

9102

NEUTRON PRODUCTS inc

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October 7, 2003

Mr. E. William Brach,
Director
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike 20555
Rockville, MD 20852-2738

VIA FAX: 301/415-8555 (Original to be sent by UPS Overnight)

Re: Renewal of Certificate of Compliance USA/9102/B0

Dear Mr. Brach:

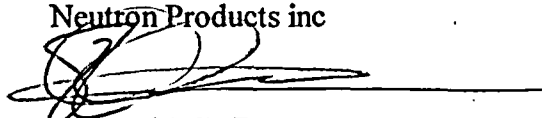
Confirming our telephone conversation of October 1, 2003 with Ms. Julia Barto, enclosed are three each, properly stamped copies of:

- Teletherapy Shipping Packaging Maintenance Procedure R-2019-G, Revision 0; and,
- Teletherapy Shipping/Transfer Cask Unloading And Loading Procedure R-2014-G, Revision 0.

The original procedures that were improperly stamped and submitted with our request for Renewal of Certificate of Compliance USA/9102/B0 dated September 29, 2003 have been returned to us, and these are to replace them.

If there is anything further that we should do, please let me know.

Sincerely
Neutron Products inc


Edmond J. DeRosa
RSO, MD-31-025-03 license

NM3501

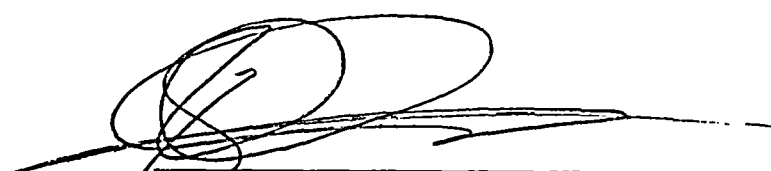
TELETHERAPY SHIPPING PACKAGING
MAINTENANCE PROCEDURE

PROCEDURE R-2019 G

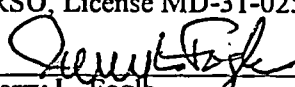
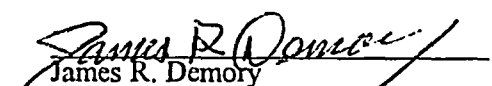

REVISION 0

May 1, 2003

Reviewed for Compliance, Safety,
and Adequacy for Intended Purpose
and Approved



Edmond J. DeRosa
RSO, License MD-31-025-03


Jerry L. Fogle
Division III Manager
Date: 5-1-03
James R. Demory
Manager, LAA
Date: 5-1-03
Jeffery D. Williams
Division III Quality Assurance
Manager
Date: May 1, 2003

Author: Marvin M. Turkanis

Change record: This is the Original

This is a controlled document and as such shall only be modified in accordance with the latest revision of Procedure C 9000, Preparation of Quality System Procedures, and Procedure C 9001, Document and Data Control. This document is valid only after it has been reviewed and approved with dated signature by all of the above listed authorized personnel.

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TELETHERAPY SHIPPING PACKAGING
MAINTENANCE PROCEDURE
Procedure R-2019

1. Purpose

This procedure sets forth the maintenance program for Neutron Products' teletherapy source shipping packaging that is adequate to assure meeting the requirements of 10 CFR Part 71 during their useful life.

2. Scope

This procedure applies to Neutron Products' teletherapy source packaging, Model Numbers NPI-20WC-6 (CoC 9102), NPI-20WC-6 MkII (CoC 9215), and U.S. DOT Type 20WC-6.

3. Definitions and Abbreviations

CoC: Certificate of Compliance

LAA: Limited Access Area

OP: Steel and wood protective jacket portion of the packaging

Permanent site: All other sites (usually Neutron's Dickerson facility)

RPP: Radiation Protection Program to assure radiological operations are conducted safely and in compliance with 10CFR20 or equivalent Agreement State regulations for domestic shippers or their equivalent for shipments from foreign locations

RSO: The applicable Radiation Safety Officer for Neutron's MD-31-025-03, the shipper's facility or their designee

TC: Transfer Cask, lead-steel inner portion of the packaging

Temporary job site: A site where Neutron personnel are working in accordance with a reciprocity agreement or license held by others.

