QUALITY ASSURANCE PROGRAM

FOR

RADIOACTIVE MATERIALS

SHIPPING PACKAGES

PROGRAM QA 1000

REVISION 0

JUNE 29, 1978

Reviewed for Adequacy for Intended Purpose, and Approved

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QUALITY ASSURANCE PROGRAM

PROGRAM QA 1000

REVISION SHEET

Revision Number	Section Revised	Approved By	Date Revised

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REVISION 0

SCOPE

A Quality Assurance Program is described herein for Shipping Packages for Radioactive Materials in accordance with the overall provisions of 10 CFR Part 71, revised October 18, 1977 and the criteria of Appendix E. The general provisions for Neutron Products, Inc. shipments is discussed in sections 1 through 10 with the specific provisions for package approvals in section 7.

Neutron Products, Inc. is in the business of fabricating, distributing and transporting radioactive sources. In the transportation of these sources, the company uses its own NRC approved shipping packages, shipping packages for which others have obtained and maintain NRC approval, and DOT specification packages. The program and procedures described herein are intended to provide continuing assurance for the safety and integrity of all shipments and compliance with all regulatory requirements.

The company handles and is licensed for by-product and source materials, and therefore, there is no need for this program to consider fissile materials at this time.

The largest number of shipments are to, from and between licensed facilities of private physicians or hospitals. This plan, therefore, recognizes that there is no on-site availability of the corporate organization for shipments from and between these facilities.

1. GENERAL QUALITY ASSURANCE PROVISIONS

The following provisions are intended to assure compliance with the criteria for use, testing and maintenance of shipping packages. It also applies to the package design and fabrication except for certain specific provisions applicable to the initial package approvals as discussed separately.

