

71-0714

Process Technology, (NC) Inc.



FACILITIES AT:
Exit 150 Off I-85
Service Road & Porter Avenue
Haw River, N.C. 27258
(919) 578-5878

January 11, 1991

Director,
Office of Nuclear Material Safety
and Safeguards
US Nuclear Regulatory Commission
Washington, DC 20555

Dear Sir:

In compliance with 10 CFR 71.101(c) we are submitting our Quality Assurance Program for approval. Enclosed is our Procedure 3.12.A "Quality Assurance Program For Shipping Radioactive Material" and our check for \$150 to cover the renewal charges

Respectfully yours,

Paul O. Shapiro, VP and
Corporate Radiation Safety Officer

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Rec'd 1/22/91
w/ck. # 4180
\$150.00

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Subject: QUALITY ASSURANCE PROGRAM FOR SHIPPING RADIOACTIVE MATERIAL		Section/Number/Revision 3.12 A
Effective Date: APRIL 2, 1990		Approved By Quality P.O. SHAPIRO
Prepared By: P.O. SHAPIRO	Approved Technically J. SCHLECHT	

1.0 PURPOSE

To establish the Quality Assurance Program (QAP) for the procurement, use, handling and returning of shipping containers for radioactive material (RAM) in accordance with all pertinent laws.

2.0 SCOPE

Applies to all RTI and PTI facilities shipping or receiving Type B packages of Cobalt 60 for gamma irradiators. Applicable to containers owned by another party and for which RTI is an authorized user. Safety controls will be applied to each container and to each shipment through procedures, special checklists, other necessary documents and training, to the degree required, to assure the safety of each shipment.

3.0 REFERENCES

3.1 10 CFR 71

4.0 DEFINITIONS

4.1 "Quality Assurance" (as defined in 10 CFR 71, subpart H) - comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality Assurance includes quality control which comprises those quality assurance actions related to the control of the physical characteristics and quality of the material or component to predetermined requirements." RTI personnel, (the Operations and Engineering staff, the Quality staff, and other personnel assisting in each shipment of RAM) will assure that all shipments from RTI facilities are made in a safe manner and comply fully with existing regulations.

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5.0 EQUIPMENT

- 5.1 Current RTI Procedure for shipping container being used.
- 5.2 Appropriate checklists.
- 5.3 Information on special handling, storage and cleaning of the container from the owner.

6.0 SAFETY REQUIREMENTS

- 6.1 All personnel involved will have documented training to safely accomplish the specific task.
- 6.2 All personnel involved shall be equipped with film badges.
- 6.3 At least 2 people involved will have self-reading dosimeters.

7.0 PROCEDURE

- 7.1 RTI Inc. through its Corporate Quality Department, shall retain and exercise responsibility for the QAP applicable to the containers in which RAM will be shipped.
- 7.2 A QA Program Manager (QAPM) shall be designated. The QAPM is responsible for preparing the QAP, making changes, additions or modifications as necessary and to submit the QAP, and/or changes, etc., to the RTI staff for review and approval. The QAPM is responsible for preparing supporting documents to the QAP, such as procedures, checklists, etc. These supporting documents shall be reviewed by the RTI staff, and when appropriate, shall be approved by the QAPM. The QAPM shall supervise the operations performed under this plan.
- 7.3 The facility or corporate Radiation Safety Officer will exercise overall supervision of the work performed.
- 7.4 Senior management shall review and approve the procedure and any subsequent revisions.
- 7.5 Quality will appoint an auditor to audit all shipment records. The auditor will not participate in the receipt, inspections, loading, or preparation for shipment activities.

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7.0 PROCEDURE

- 7.6 The QAP and implementing procedures will be reviewed by the QAPM prior to each shipment. Changes to procedures, checklists, etc., will be made as necessary, reviewed internally, and submitted to senior management for approval prior to actual use. The QAPM, during actual container loading operations, will resolve any QA and/or safety questions raised by any member of the loading crew. The QAPM has the authority to cease operational functions whenever there is justifiable cause. Only the QAPM, or his representative, may direct continuance of the operation and then only after resolving the cause for the cessation of activities.
- 7.7 RTI Operations personnel may question any point of the QAP and refer this topic to the QAPM for resolution. The RTI quality personnel, whenever they perceive an act or omission they believe to be unsafe, have the authority to halt the immediate operation and refer the matter to the QAPM for resolution. RTI personnel, as well as the QAPM, may suggest possible solution(s) to problems, but only the QAPM or his designated representative may approve a procedural change.
- 7.8 Quality Assurance Program
- 7.8.1 This program includes the procurement, handling and use, operational testing prior to use, housekeeping, and return to owner, as applicable.
- 7.8.2 The container owner will be required to furnish the documentation required by 10 CFR 71 relative to the container.
- 7.8.3 Implementing procedures, checklists, pre-load testing, loading procedures, pre-shipping checklists, instructions for truck driver, and housekeeping actions will be prepared.
- 7.8.4 Required records will be identified. These records and other documents pertaining to shipment shall be filed for retention and retrieval as required by 10 CFR 71.