4. References

Neutron Procedure R-2014, Teletherapy Shipping/Transfer Cask, Unloading and Loading Procedure

U.S. NRC Certificates of Compliance 9102 and 9215

U.S. DOT Certificate of Competent Authority USA/9215/B(U)

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PROCEDURE R 2019 DRAFT WITH ADDITIONS AND DELETIONS
TELE THERAPY SHIPPING PACKAGING MAINTENANCE PROCEDURE

May 1, 2003
Page 3 of 7

U.S. DOT Regulations, 49 CFR 173.416(e)

U.S. DOT Specification for Maintenance for 20WC-6 Wooden Protective Jacket, 49 CFR 178.362

Neutron's Quality Assurance Program Approval for Radioactive Material Packages, NRC 0121

Neutron Drawing 240116 (for OP)

Neutron Drawing 240122 (for TC)

5. Qualification and Responsibilities

Personnel shall be qualified and supervised in accordance with the applicable QA program and RPP to perform their assigned responsibilities for operations conducted in accordance with this procedure.

6. Safety

All procedures, regulations and precautions associated with:

- radioactive materials; and,
- lifting, rigging and moving heavy objects

shall be followed.

7. Maintenance Program

7.1 Each Shipment

7.1.1 TC

7.1.1.1 Confirm that gaskets meeting the specification in Appendix I have been replaced in the prior 18 months.

7.1.1.2 The two gaskets and all of the gasket surfaces on the TC shall be visually inspected whenever the end covers are installed or removed for any damage including cracking of the gaskets, but excluding normal marking.

7.1.1.3 All closures and fasteners shall be visually inspected to the extent possible without dismantling the packaging further than required to load the source and ship, and the bolts shall be replaced as necessary in accordance with the specifications in Appendix I.

7.1.1.4 Any damage to the TC, except for superficial defects such as marks or dents, shall be reported to the RSO for evaluation in accordance with section 7.2, Corrective Action.

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7.1.2 Wooden Protective Jacket

7.1.2.1 Prior to each use and without dismantling the packaging further than required to ship the packaging, the individual responsible for the shipment shall inspect the portions of the wooden protective jacket that are visually accessible for:

- loss of plywood bonding;
- cracks;
- water logging;
- corrosion of the steel rods;
- warping of the steel rods that cause the cover not to fit and cannot be corrected by bending the rods by hand without the application of heat; and,
- functional status of all closures and fasteners.

7.1.2.2 Any damage to the wooden protective jacket, except for superficial defects such as marks or dents, shall be reported to the RSO for evaluation in accordance with section 7.2, Corrective Action.

7.1.3 Outer Steel Shell

7.1.3.1 The steel outer shell of the OP that is accessible without dismantling the packaging further than required to ship the packaging shall be visually inspected for any damage:

- after receipt of a shipment by Neutron at a permanent or temporary job site; and,
- prior to the next use of the OP.

7.1.3.2 All closures and fasteners shall be visually inspected to the extent possible without dismantling the packaging further than required to load the source and ship and shall be replaced as necessary in accordance with the specifications in Appendix I.

7.1.3.3 Any damage to the outer steel shell, except for superficial defects such as marks or dents, shall be reported to the RSO for evaluation in accordance with section 7.2, Corrective Action.

7.1.4 Assembled Package/Packaging

7.1.4.1 The assembled package/packaging shall be visually inspected to the extent possible without dismantling the packaging further than required to load the source into and ship the packaging for any damage.

7.1.4.2 Any damage to the assembled package/packaging, except for superficial defects such as marks or dents, shall be reported to the RSO for evaluation in accordance with section 7.2, Corrective Action.