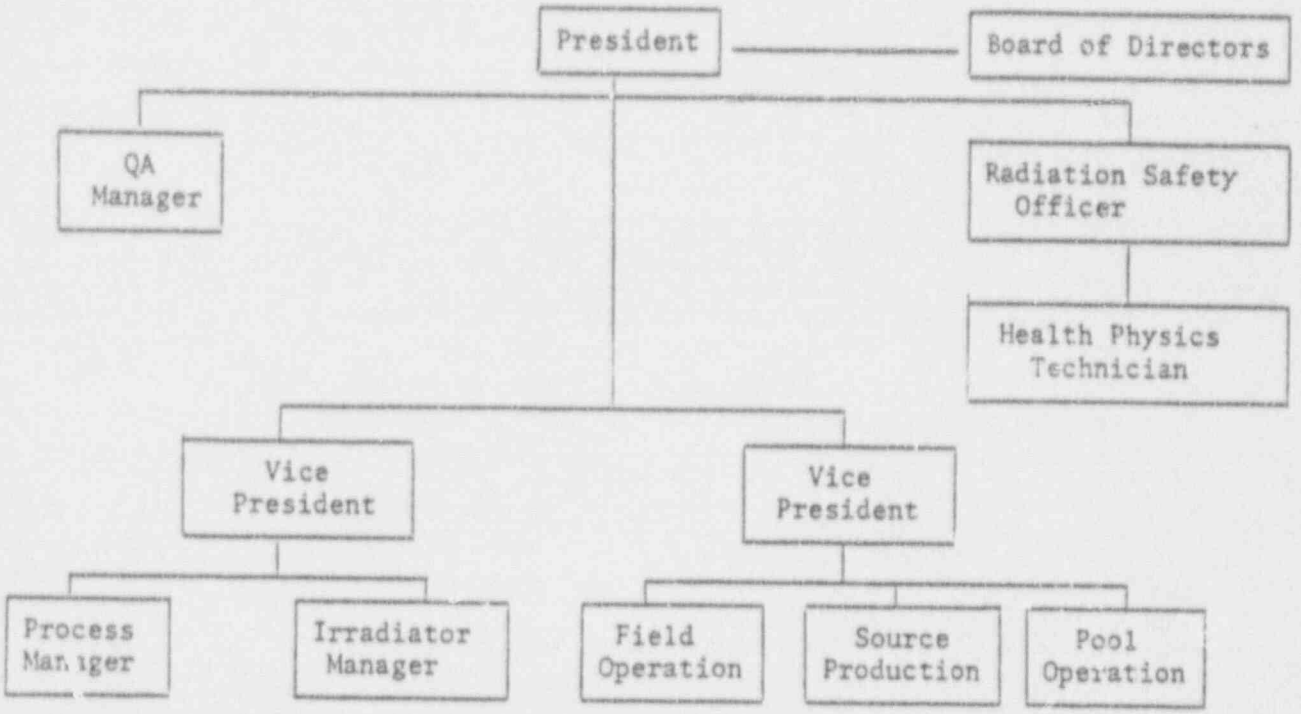
1.1 Organization

1.1.1 A company organizational chart is indicated in Figure 1. Mr. J. Ransohoff, President of the company, is responsible for overall management and operation. Mr. M. Turkanis, is the Vice President, who is directly responsible for the Source Production Department and is also Radiation Safety Officer for the company. Other company departmental functions are indicated.

1.1.2 The organizational responsibilities for the QA program will be assigned as described below. Neutron Products, Inc. shall retain full responsibility for the complete program for both general and specific requirements including design, fabrication and testing of new shipping packages whether performed by or for Neutron Products. Neutron Products, Inc. is a small

FIGURE 1

COMPANY ORGANIZATION



organization and therefore multiple QA functions may apply to the same individual. Management shall be responsible to assure that the independent nature of functions will be recognized.

1.1.3 Responsibility assignments are:

(a) The President has the overall responsibility for the establishment and the implementation of the QA program. He shall approve the program and concur with any revisions or modifications.

(b) The QA Manager is responsible for managing and implementing the program and reports directly to the President. He shall maintain all QA documents, records and procedures and shall perform audits or direct these to be performed. The QA Manager shall also concur with modifications to procedures and documents which shall be made in accordance with established procedures. He has full authority to verify, check, audit, inspect and take any steps as required to assure the effectiveness of the program. All persons involved in QA procedures shall have direct access to the QA Manager to report and identify any safety assurance problems and to discuss solutions or improvements to the program.

(c) The Operating Department Managers, Source Fabrication, Pool Operation and Field Operations Managers are each responsible for their own packages and shipments. They are each individually responsible for adherance to established procedures, and will correct and report any deficiencies. Their QA functions are handling, storage, shipping, maintenance and repair. They are responsible for their departments' preparation of each package for shipment and shall sign or designate an approved operator to sign the QA Inspection, Test and Operating Status Record as an indication that the package has been properly prepared. They also may be involved in modification work but only on written authorization from the QA Manager. The Operation Department Managers report on their QA functions directly to and submit reports and records for each individual shipment directly to the QA Manager.

(d) Whenever the shipment originates at the company's Dickerson facility, the Health Physics Technician is responsible to concur with the preparation of each radioactive shipment in accordance with the established procedures. He shall either sign or authorize the signing of the QA Inspection, Test

and Operating Status Record concurring with the shipment approval.

He also performs or authorizes the performance of the Health Physics radiation and contamination survey for all package shipments. He reports on QA functions directly to the QA Manager.

Whenever Neutron Products originates a shipment from a temporary job site, a source handler licensed by the State of Maryland shall assume and perform the Health Physics Technician's duties and responsibilities.

For new package designs and fabrication, either this program will apply or management may rely on the NRC approved QA plans of vendors and may request appropriate certifications of compliance, recognizing that it is management's responsibility to become satisfied that an acceptable program was in force during the design and/or fabrication.

Figure 2 indicates a job function-responsibility matrix.

1.2 Quality Assurance Program

1.2.1 Management Responsibilities

Management shall establish and implement the QA program. This implementation shall include an active role in participating in audits, and supervisory checking of the program by the QA Manager.

1.2.2 Training Procedures for QA Responsibilities

Management shall initiate and approve a written procedure for each of the QA functions and shall implement the training of those individuals performing their functions. The training shall consist of indoctrinating and training the individuals on-the-job, and reviewing performance for a period of time sufficient to assure proficiency. These individuals when trained shall be designated by written notice that they are qualified by management for the job function.

