and with the requirements of 10CFR71, Subpart H.

3.6 SAFETY ANALYSIS REPORT

- 3.6.1 A safety analysis report (SAR) shall be prepared for each new package design or modification. The SAR shall evaluate the design with respect to all requirements of 10CFR71 and shall be written in accordance with, and account for, all items covered in Regulatory Guide 7.9.
- 3.6.2 The SAR shall be submitted to the U.S. Nuclear Regulatory Commission in request for a Certificate of Compliance. No new package design shall be placed in operation for the transportation of radioactive nuclear fuels without such NRC approval.
- 3.6.3 Preparation of the SAR and all liaison with NRC are the responsibility of the President.

3.7 NRC APPROVAL REQUIREMENTS

- 3.7.1 Upon receipt of NRC approval of a package design, a final review shall be made to assure that all NRC approval requirements are correctly defined in the drawings, specifications, manufacturing plans and processes, QA plans and procedures, and operating and maintenance procedures. This final review is the responsibility of the President.

4.0 PROCUREMENT DOCUMENT CONTROL (71.109)

4.1 PURCHASE ORDERS

4.1.1 The Purchasing Department shall order materials, services and subcontracted work on written purchase orders per Section 7.0. Any special requirement or test shall be indicated in the purchase order (e.g. applicable specifications, sketches or drawings required for procurement).

4.2 MATERIAL TAKEOFF

4.2.1 The Operations Department is responsible for specifying material quantities, sizes, types, and stating or referencing any additional information needed to clearly define to the Purchasing Department the specification requirements for materials.

4.2.2 The Engineering Department shall be responsible for the resolution of any conflicts or questions involving the interpretation of drawings or specification requirements.

4.3 SUBCONTRACTOR CONTROL

4.3.1 Purchase orders shall make provisions that require subcontractors to provide a Quality Assurance Program to the extent necessary; such QA Programs must be consistent with the applicable provisions of the Code.

5.0 INSTRUCTIONS, PROCEDURES & DRAWINGS (71.111)

5.1 INSTRUCTIONS AND PROCEDURES

5.1.1 The Quality Assurance Manager is responsible for preparing written instructions in the form of Standard Operating Procedures in conjunction with the appropriate personnel. These procedures must include appropriate acceptance criteria in order to determine that the activities have been accomplished.

5.2 DRAWINGS

5.2.1 The requirements of the Contract Specifications, Design Calculations and Design Drawings (or sketches) are translated into Fabrication Drawings when needed to facilitate traceability and/or when contract drawings need to be detailed for fabrication purposes.

5.2.2 Each drawing is identified by a drawing number.

5.2.3 When fabrication drawings are required, each drawing and revision is prepared by assigned draftsmen and checked by an individual other than the person who prepared the drawing or revision. The drawings are then approved by the President.

5.2.4 Included on the Fabrication Drawings are Material Bills which list the pieces to be cut. Required material types are identified on the Fabrication Drawings.

5.2.5 The Engineering Department is responsible for assuring that drawings, including revisions, contain all information necessary to manufacture, examine, inspect and test the product being fabricated in accordance with all applicable Code and specified requirements.

6.0 DOCUMENT CONTROL (71.113)

6.1 CONTROL OF QUALITY ASSURANCE MANUALS & REVISIONS

6.1.1 The QA Manager has overall responsibility for this QA Manual and revisions.

6.1.2 Code requirements are reviewed by the QA Manager upon receipt of code revisions to determine if any changes to the Manual are necessary. If changes are required, a Manual Review Committee is appointed by the QA Manager to review any proposed changes to the Manual. Proposed changes are approved by the QA Manager and the President. Approvals are indicated by sign-off on the Log of Revisions.

6.1.3 Revisions are indicated by a vertical line in the right hand margin. Each issue of revised pages forms a Manual Revision. The cross reference between the Manual Revision Number and the related page revision number is indicated on the Log of Revisions. (See first page)

6.1.4 The QA Manager maintains a list of holders of Controlled Manuals. He controls distribution of manuals and revisions and maintains records of distribution.

6.2 INSTRUCTIONS AND PROCEDURES

6.2.1 The QA Manager has responsibility for distribution and control of all instructions and procedures. He shall maintain a list of the holders of instructions and procedures including the appropriate revisions.

6.2.2 Revisions shall be prepared and approved prior to distribution. Vertical lines shall be drawn in the right-hand margin adjacent to the revised portions of the procedure except as permitted by the appropriate Standard Operating Procedure.

