2.1

QUALITY ASSURANCE MANUAL

FOR

RADIOACTIVE MATERIAL SHIPPING CONTAINERS

NO. B-1

NUCLEAR SOURCES & SERVICES, INC.

5711 ETHERIDGE

(P. O. BOX 34042)

HOUSTON, TEXAS

713-641-0391

APPROVED:

_____

MANAGER, QUALITY ASSURANCE

APPROVED:

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PRESIDENT

COPY NO. ____

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REVISION PAGE

DATE	REVISION	REV. LEVEL	APPROVAL

PARAGRAPHS WHICH HAVE BEEN REVISED OR NEW EXHIBITS INCORPORATED UNDER EACH REVISION WILL BE IDENTIFIED BY THE REVISION LETTER IN THE LEFT MARGIN ADJACENT TO THE PARAGRAPH OR EXHIBIT.

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2.4 INTRODUCTION

A. PURPOSE: This manual defines the systems employed by Nuclear Sources & Services, Inc., 5711 Etheridge, Houston, Texas, 77087, for the control and assurance of product quality in the manufacture of approved shipping containers and components.

B. SCOPE: The systems have been established through consultation with customers, regulatory agents, and coordinated efforts of all departments concerned. They are designed to be effective and to be economically palatable for a company of Nuclear Sources & Services, Inc.'s size, organization, and product line. The intent of this manual is to define and implement systems for compliance with requirements for manufacturing of radioactive materials transport containers and transportation equipment as stated in Section 71.51 of 10 CFR Part 71 and to include the applicable requirements found under Appendix E.

C. COORDINATION AND REVISION

1. COORDINATION: The quality assurance manager is responsible for the issue, revision, and compliance with this manual. Copies are issued to key personnel. Upon the authorization of the Director of Purchasing, copies will be furnished to suppliers, customers and government representatives as needed. The names of all receivers will be recorded in a master log, but copies will not be subject to periodic revision unless contractually obligated.

2. REVISIONS: Revisions to this manual may be proposed by any employee holding a controlled copy. A written proposed revision will be submitted to the quality assurance manager for his determination of compliance with the applicable specifications, and

2.4 INTRODUCTION (Continued)

for review by other departments. Changes will be reviewed with departmental managers, and will become effective only when approved by both the Q. A. Manager and the Vice President.

2.5 APPENDIX E CRITERIA

A. ORGANIZATION

1. The Quality Assurance Department, hereafter referred to as Q. A. Department, is by definition a support department with both management and line functions. The Quality Assurance Manager is directly responsible to the Vice President. The Q. A. Department is responsible for assuring that an adequate system of controls is established, defined, and maintained over operations which have an effect on product quality, and to assure that the control systems are in compliance with the applicable specifications. The Q. A. Department is also responsible for product inspections, for maintenance and calibration of all instruments used for evaluating product quality and characteristics, for assuring product compliance with acceptance criteria, and for maintenance of test and inspection records. This responsibility includes the evaluation and correction of customer quality control problems, and coordination of the activities of quality assurance representatives of suppliers and customers. The responsibilities assigned to each position in the Q. A. Department are defined under the corresponding subheading. An organizational chart defining the quality assurance departments relationship to the overall organization is contained in Section 2.6A (Appendices).

2. Corporate Responsibilities Relative to Quality Assurance

a. Management - The president is responsible for establishing the corporate policies, defining broad guidelines for the control and assurance of product quality, and delegating responsibilities for the various quality control systems. He is also directly responsible to the customer for product requirements and quality, and for assuring compliance with these requirements by all concerned departments.

b. Purchasing - This function is responsible for assuring that parts, materials, and services are obtained from qualified suppliers, and for assuring that applicable quality assurance provisions are reviewed with suppliers in quoting and procurement phases. Purchasing responsibilities include monitoring current supplier performance through quality information feedback, coordinating supplier corrective action as needed, and evaluating proposed new suppliers.

c. Accounting. This function is responsible for providing assistance to the Q. A. Department in arriving at quality/cost evaluations and collection of applicable data.

d. Manufacturing - This function is responsible for assuring that all assembly and processing operations are performed in accordance with drawings, parts list, specifications, work or process instructions, and workmanship standards. Manufacturing is also responsible for implementing all applicable provisions of the quality assurance manual.

e. Quality Assurance - Is responsible to assure that products

are manufactured to the configuration and performance requirements defined by the applicable documentation in an efficient and cost effective manner.

f. Quality Control - This function is responsible for inspecting all incoming and outgoing materials and for inspecting all phases of operations required to produce parts necessary to manufacture any radioactive materials/containers and transport equipment per customer prints and government requirements. These persons are ultimately responsible for determining whether materials and operations are according to prints and specifications and are in no way responsible for any scheduling or production quotas.

g. Inventory and Document Controller - This function is responsible to maintain records necessary for traceability required to document materials, inspection certifications, serial numbering and shipping dates of the individual units to customers. The records are maintained on a permanent basis in a separate file available for inspection at any given time to authorized customers. Duplicate copies can be furnished to customer if so desired.