1.2.3 Revisions

Any revisions to this QA program shall be first reviewed by all those involved in the preparation of this program and formally approved by the QA Manager and the President. Such approved revisions shall then be included in the program and the revision noted in the program revision sheet.

FIGURE 2

JOB FUNCTION - RESPONSIBILITY MATRIX

	OPERATIONAL FUNCTION				
	President	QA Manager	Department Manager	Field Technician	Health Physics Technician
QA FUNCTION					
QA Program	1,2	3	4	4	4
Training	2	1,3			
Handling, Storage Shipping		2	3	3	5
Inspection Test, Operational Status		2	3	3	5
Revisions or Corrective Actions	5	5	1,2	1,2	1,2
Package Maintenance, Repair or Modification	5	1,2			
Document Control	2	1,2,3	1	1	1
Audits	1,5	1,2,3			

RESPONSIBILITY:
(1) Initiate
(2) Approve
(3) Perform
(4) Accept
(5) Concur

1.2.4 Quality Assurance

Written procedures shall define the general criteria for QA functions and compliance to these shall be ensured by signed check lists for those functions effecting safety. These check lists shall be signed by the individual performing the work and by the individual checking the work. In new package design and fabrication, the specific criteria established for each package and the designs evolved shall be signed by the originating individual and signed by a qualified checking individual. Each fabricator shall be required to certify conformance with the authorized specifications.

1.2.5 Safety Criteria Control

The QA program shall emphasize the safety related criteria. This will be accomplished through the training phase, the written procedures and the QA Inspection, Test and Operational Record.

2. DOCUMENT CONTROL

All documents relating to each specific shipping package shall be controlled according to written procedures and shall be the responsibility of the QA Manager. Changes or revisions to documents will be made only by procedures reviewed and approved by the QA Manager and the President.

3. HANDLING, STORAGE AND SHIPPING

All operations concerning the handling, storage and shipping of radioactive shipping packages shall be in accordance with established written procedures. These procedures shall control all safety aspects of the package and shipment, including an outline of the detailed work instructions for the handling, storage and shipping operations, and for package loading and unloading operations. Shipments shall not be made unless all required tests, certifications, acceptances and final inspections have been completed. These operations are the responsibility of the Department Manager storing, packing or shipping the specific package. This department shall prepare the QA Inspection, Test and Operational Record for each specific shipment. Each Operating Departmental Manager is responsible for their own shipments and packages.

4. INSPECTION, TEST AND OPERATING STATUS

All operations concerning inspection, testing and operating status of shipping packages shall be in accordance with established written procedures. The status of each package shall be indicated by both labeling and inspection records. Any non-conforming parts or packages shall be clearly marked and maintained

in accordance with the procedures. Packaging, testing and shipping preparation are the responsibility of the Operating Department making the shipment. Inspection and concurrence of quality assurance is the responsibility of the Health Physics Technician as designated by the QA Manager. Concurrence is acknowledged on the QA Inspection Test and Operational Record. The health physics radiation survey has also a Health and Safety responsibility and this is acknowledged on the Package Shipping Record.

5. QUALITY ASSURANCE RECORDS

The QA Manager shall maintain or assure the maintenance of: (1) equipment descriptions, including all maintenance needs and modifications, (2) all QA procedures, (3) a copy of the QA Inspection, Test and Operational Records, (4) personnel qualification approval records, (5) results of audits, and (6) records of package maintenance, repair and modifications. All records shall be maintained in accordance with the procedure required by Document Control, Section 2 above. These records shall be identifiable and retrievable for each package shipment and a list of all shipments shall be maintained.

6. AUDITS

Audits of the QA program shall be performed on a semi-annual schedule with spot checks as deemed necessary by the QA Manager. These results shall be maintained by the QA Manager and reported to the President. If evaluation indicates deficiencies, these shall be corrected and revisions shall be considered where necessary. These audits shall stress the safety aspects of the package. All audit records shall be included in the QA document files.