6.2.3 Obsolete revisions shall be destroyed. QA copies may be marked void and retained for reference only.

6.2.4 All instructions and procedures, including revisions, must be reviewed and approved as required in Section 1.3.

6.2.5 Fabrication instructions and procedures are maintained in the shop office and are readily available for review by plant employees.

6.3 DRAWING DISTRIBUTION

- 6.3.1 The Production Department is responsible for controlled drawing distribution to each NCI recipient.
- 6.3.2 The Production Department maintains a log of recipients of Fabrication Drawings for each package. As a minimum, the distribution includes the Production Department and QA.
- 6.3.3 The Production Department forwards Fabrication Drawings and revisions to all indicated recipients and obtains receipt acknowledgement (including disposition of outdated revisions). Obsolete revisions are destroyed, except that Router and QA copies may be marked "VOID" and retained for reference only.
- 6.3.4 All drawings, including revisions, shall be reviewed and approved per Section 1.3.
- 6.3.5 Fabrication drawings are maintained in a central location and are readily available for review by plant employees.

- 7.0 CONTROL OF PURCHASED MATERIALS, EQUIPMENT & SERVICES
 (71.115)
- 7.1 PURCHASING
- 7.1.1 The Purchasing Department is responsible for preparing and issuing Purchasing Orders for the purchase of materials from vendors who have been approved by Quality Assurance and that are listed on the approved vendors list in accordance with Standard Operating Procedures.
- 7.1.2 Where possible, materials may be taken from NCI inventory. Prior to being transferred from inventory, materials must be checked to insure conformance with the correct specification and must be properly identified.
- 7.1.3 Purchase Orders for contract materials are identified by control numbers. Purchase Orders identify material requirements as specified by the Engineering Department, including identifying numbers, as required, for traceability. Identifying numbers are either applied to the material at the mill or applied by NCI upon receipt. The Purchase Orders shall include any special provisions, such as requirements for test reports, source inspection, etc., to fulfill the engineering specifications.
- 7.1.4 The Purchasing Manager reviews the Purchase Order for conformance to Engineering specifications and indicates his approval by signing the Purchase Order.
- 7.1.5 Changes in material requirements are handled by means of Order Amendments which are prepared and issued in the same manner as the original Purchase Order.

7.2 MATERIAL APPLICATION

- 7.2.1 A copy of the Purchase Order and the Bill of Material is furnished to the Production Manager.

7.3 MATERIAL DOCUMENTATION CHECK

- 7.3.1 Purchasing obtains documentation from the vendor as required by the Purchase Order and sends copies to QA.

- 7.3.2 QA checks documentation for completeness and conformance to applicable Purchase Order requirements. QA checks reported values of specific material properties, such as physical and chemical test results, against requirements that are stipulated or referenced in the applicable Purchase Order. Each person making the above check dates and initials approval on documentation when it is complete and correct. This documentation is included in the final records. (See Section 7.5.1)

- 7.3.3 QA assures that incomplete or unacceptable documents are resolved with the vendor.

7.4 RECEIVING & IDENTIFICATION

- 7.4.1 As material is received (or as soon as practicable thereafter) a receiving inspection is conducted to verify compliance with the purchase documents (including attachments and drawings) and the shipping papers (including sizes, quantities, heat/lot markings, etc.). Material which has not undergone a receiving inspection is placed in a designated Hold Area or marked or tagged "HOLD".
- 7.4.2 Acceptable material is marked with the Job Number and Item Number as required. Each piece of material is marked or tagged and maintained traceable throughout receiving and storage by heat/lot or purchase order number. Where containerization and bundling is permitted, the information may be applied to a tag securely affixed to the bundle or container.
- 7.4.3 Material that is not approved by QA is placed in a Hold Area or remains marked or tagged "NR-HOLD" pending resolution of any discrepancies.
- 7.4.4 The results of the inspection, including a copy of the shipping papers used for the inspection, are forwarded to QA for a documentation review.
- 7.4.5 QA receives the results of the receiving inspection and compares them with the applicable material specifications. Results of the inspection and documentation check are recorded on the Receiving Report.
- 7.4.6 QA, in consultation with Purchasing, assures that discrepancies are resolved and the resolution documented as a part of the receiving inspection records.
- 7.4.7 QA/QC assures that material is disposed of in accordance with the documented resolution of discrepancies. For acceptable material, QA assures that any "HOLD" or "NR-HOLD" markings or tagging are removed and the material released for storage or fabrication.