B. QUALITY ASSURANCE PROGRAM

Nuclear Sources & Services, Inc.'s quality assurance program is headed up by the president. The Quality Assurance Manager reports directly to the president. The program is designed to inspect, manufacture, and record information necessary to build and certify any and all radioactive material transportation packages covered by Section 71.51

10 CFR Part 71. The Quality Assurance Manager is responsible for evaluating all personnel and maintaining qualified persons required to manufacture quality products per requirements set forth in customer documents and government regulations.

A permanent file is maintained on manufacturing procedures and inspection check points. Manufacturing procedures and check points are permanent records, and are maintained in separate file folders from other manufacturing records.

1. Inspection and Test Planning. The inspection instruction and report is a typical form for documenting and communicating inspection and test instructions for quality assurance operations at designated stages of fabrication or assembly. Other forms or mediums for documenting and communicating inspection/test instructions may be used as long as the objectives of inspection system and quality assurance program are satisfied.

   Each transport unit will be serial numbered and records maintained throughout the manufacturing process for inspection and testing purposes.

2. Outside Source Documents. The Purchasing Division is responsible for obtaining and maintaining control of technical documents and specifications submitted to Nuclear Sources & Services, Inc., by customers, contacting agencies, and to subcontractors, or suppliers by Nuclear Sources & Services, Inc. These responsibilities include control and coordination of the use of the documents and liaison with the outside sources regarding changes, corrections, and variances.

C. DESIGN CONTROL.

All design controls are to be in the hands of Nuclear Sources & Services, Inc., customers. Customers are to furnish the necessary prints and specifications required to manufacture said goods.

D. PROCUREMENT DOCUMENT CONTROL.

All purchased material, equipment, parts, and services are made using written purchase orders listing any and all required specifications. All purchase orders will contain a statement requiring certification of furnished goods or services. If drawings or formal engineering specification are required, these are furnished with each order to insure that proper revision levels are being met. Records of applicable purchases will be maintained in separate files for future reference.

E. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Procedures for the manufacturing of any and all transport equipment are filed in Quality Assurance Manager's Department. Procedure manuals define where inspection points will occur. The Quality Control Department conducts and records each inspection of serial numbered units. These records are to be maintained for future reference. One set of current drawings are maintained in office permanent files. Current prints are furnished with new orders to assure proper revision levels are being met.

F. DOCUMENT CONTROL.

The inventory and document controller is responsible for maintaining permanent documents in proper files under the direction of the Quality Assurance Manager.

All prints or engineering specification changes are provided by customers for the transport equipment. Changes are implemented upon receipt of written request. All out of date prints or procedures are removed from permanent files and current work in plant is revised as per customer request and per new revision levels.

All test procedures and results of tests are filed for future use. Copies can be made from the original, but the original will remain in the permanent file at all times.

G. CONTROL OF PURCHASED MATERIALS, PARTS, AND COMPONENTS

All incoming material is accepted and processed through the Receiving Department. Control of incoming materials for resale is accomplished by processing materials through the Receiving Inspection Department where inspections are performed to assure conformance to applicable acceptance criteria. Accepted materials are appropriately identified and forwarded to the using department or storage area. Nonconforming materials are rejected and returned to the supplier or placed in controlled storage pending disposition.

The supervisor of Receiving Inspection is responsible to the Q. A. Manager for the operation of the Receiving Inspection Department. Copies of purchase orders are forwarded to the Receiving Department and placed in a file to insure proper handling of incoming materials. Material receipts are checked against purchase orders for correct type, quantity, documentation, and any indication of damage in shipment.

Inspections, tests, or verifications are performed by Receiving Inspection in accordance with instructions contained in Receiving

Inspection Instruction and Report Sheets and its referenced documents. All materials after receiving inspection and acceptance are properly marked as to job numbers and part numbers and are moved to the proper storage or manufacturing area. Stock identification tags are placed on each applicable container or item.

EXAMPLE: STOCK IDENTIFICATION TAG

Part No._____
P.O. No._____
Job No._____
Quantity_____
Date_____
Inspected By_____

H. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

The control of material storage and issue is accomplished by assuring that only acceptable material is placed in the stockroom, maintaining positive identification and control of materials in stock, and by observing shelf life limitations where applicable. Each material lot from Receiving Inspection is accompanied by a Receiving Report and Stock Identification Tag attached to the material. Questions regarding material identification or acceptance will be referred to Receiving Inspection for clarification.