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7.0 PROCEDURE (CONT)

7.8.5 All personnel involved in moving cobalt will have received documented training to cover, as appropriate, the purpose of the QAP, its scope, documentation requirements, review of audit procedures, safety, operational procedures, container receipt, inspection, operational testing, handling, loading, and audit.

7.9 Design control is not applicable.

7.10 Procurement Document Control. The container owner will be required to furnish evidence of compliance with 10 CFR 71, subpart H.

7.11 Instruction, Procedures and Drawings.

Instructions, procedures and drawings will be prepared and documented for actions affecting quality. These procedures will be in sufficient detail to describe the sequence of events essential to achieving the desired quality objective. These instructions, procedures, etc., will be reviewed prior to the time of intended usage to insure their applicability.

7.12 The unloading procedures shall be the responsibility of the consignee.

7.13 Document Control

7.13.1 This QAP and the documents, instructions, procedures, relating thereto shall be controlled to prevent unwarranted changes being made. Changes to the QAP shall be approved by senior management. The QAPM is authorized to review and change the instructions, procedures, checklists, etc., implementing the QAP.

7.13.2 The QAPM shall maintain a current master list of applicable documents.

7.14 Control of Purchased Material, Equipment and Services Is not applicable to the QAP.

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7.0 PROCEDURE (CONT)

7.15 Identification and Control Materials, Parts and Components

This paragraph is not applicable to the QAP.

7.16 Control of Special Processes

This paragraph is not applicable to the QAP.

7.17 Inspection

Inspections as applied to the design, fabrication, assembly, and proof testing is not a part of this QAP.

7.18 Test Control. All tests necessary to assure that the container functions properly while loading will be performed.

7.19 Control of Measuring and Test Equipment shall be limited to that necessary to verify the container is ready and safe for use.

7.20 Handling, Storage, and Shipping

7.20.1 Information on special handling, storage, and cleaning will be requested of the container owner.

7.20.2 Upon receipt of this information, procedures will be prepared on the loading of the cask and shipping requirements. Particular attention will be given to advance agreement on the receipt of the RAM, and on advance notification of the actual shipment.

7.20.3 Coordination with local and State officials will be done as necessary.

7.20.4 Shipping papers, special notices, if any, and a reference to pertinent NRC and DOT shipping regulations will be identified.

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7.0 PROCEDURE (CONT)

7.21 Inspection, Test and Operational Status

Markings, tags, labels, etc., affixed to the container by its owner to show evidence of satisfactory testing and operational status will not be removed or obliterated.

7.22 Non-Conforming Materials, Parts or Components

Procedures will be prepared, as necessary, for the identification, documentation, tagging, segregation, and notification of the container owner of the non-confirming materials, parts and/or components. The maintenance of the shipping container shall remain the responsibility of the container owner.

7.23 Corrective Action

7.23.1 The QAPM has the authority to cease operations and/or institute corrective actions whenever it is deemed the working conditions are adverse to the achievement of the requisite safety controls.

7.23.2 Necessary corrective action shall be accomplished prior to the use of any container and/or prior to the continuance of procedure during which a deficiency, deviation, etc., is recognized. The deficiency, etc., and the requisite corrective action shall be documented.

7.24 Quality Assurance Records

7.24.1 All records shall be retained and readily retrievable for a period of 2 years after shipment.

7.24.2 These records shall include the QAP, procedures, checklist, results of tests, copies of shipping papers, results of inspections and audits with deficiencies noted and corrective actions taken, procurement actions, and non-conformance reports.

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7.0 PROCEDURE (CONT)

7.25 Audits

7.25.1 Audits of the QAP will occur shortly after the shipment. The audit objective will be to assure the records have been properly completed, assembled, and prepared for storage.

7.25.2 Personnel to accomplish these audits will not be selected from the individuals who performed the safety-related functions.

7.25.3 Written procedures and/or checklists will be prepared to assure a thorough checking and verification of the actions being audited. The results of the audits will be given to the President, the Vice President Quality, and Vice President Operations and Engineering, and the QAPM.