7.5 DOCUMENTATION CHECK

- 7.5.1 At the completion of fabrication and prior to shipping, QA completes a final review to assure that all required documentation is complete. This documentation shall be filed in accordance with QA Records Retention as described in Section 17.

7.6 FABRICATION BY SUBCONTRACTORS

- 7.6.1 It is the responsibility of the Quality Assurance Department to assure that all subcontracted fabrication and services have been properly audited and approved as outlined in the appropriate Standard Operating Procedures.
- 7.6.2 Sublet fabrication and services must be procured on a Purchase Order and shall include objective evidence of quality furnished by the contractor, inspection at the contractor or subcontractor source and examination of products upon delivery.
- 7.6.3 Quality Assurance shall maintain documented evidence (visual inspection reports, receiving reports, etc.) that the requirements of the Purchase Order have been met.
- 7.6.4 Quality Assurance shall at the appropriate intervals (not to exceed 3 years) evaluate all vendors of fabricated products or services to assess the effectiveness of their ability to meet the requirements as imposed by the Purchase Order.

8.0 IDENTIFICATION & CONTROL OF MATERIALS,
PARTS & COMPONENTS (71.117)

8.1 MATERIAL TRACEABILITY

8.1.1 Identification marks are assigned by the drafting organization and are marked on the piece or appear on the appropriate Fabrication Traveler or Route Sheet. Pieces, subassemblies and final products with identical configurations are assigned the same mark.

8.1.2 Standard Operating Procedures shall be established to assure traceability is maintained throughout the fabrication process.

8.1.3 When traceability marks may be lost due to a fabrication process, such as blast cleaning, the Standard Operating Procedure must provide for maintaining traceability as required.

8.1.4 QA assures that, before shipping, the Shipping Mark (including suffix, if any) is stamped or painted on each shipping piece by Production except that:

- Miscellaneous structural material (e.g. angles, bars and rods) may be bundled or containerized and marked with a tag securely affixed to the bundle or container.
- Materials such as nuts, bolts, gaskets, weld wire and fittings and small parts may be containerized, with identification marked on the container.

9.0 CONTROL OF SPECIAL PROCESSES (71.119)

- 9.1 It is the responsibility of the Quality Assurance Manager to prepare all special process Standard Operating Procedures, in conjunction with the appropriate Department Heads.
- 9.2 Special processes shall include, but not be limited to, such operations as welding, heat treating, foaming and non-destructive testing.
- 9.3 These procedures, and operating personnel, shall be qualified in accordance with applicable codes, standard specifications or other special requirements.
- 9.4 The use of standardized procedures and qualifying records are encouraged, e.g. Welding Procedures Specifications (WPS) of the ASME Boiler and Pressure Vessel Code, Section IX.

- 10.0 INTERNAL INSPECTION (71.121)
- 10.1 The Quality Assurance Department shall establish a QC Plan or outline for inspection of the activities affecting quality in order to verify conformance with instructions, procedures and drawings.
- 10.2 Inspections must be performed by individuals other than those performing the activity being inspected.
- 10.3 Inspections and/or hold points required to maintain the appropriate level of quality should be indicated on the necessary documents such as Manufacturing Plans or outlines, Fabrication Control Records, Route Sheets, Purchase Orders, etc. No work should progress beyond a hold point until the inspection or activity is completed.

11.0 TEST CONTROL (71.123)

11.1 A test program for each radioactive nuclear fuel package manufactured, modified, or refurbished at NCI is established in the QC or Inspection Plan for that package. All tests are performed and documented in accordance with written procedures as required by the QC or Inspection Plan. Modifications, repairs and replacements are tested in accordance with the original designs and testing requirements or acceptable alternates which must be approved by the Engineering Department and which must meet Regulatory requirements.

11.2 The Quality Assurance Department is responsible for writing all testing and inspection procedures in accordance with the appropriate Standard Operating Procedure; all such testing and inspection procedures shall be approved by the Operations Manager.