All materials in stock will be suitably protected against contamination, deterioration, and damage. Materials will be systematically stored and arranged so that materials can be readily located.

I. CONTROL OF SPECIAL PROCESSES.

Measures to be taken for control of any special processes are:

1. Permanent identification numbers are placed on all units for future traceability.
2. Requirements of any outside services are required to be certified as to specifications furnished. Examples are: Heat treating or painting.
3. All container welds are pressure tested before filling with shielding materials.
4. Nondestructive testing is utilized as required to insure container integrity.
5. Qualified personnel and a training program are utilized to maintain any in-house special processes.
6. Proper records of test results on any special processes are maintained on file.

J. INSPECTION

Inspections are performed by Q. A. personnel in accordance with latest revisions of the inspection and report sheet and the referenced engineering or manufacturing documents. The revision level of referenced documents used for inspection is recorded on the inspection report. Following operations are not performed unless previous inspections or test operation have been signed off. Master copies of inspection sheets to be used on machined or fabricated parts are maintained by the Q. A. Manager and are issued as needed to inspect parts in process or completed parts.

These reports when completed are filed in the Q. A. Manager's files.

K. TEST CONTROL

Test controls are established through coordination of Nuclear Sources & Services, Inc., and the customer's Engineering Department to test each piece of transport equipment before final shipment to customer. Records of test results and certification of compliance are required on each unit. One copy of the certification papers and test results is maintained at Nuclear Sources & Services, Inc., and a copy is shipped with each unit.

L. CONTROL OF MEASURING AND TEST EQUIPMENT

All measuring and test equipment used to verify the quality of material and parts to be used in the production of any transport equipment is maintained by the Quality Control Department under the direction of the Quality Assurance Manager. Measuring equipment to be used such as micrometers is calibrated or checked once each work week to assure proper calibration for inspections. Calibration of vendor supplied test equipment is to be certified in writing by vendors on a regularly scheduled basis agreed upon with vendor. Certification papers are dated and furnished with each new calibration check of the equipment.

M. HANDLING, STORAGE, AND SHIPPING

Proper cleaning of all component parts is established in a procedure outline to insure consistency in preparing items for shipment. This procedure also includes the method of packaging and identifying each part where necessary. All inspection data and certification data

accompany each shipment. No shipments are made unless units are properly serial numbered, properly marked, certified, and the test reports are accompanying each unit. Deliveries of transport equipment are made by employees of Nuclear Sources & Services, Inc., directly to customers on company owned trucks. Units are delivered to the receiving dock and unloaded with proper papers and certifications furnished to the customer.

N. INSPECTION TEST AND OPERATING STATUS

All materials that are received are properly inspected, tagged and stored for use in proper areas. These processes are controlled by the Quality Assurance Manager and his staff.

Any materials that are not to specification or do not come up to manufacturing standards are rejected and marked with defective material tags for return to the supplier or are defaced prior to being scrapped to insure that parts will not be used at any future date.

O. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

Nonconforming materials are identified, documented and controlled to prevent use until evaluated and dispositioned under appropriate material review actions.

Manufacturing is responsible for coordinating material review actions so that all factors relative to product design, quality, schedule impact, cost of repair or rework are adequately considered in disposition of nonconforming materials.

Quality control is responsible for proper identification and definition of material discrepancies, for assuring control to prevent

inadvertent use until proper disposition is made, and for assuring that manufacturing and inspection documents provide adequate records of rejections and material review actions.

Where incoming materials are to be returned to the supplier, pertinent information is recorded on a rejection tag and forwarded to purchasing for review with the supplier. Rejected items are placed in specific holding areas under control of the appropriate inspection station pending disposition. If evaluation of rejected items requires physical removal from the holding area for testing or examination, the items remain under the control of the inspection station and continue to be identified with the reject tag until released for disposition by the Quality Assurance Manager.

P. CORRECTIVE ACTION

The Manager of Manufacturing is responsible for determining disposition or correction of rejected items under the following guidelines.

1. Scrap or Rework - Manufacturing may scrap or replace defective items at its discretion. No further approvals are required except where limited by management policies.
2. Use-As-Is - Manufacturing may render use as is decisions but only with Quality Assurance Manager concurrence.
3. Repair - Manufacturing may select and apply standard repair procedures, or may develop repair procedures appropriate for the circumstances that may commonly occur during manufacturing.

Q. QUALITY ASSURANCE RECORDS

Proper documented evidence of all manufacturing and inspection processes is maintained in a central file by the Inventory and

Document Controller supervised by the Q. A. Manager. Also included in these files are the qualifications and history of personnel who work on jobs subject to this manual.

All records are properly identified and recorded. Files are maintained intact and current at all times. Files are to be located in an area separate from manufacturing operations. Files are locked when not in use. Duplicate files may be maintained by customer if required.