7.25.4 APPROVAL OF PROGRAM

The RTI Quality Assurance Program Procedures (QAP) shall be submitted to Director, Office of Nuclear Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Commission approval is required prior to the use of any package for the shipment of licensed material.

8.0 EXHIBITS

- A Quality Assurance Checklist
- B Cask Procurement Checklist
- C Pre Shipment Checklist
- D Pre Operations Checklist
- E Receiving/Shipping Checklist

RTI 1002

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EXHIBIT A
QUALITY ASSURANCE CHECKLIST
for
SHIPPING RADIOACTIVE MATERIAL

This program details the operations concerning the movement of cobalt from the _____ facility in compliance to the requirements of the program format submitted to the NRC on _____.

QA Program Manager is _____

References:

- * 10CFR.71.101 Subpart H - Quality Assurance
- * RTI Quality Assurance Program dated _____
(Exhibit #1)

Applicable procedures:

- * 9.302 current revision "Water Sampling and Analysis".
- * 9.304. current revision "Contamination Test of Inside of Shipping Containers".
- * 9.402. current revision "Loading/Unloading of AECL F 168 Shipping Container" (Exhibit #3)
- * 9.403. current revision "Loading/Unloading of GE Model No. 1500 Shipping Container".
- * 10.103 current revision dated 11/10/88 "Calibration and Use of Counter Scaler".

QA Auditor is _____

Applicable checklists:

- * Cask Procurement (page 2)
- * Pre-Shipment (page 3)
- * Pre-operations (page 4)
- * Receiving/Shipping (page 5)
- * User Checkoff Sheet, See Proc. 9.402 or 9.403, whichever is applicable.

Approvals:

J. Schlecht RSO Date _____

P.O. Shapiro V.P. Date _____

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EXHIBIT B

Cask Procurement Checklist

<u>ITEM</u>	<u>INITIALS</u>
1. Cask procured from _____	
2. Container owner supplied information on:	
a - special instructions _____	
b - owners checklist supplied _____	
3. Document required by 10CFR71 supplied _____	
(Certification of Compliance for container)	
4. Advance notification requirements completed _____	
a - notification to Governor or designee of	
each State the material is to pass through.	
State _____ Date _____	
State _____ Date _____	
State _____ Date _____	
State _____ Date _____	
b - notification made by mail _____ messenger _____	
c - name of individual notification made to:	

d - Notification contained:	
Name, Address, Telephone Number of shipper,	
carrier, and receiver.	
Description of material, shipping times	
point of contact for current shipping info.	
5. State Licenses obtained:	
a - from _____	
b - via phone _____ mail _____ in person _____	

Reviewed and approved by QA Program Manager _____
date _____

Reviewed by Auditor _____ date _____

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EXHIBIT C

Pre-shipment checklist:

<u>ITEM</u>	<u>INITIALS</u>
1. Implementing procedures _____	
2. Checklists _____	
3. Pre-load testing _____	
4. Loading procedures _____	
5. Instructions for truck driver _____	
6. Housekeeping actions _____	
7. Training of personnel _____	
Names of personnel trained _____	

Reviewed and approved by QA Program Manager _____
Date _____

Reviewed by Auditor _____ Date _____

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EXHIBIT D

Pre-Operations Checklist

Equipment

Calibrated ionization chamber _____

Calibrated survey instrument _____

wrenches _____ sockets _____

crane with proper slings _____

under water lights _____

disposable gloves _____

survey swipes _____

swipe envelopes _____

radioactive materials instruction and shipping forms _____

vehicle survey form _____

security seals _____

self reading pocket dosimeters (at least two) _____

film badges (one per person) _____

shipping labels and placards _____

special long handled tools _____

drivers certification to transport radioactive material _____

Reviewed by Auditor _____ Date _____

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EXHIBIT I

Receiving/Shipping Checklist
(for receipt of cobalt)

prior to placing cask in the pool:
 measure external surface radiation of cask _____
 swipes taken on external cask surface _____
 pool water sample taken and analyzed _____
 pool area radiation levels checked _____
 vent and drain plugs removed from cask _____
 level of pool water lowered _____
 cask washed to remove dirt _____

when removing cask from pool:
 raise the cask to within two feet of water surface _____
 radiation monitor acceptable _____
 rinse outside of cask and allow to drain into pool _____
 replace plugs and bolt cover _____
 replace protective jacket _____
 measure surface dose rate _____
 take swipes over surface _____
 secure cask _____
 measure dose rate at 1 meter _____
 measure dose rate in cab of truck _____
 measure dose rate around the outside of the truck and record the
 highest reading _____
 complete shipping papers _____
 remove old labels and tags as required _____
 attach new required labels _____

QC Audit performed by:

_____ on _____