11.3 SPECIFIC PROCEDURES

11.3.1 A detailed procedure shall be written for each test, inspection, qualification and calibration required to insure conformance to package specifications. Each inspection procedure may reference the following:

- (a) The requirements and acceptance limits contained in applicable design and procurement documents.
- (b) Instructions for performing the test.
- (c) Test prerequisites, such as:
 - Calibrated instrumentation.
 - Adequate and appropriate equipment.
 - Trained, qualified and licensed or certified personnel.
 - Completeness of item to be tested.
 - Suitable and controlled environmental conditions.
 - Provisions for data collection and storage.
- (d) Mandatory inspection hold points for witness by owner, contractor, or inspector.
- (e) Acceptance and rejection criteria.
- (f) Methods of documenting or recording test data and results.

11.4 EQUIPMENT, APPARATUS & ENVIRONMENTAL REQUIREMENTS

11.4.1 The test or inspection procedure shall list and describe all equipment and apparatus required to perform the procedure. A simple schematic or pictorial drawing should be included whenever an assembly of equipment is required for the procedure such as required in the hydrostatic testing of a pressure vessel. The description should include the manufacturer, model or type number, serial number, tolerance capabilities and, if necessary, drawings.

11.4.2 Any requirements for controlled environmental conditions shall be delineated in the procedure. Of general concern for many tests and test equipment are such environmental conditions as temperature, cleanliness, air movement, barometric pressure, background levels, etc. Adequate controls shall be required in the procedure to assure that equipment requirements are met per manufacturer's recommendations and to assure the required precision and accuracy of the test or inspection.

12.0 CONTROL OF MEASURING & TEST EQUIPMENT (71.125)

12.1 GENERAL

12.1.1 QA is responsible for having measuring and test equipment used in activities affecting quality calibrated and properly adjusted or replaced at specific periods or use-intervals to maintain accuracy within necessary limits.

12.1.2 The Quality Assurance Manager is responsible for establishing the necessary written Standard Operating Procedures as required.

12.1.3 Calibration is accomplished using certified measurement standards (of the same or higher degree of accuracy than the equipment being calibrated or checked) which have known relationships to National Standards where such standards exist. Where National Standards do not exist the basis of calibration is established and documented.

12.1.4 All such equipment (except certain small measuring scales) is identified by serial number affixed in a suitably permanent manner and flagged with tags, labels, or stickers to identify the date last calibrated or checked and the due date.

12.2 DISCREPANCIES

12.2.1 QA is responsible for having tools, gages, instruments and other measuring and test equipment adjusted, repaired, or replaced as necessary. Results of these activities are recorded and maintained by QA.

12.2.2 When discrepancies in measuring and testing equipment are found at calibration they are documented and reported to the QA Manager who determines the required corrective action. Materials, fabricated items and components previously checked (since last valid calibration) with equipment which is out of calibration are considered unacceptable until QA can determine that all applicable requirements have been met. Whenever discrepant equipment is discovered, the QA Manager investigates to determine and document the acceptability and disposition of items inspected. Out of calibration equipment is so identified.

12.3 RECORDS

12.3.1 Calibration records include equipment identification, calibration standard identification, calibration frequency, calibration tolerances, date last calibrated, date next calibration due, identification of person performing the calibration and identification of calibration procedure used.

12.3.2 QA is responsible for the overall calibration system and for maintenance of calibration system and for maintenance of calibration records. Calibration records are available to the customer.

12.4 SUBCONTRACTED CALIBRATIONS

12.4.1 Outside laboratories and testing agencies may perform calibrations for NCI. Reports of calibrations performed by outside agencies include equipment identification, calibration standard (relationships to national standards), identification, date last calibrated, results prior to adjustment, repair or replacement and a description or a copy of the procedure used to ensure compliance to Code, standard, or contract specification requirements unless the calibration is of a simple nature in which case no procedure description is required. Typically, simple calibrations would include comparative calibrations such as thermometers, gauge-blocks, etc.

13.0 HANDLING, STORAGE & SHIPPING CONTROL (71.127)

- 13.1 It is the responsibility of the Quality Assurance Manager, in conjunction with the appropriate Department Head, to prepare written instructions in the form of Standard Operating Procedures for handling, storage and shipping. These procedures should include methods for cleaning, packaging and preservation of material, components, parts and finished products, as required, and for handling and moving of all material before, during and after fabrication to prevent surface damage, deterioration, obliteration of identification, or distortion of shape and dimensions.