7.2 Corrective Action

7.2.1 When a report is made in accordance with Sections 7.1.1.4, 7.1.2.2, 7.1.3.3 or 7.1.4.2, the RSO shall evaluate the condition in accordance with the applicable non-conformance procedure, and the package/packaging shall not be shipped until the:

- damage is determined not to impair the integrity of the packaging to meet the required performance specifications; or,
- packaging is repaired in accordance with an NRC approved QA Program.

7.2.2 The gasket(s) shall be replaced with gaskets meeting the specification in Appendix I if :

- any damage is observed, including cracking , but excluding marking; OR,
- they have not been replaced within the prior 18 months.

7.3 Annual Inspection

7.3.1 Each wooden protective jacket shall be weighed annually.

7.3.2 If the weight gain or loss exceeds 10 pounds, it shall be reported to the RSO for evaluation and the OP shall be taken out of service until it is determined that performance of the OP has not been compromised or the jacket is repaired in accordance with an NRC approved QA Program.

7.4 Packaging Maintenance

7.4.1 Maintenance includes:

- painting of the metal shells, wooden protective jackets and TCs;
- replacing waterproof coverings on vent holes;
- inspection and/or replacement of the threaded rods in the wooden jackets;
- replacing gaskets, bolts and nuts;
- replacement of up to 3 layers of wood in the wooden protective jacket in accordance with approved written procedures;
- inspection and/or replacement of permanent I.D. plates, durable signs and holders, and radiation symbol plates;
- inspection and replacement of lid lifting chains and brackets, bale covers; and,
- welding and/or patching of tears in the outer steel shell in accordance with approved written procedures

in accordance with the applicable specifications of Appendix I and 49 CFR 178.362.

7.4.2 Maintenance can either be effected in the course of loading or unloading operations, or be specially scheduled.

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7.4.3 Maintenance is to be made by qualified employees and/or vendors, working in accordance with an NRC QA Program for Radioactive Materials.

7.5 Packaging Fabrication

In accordance with 10CFR71.13, no new packaging shall be fabricated for the models NPI-20WC6 and NPI-20WC6 MkII packaging.

8. Records

8.1 The Manager of Field Services shall maintain a documented record of all packaging inspection, maintenance and repairs.

8.2 The record shall be kept for a minimum of three years after the packaging is no longer in use.

APPENDIX I

1. The following parts shall be used for the maintenance of the TC:

- Bolt: hex head cap screw $\frac{1}{2}$ -13 x 1 $\frac{1}{4}$ ", SAE Grade 8 steel per Item 71, Drawing 240122
- Gasket: Gasket Silicone Rubber, 1 $\frac{1}{16}$ " thick, ASTM D-2000-80, per Item 47, Drawing 240122 for the CoC 9215 packaging.
- Gasket: Gasket Silicone Rubber, 1 $\frac{1}{16}$ " thick, ASTM D-2000-70, per Item 47, Drawing 240122 for the CoC 9102 packaging.
- TC identification tag, per Item 49 Drawing 240122

2. a. The following parts shall be used for the maintenance of the OP

- Threaded rod: 5/8 UNC threaded rod 41 $\frac{1}{4}$ " long nominal per Drawing 240116, View D
- Nut for wood shield: 5/8 UNC nut per Drawing 240116, View D
- Washer: 5/8" washer per Drawing 240116, View D
- Hex nut: 5/8" UNC per Drawing 240116, View E (bottom)
- Plywood sheet: 3/4" plywood sheet per Drawing 240116, Section F-F
- Screw for steel shell: Grade 5 Hex head cap screw - $\frac{1}{2}$ - 13 per Drawing 240116, Section A-A
- Nut for steel shell: Grade 5 Hex nut - $\frac{1}{2}$ - 13 per Drawing 240116, Section A-A

b. The parts listed in 2.a. above shall met the requirements of 49CFR 178.362.