R. AUDITS

The following areas are subject to audit by the Q. A. Manager:

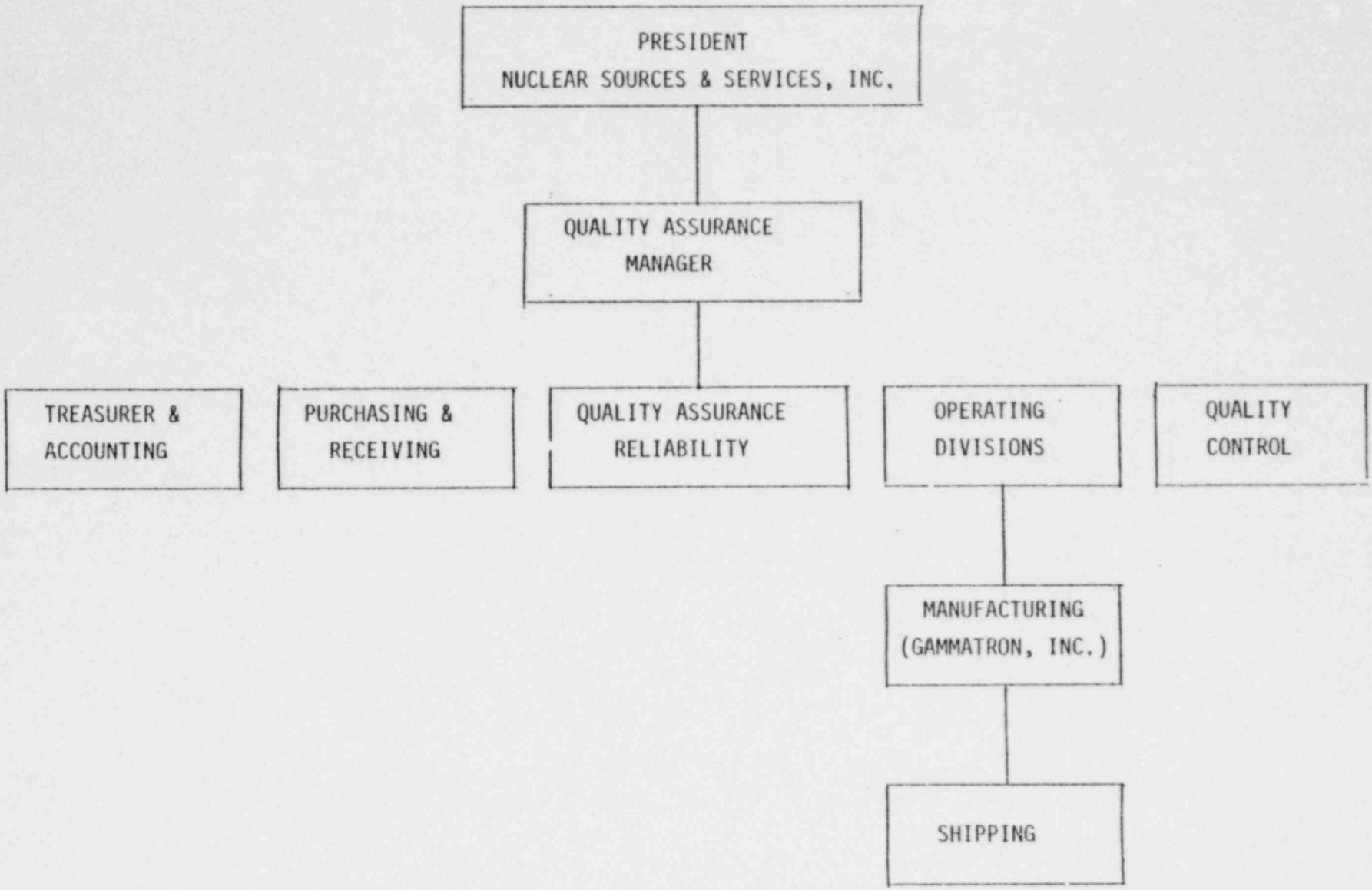
1. Incoming material control
2. Documentation control
3. Material storage, handling and issue control
4. Electronic and mechanical instrument control
5. Control of purchasing
6. In process controls
7. Final inspections and tests
8. Packing and packaging

When an audit has been completed the Q. A. Manager will review the findings with the appropriate supervisor. On a regular basis the Q. A. Manager will review the supervisors areas of responsibility and assign specific audit assignments. The Q. A. Manager monitors the audit program to assure that each major functional area is audited at least every six (6) months.

Customer representatives are included on each biannual audit if the customer wishes.

Permanent records of all audits properly dated will be maintained.

2.6. A P P E N D I X



QUALITY ASSURANCE DEPARTMENT

RELATIVE TO OVERALL ORGANIZATION

APPENDIX 2.6A

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