14.0 INSPECTION, TEST & OPERATION STATUS (71.129)

14.1 CONTROL OF FABRICATION

- 14.1.1 The Production Department prepares a manufacturing plan or outline which includes Process Control Documents (Route Sheets and Fabrication Travelers) to describe operations necessary to complete the work. Route Sheets, as required, are used to document material preparation activities and Fabrication Travelers are used, as required, to document material assembly activities.
- 14.1.2 Prior to fabrication, the QA Manager reviews and approves the manufacturing plan or outline, including Marking, Route Sheets and Fabrication Travelers, to ensure that all required inspections, examinations and tests covering the fabrication activities are included.
- 14.1.3 During the course of fabrication, the QA Department accumulates quality documentation and maintains records of inspections, examinations and tests.

15.0 NON-CONFORMANCE OF MATERIALS, PARTS OR COMPONENTS
(71.131)

15.1 Non-Conformance Reports (NR) are generated for all deficiencies resulting from inspection or review. The Quality Assurance Department is responsible for generating all Non-Conformance Reports.

15.2 The QA Manager is responsible for documenting and approving the disposition of non-conforming items on an NR. Items associated with an NR are clearly identified by a NR-Hold Tag and removed to a designated Hold Area where practicable. The NR number is shown on the applicable Process Control Document and the NR-Hold Tag. NR-Hold Tags can be removed only by QA, after which the item returns to fabrication.

15.3 The QA Manager is responsible for maintaining a log of all NR's, along with a copy of the Non-Conformance Report and the NR-Hold Tag.

- 16.0 CORRECTIVE ACTION (71.133)
- 16.1 The Quality Assurance Manager is responsible for documenting all corrective action reports and evaluating possible trends. He shall, in conjunction with the appropriate department heads, find and institute the proper measures necessary to resolve any trends or non-conforming items.
- 16.2 If the non-conforming item is reworkable it is reworked to the original drawing, specification, procedure or requirement. Rework is the process by which the non-conforming item can be made to conform to a prior specified requirement by completion, remachining, reassembling or other means without affecting the quality of the item or Code compliance. Fabrication and special process procedures should anticipate and include provisions for repair and/or rework.
- 16.3 Deviations from contract requirements are not permitted without customer approval.
- 16.4 Deviations from the Code requirements are not permitted.
- 16.5 As required by 10CFR21, each employee is responsible for bringing to the attention of his Foreman any material, part or component which does not conform to the applicable requirements.

17.0 QUALITY ASSURANCE RECORDS (71.135)

17.1 CONTENT

17.1.1 Quality Assurance shall maintain written records to describe activities affected quality such as instruction, procedures and drawings. The records shall include closely related data such as qualifications of personnel, procedures, equipment and all records required.

17.1.2 QA accumulates and controls the documentation. As documentation is received and before shipment of materials or assemblies, QA reviews the documentation for completeness and correctness.

17.1.3 The final records shall be retained, in accordance with the Code, for a minimum of three years beyond the termination of activities covered by the QA Program per written Standard Operating Procedures approved by the Quality Assurance Manager.

17.2 ACCESS, SECURITY & STORAGE

17.2.1 The above records are collected, organized and maintained on a current basis in a manner which will allow access by the owner or his representative to specific information contained therein.

17.2.2 The QA Manager is responsible for the final completion of the above NCI records and of records from vendors who perform any portion of shop fabrication, examination, or testing.

17.2.3 Storage of such records shall be accomplished through the use of facilities designed to prevent damage, deterioration and loss.

18.0 AUDITS (71.137)

18.1 The QA Manager is responsible for generating a written Standard Operating Procedure for the planning and scheduling of internal audits and for the selection, training and qualification of audit personnel. This Standard Operating Procedure shall be approved by the President. Audit personnel must not have direct responsibilities in the area being audited. Although he may not audit the Quality Assurance Department activities, the QA Manager may perform internal audits on all other departments.

18.2 Internal audits are conducted at intervals not exceeding one year. The Standard Operating Procedure for internal audits must insure that:

- a. Activities are accomplished in accordance with the requirements of the QA Program, manuals and procedures.
- b. Deficiencies are identified, documented and reported to appropriate management personnel having responsibility in the area being audited.
- c. Deficiencies are corrected by appropriate measure in a timely manner.

18.3 Corrective action is specified by responsible management individuals and approved by the Operations Manager. Deficient areas are reaudited to ensure that appropriate correction action has been specified, approved and implemented.

18.4 The President is responsible for evaluating the status and effectiveness of the QA Program through management reviews which may be supplemented by management audits conducted at the sole discretion and under the direction of the President.

18.5 Audit activities may be subcontracted to an approved supplier of quality services and the results evaluated by the Operations Manager and/or President, as applicable.