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**TELE THERAPY SHIPPING/TRANSFER CASK
UNLOADING AND LOADING PROCEDURE**

PROCEDURE R-2014-G

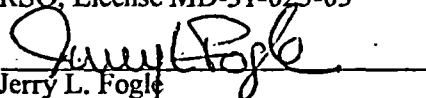
REVISION 0

Effective Date:

Reviewed for Compliance, Safety,
and Adequacy for Intended Purpose
and Approved



Edmond J. DeRosa
RSO, License MD-31-025-03



Jerry L. Fogle
Division III Manager

Date: MARCH 12, 2003



James R. Demory
Manager, LAA

Date: MARCH 12, 2003



Jeff Williams
Division III Quality Assurance
Manager

Date: MARCH 12, 2003

Author: Marvin M. Turkanis

This is a general procedure.

The current revision of Procedure R-2014 shall be used to fulfill the requirements of this procedure at Neutron Products Dickerson, Maryland facility.

Change record: This is Revision 0

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TELE THERAPY SHIPPING/TRANSFER CASK UNLOADING AND LOADING PROCEDURE

Procedure R-2014-G

Revision 0

1 Purpose

- 1.1 This procedure describes the loading and unloading of Special Form teletherapy sources into and out of shipping/transfer packages in accordance with the applicable provisions of 10 CFR 71 Subpart H.
- 1.2 This is a general procedure applicable to any authorized user and facility. Authorized users may wish to develop and implement specific procedures, work instructions, or other documents covering aspects of implementation which are specific to their operations.

Note: At Neutron Products' Dickerson, Maryland facility, the latest approved revision of Procedure R-2014 shall be used to fulfill the requirements of this procedure.

2 Scope

- 2.1 This procedure applies to loading and unloading shipping packagings, Model Numbers NPI-20WC-6 (CoC 9102), NPI-20WC-6 MkII (CoC and CoCA 9215), and U.S. DOT Type 20WC-6 in a hot cell.
- 2.2 Transferring sources between a TC and a unit that utilizes the teletherapy source is within the scope of Neutron Products' radioactive materials license MD-31-025-03 and is not within the scope of this procedure.

3 Definitions and Abbreviations

Quality Assurance Plan (QAP): A U.S. Nuclear Regulatory Commission approved Quality Assurance Plan, required by 10 CFR 71 Subpart H

Radiation Protection Program (RPP): A documented program used to assure that radiological operations are conducted safely and in compliance with 10CFR Part 20, or equivalent Agreement State regulations.

ALARA: As low as reasonably achievable per 10 CFR 20.1003

CoC: Certificate of Compliance

CoCA: Certificate of Competent Authority

DOT: Department of Transportation

LAA: Limited Access Area at Neutron's Dickerson facility

OP: Steel and wood protective jacket portion of the package.

RSO: Radiation Safety Officer for the shipper's facility or his designee

TC: Transfer Cask, lead- steel inner portion of the package

TI: Transport Index per 49 CFR 173.403

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4 References

Applicable Certificate of Compliance (for domestic destination) or Certificate of Competent Authority (for foreign destinations) for the shipping package.

Applicable portions of a QAP authorized in accordance with 10 CFR 71 Subpart H.

Applicable portions of the American National Standard for Sealed Sources - Classification, ANSI N43.6

5 Qualification and Responsibilities

5.1 Personnel shall be qualified and supervised in compliance with the applicable QAP and RPP to perform their assigned responsibilities for operations conducted in accordance with this procedure.

5.2 An RSO or equivalent authority shall be responsible for administrating the RPP including evaluation of all nonstandard events; establishing corrective action, when appropriate; and making the required notifications on a timely basis. The RSO should be vested with sufficient authority to halt operations deemed to be unsafe or not compliant with regulations.

5.3 For operations at Dickerson:

5.3.1 The LAA Manager is responsible for all those operations conducted in the LAA, including verification of the authorization of the TC and OP for the source(s) to be loaded and the documentation of the identity of sources.

5.3.2 Hot cell operators report to the LAA Manager and are responsible for loading and unloading sources under his or his designee's supervision.

6 Safety

All procedures, regulations and precautions associated with handling radioactive materials shall be followed.