7. SPECIFIC PROVISIONS

In evaluating packages for approval, specific considerations of the package design, testing and fabrication may require specific QA procedures. These QA procedures will be included in the package approval application and considered for each individual case.

The following general provisions will apply however to each individual package. The QA Manager will be responsible to fulfill the specific provisions requirements in both the design-fabrication phase and in its ultimate use. The specific provisions will be written into the operating procedures when required.

8. MATERIALS PROCUREMENT AND CONTROL

In new package fabrication, all materials and equipment critical to safety or structural integrity of the package shall be clearly identified in the specifications of the original design. These items shall be procured by specification and certified as complying by the vendor and/or Neutron Products, Inc. Records shall be maintained by the QA Manager in accordance with the Document Control procedure.

In maintenance of a package, replacement items will be procured by specification , and will be certified as acceptable and these certifications w ll be maintained by the QA Manager. Replacement items will be labeled or marked by the appropriate Operating Department Manager to indicate approval for use on a specific package or package type.

9. PACKAGE MAINTENANCE, REPAIR AND MODIFICATION

A record of package maintenance, repair and modifications work will be maintained. A copy of this record shall be maintained by the QA Manager with the original being maintained by the Operating Department responsible for the individual package. All major maintenance, repair or modification shall first be approved by the QA Manager with the concurrence of the President. Requests for maintenance, repairs or modifications may be initiated by anyone involved in the QA program directly to the QA Manager.

10. SUMMARY OF QA PROCEDURES AND DOCUMENTATION

The following QA Procedures and Documents, not included in this QA Program description are listed below. Establishment, implementation and maintenance of these procedures and records are a part of the QA Program.

Procedures:	Scheduled Completion Dates
Handling, Storage, Shipping and Maintenance Procedures	11/1/78
Inspection, Test and Operational Status Procedures	1/1/79
Packaging Loading and Unloading Procedures	9/15/78
Revisions and Modifications Procedures	8/15/78
Document Control Procedure	8/1/78

Documents:

QA Inspection, Test and Operational Record

Radioactive Shipment Record

Package Repair or Modification Authorization

Package Maintenance, Repair and Modification Log

Truck Drivers Log

Personnel Certification Notice

QA INSPECTION, TEST AND OPERATIONAL RECORD

SHIPMENT

Shipment Work Order: _____ Shipment Date: _____ Package Number: _____ Source Loading: _____ curies Shipment Prepared by: _____

INSPECTION AND OPERATIONAL STATUS

	Certificate 5364, Rev. 0 (NPI-67-0442)	Certificate 9102, Rev. 0 (NPI-20MC-6)	Certificate 6400, Rev. 3 (Supertiger)	USA/5800/B and 20MC6
1. Copy of Certificate (authorization available)				
2. Package meets physical description in Certificate				
3. Bolts and nuts, number and type				
4. Bolts secured				
5. Tungsten alloy plugs	N/A		N/A	N/A
6. Source movement less than 0.025 in any direction	N/A			
7. Gasket inspected			N/A	
8. Dunnage proper (snug fit)	N/A			
9. Protrusions proper (See Item 10 of Certificate)		N/A	N/A	N/A
10. Package labels correct and in place				
11. Truck labels correct and in place				
12. Radiation survey completed				
13. Pressure relief valve in place	45 psig	N/A	N/A	N/A
14. Package cavity dried (wet load cask only)		N/A	N/A	N/A
15. Inert gas filled		N/A	N/A	N/A
16. Package secured in overpack	N/A			
17. Package secured on truck				
18. Package cage in place		N/A	N/A	N/A
19. Relief valve tested		N/A	N/A	N/A
20. Package pressurized	___psig @___(time)	N/A	N/A	N/A
21. Pressure checked	___psig @___(time)	N/A	N/A	N/A

Tested by: _____ Concurred by: _____

Remarks:

Equipment Certifications

Certificate of Compliance 5364, Revision 0, NPI-67-04

Certificate of Compliance 9102, Revision 0, NPI-20WC-6

Certificate of Compliance 6400, Revision 3, Supertiger

Certificate of Compliance USA/5800/B, 20WC6