7 Equipment

7.1 Tools, gauges, instruments, and other measuring and testing devices (including radiation monitors and receiving inspection gauges and instruments) shall be controlled, calibrated and adjusted in accordance with the requirements of 10 CFR 71.125.

7.2 Maintenance and calibration of all radiation and contamination monitoring equipment provided by Neutron shall be in accordance with Neutron's RPP.

7.3 Maintain and calibrate all other radiation and contamination monitoring equipment used in performing this procedure in accordance with their authorization for use.

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8 Qualification and Responsibilities

8.1 General

- 8.1.1 When Neutron is the shipper or when others are the shipper from sites within the United States, the shipment will be made in accordance with a U.S. Nuclear Regulatory Commission approved QAP, required by 10 CFR 71 Subpart H.
- 8.1.2 Only sources which have been specifically approved by the Division III Manager or his designee shall be loaded.

8.2 Personnel and Supervision Requirements

Radioactive materials shall be loaded or unloaded from transfer containers only by qualified hot cell operators, acting under the authority of the LAA Manager or the RSO or their designees.

8.3 Receipt of Incoming Shipping/Transfer Package

- 8.3.1 Packages shall be received in accordance with 10 CFR 20.1906 or equivalent Agreement State regulations.
- 8.3.2 Before the shipping/transfer package is removed from the vehicle, the radiation from the external surfaces of the package shall be monitored.
- 8.3.3 The receipt of the shipment shall be continued only if the radiation levels are within the limits specified in 10 CFR 71.47.
- 8.3.4 If the radiation levels are not within the limits specified in 10 CFR 71.47,
the package shall not be removed from the vehicle until instructed to do so by the RSO; and,
the RSO shall, within three (3) hours or the next working day after the receipt of the package, make the notification required by 10 CFR 20.205 to the carrier or Neutron's driver and the Administrator of the appropriate NRC Regional Office by telephone and telegram, mailgram or facsimile.
- 8.3.5 If the shipping/transfer package contains radioactive material, verify that the seal is unbroken.
- 8.3.6 Visually inspect the package for damage.
- 8.3.7 If the seal is broken or if there is no seal, OR if the package appears damaged, notify the RSO and proceed according to his instructions.

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- 8.3.8 If the tamper-indicating seal is missing or if there is damage to the package, excluding superficial dents and marks, the RSO shall evaluate the situation and shall develop a plan of action, which shall include wipe testing and notification of the licensee and shipper.
- 8.3.9 Remove the plates or cover that make the lid lifting eye inoperable.
- 8.4 Unloading the Incoming Shipping/Transfer Package
 - 8.4.1 Remove the TC from the OP. Inspect the OP for damage, and repair, if necessary, in accordance with a written procedure pursuant to an NRC Quality Assurance Program
 - 8.4.2 If the TC is documented as empty and is confirmed to be empty by a radiation survey, proceed to Step 8.5.
 - 8.4.3 After confirming that one end of the TC faces a shield wall, remove the bolts holding the cover and remove the cover.
 - 8.4.4 Open the cell door and put all necessary tools into the hot cell with the TC.
 - 8.4.5 Exit the hot cell and close the hot cell door.
 - 8.4.6 Remove the source holder from the TC and remove the source from the holder.
 - 8.4.7 Visually inspect the source for damage and evidence of failure of source integrity.
 - 8.4.8 If a certificate attesting that the source(s) is not leaking is not available, leak test the source in accordance with one of the procedures in the American National Standard for Sealed Sources - Classification, ANSI N43.6.
 - 8.4.9 If there is any sign of cladding failure, or if the wipe test after decontamination is greater than 0.005 uCi, notify the LAA Manager or his designee and the facility RSO to establish the corrective action to be taken to prevent significant contamination in storage. Do not proceed without approval from the RSO. Note condition and action(s) taken in the hot cell log.
 - 8.4.10 After the source has been properly stored, open the hot cell door using the applicable procedure and move the empty TC into the hot cell access area.
- 8.5 Cleaning
 - 8.5.1 Remove and clean the sleeves and inserts, clean the inside of the container,

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wipe test the inside of the container and inserts, and reinstall applicable sleeves and inserts.

- 8.5.2 Smears from inside the inside surface of the TC and the inserts should not exceed 500 dpm per 100 cm²; clean and rewipe as necessary to meet this limit.
- 8.5.3 After determining that the requirements of 49 CFR 173.428 regarding shipment of empty radioactive packaging materials are met, proceed to Step 8.6.19.

8.6 Loading

NOTE: Before loading, verify that the TC has been cleaned according to Step 8.5.

- 8.6.1 Confirm with the LAA Manager or other individual responsible for the shipment, the following:
- the availability of the applicable package Certificate, applicable portions of 10 CFR 71 and 49 CFR 173.471;
 - the TC and source holder are appropriate for the activity of the source(s) and the package Certificate;
 - the OP (wooden protective jacket and steel shell) is applicable for the package Certificate;
 - assure that the package maintenance is current and that the package components pass a visual inspection, including the gaskets and gasket surfaces.
- 8.6.2 Return the clean empty TC to the hot cell and close the door.
- 8.6.3 Visually inspect the sources to be loaded in the package for damage and evidence of failure of source integrity.
- 8.6.4 Leak test the source in accordance with the applicable procedure, if the source has not previously been leak tested subsequently to its removal from storage.
- 8.6.5 Acceptability for source shipment:
- 8.6.5.1 If the source passed the visual examination and the removable contamination, as determined by the wipe test, is less than 0.005 uCi, the source is acceptable for shipment.
- 8.6.5.2 Repeatedly decontaminating and wipe testing the source is acceptable to meet these criteria.

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- 8.6.6 If the source does not pass the visual examination or the wipe test, notify the RSO and proceed according to his instructions.
- 8.6.7 Load the source into an appropriate holder and insert the loaded holder into the designated position in the TC.
- 8.6.8 Record the identification of each source in the hot cell log.
- 8.6.9 Open the hot cell door using the applicable procedure.
- 8.6.10 Verify that the gasket surfaces have not been damaged during loading.
- 8.6.11 Place the gasket on the TC.
- 8.6.12 Hang the end cover on the pin and insert one bolt.
- 8.6.13 Remove the TC from the hot cell and place on the dolly.
- 8.6.14 Install and tighten bolts to firmly compress the gasket.
- 8.6.15 Decontaminate the external surfaces of the TC to contamination levels that are as low as practical in accordance with ALARA.
- 8.6.16 Visually inspect the TC and OP subassembly and lids before loading the TC in the OP in accordance with the Checklist in Appendix I, to ensure that the package satisfies the regulations and the Certificate.
- 8.6.17 Load the TC into the OP and install the wood and steel lids.
- 8.6.18 Bolt the wood lid firmly into place, making certain that all thread reinforcement rod ends remain recessed at least 1.5 inches below the surface of the wooden protective jacket.
- 8.6.19 Fit the steel shell lid and bolt into place.
- 8.6.20 Visually inspect the assembled package in accordance with the Checklist in Appendix I, to ensure that the package satisfies the regulations and the Certificate.
- 8.6.21 Render the lid lifting eye inoperable for lifting the package.
- 8.6.22 If a lid lifting bail is used instead of the lifting eye, remove the lid lifting bail before shipping the package.
- 8.6.23 Decontaminate the outside of the package to levels that are as low as practical in accordance with ALARA, except when shipment is from facilities which only have sealed sources or hospitals, clinics or private

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offices which have only nuclear medicine.

8.6.24 Proceed with the shipment after the smearable, removable contamination meets the requirements of 10 CFR 71.87(i) and 49 CFR 173.443.

8.6.25 Affix the appropriate labels for the shipment and load the package onto the truck in accordance with 49 CFR 173.444.

8.6.26 Perform a radiation survey of the vehicle in accordance with the applicable requirements of 10 CFR 71.47 and 49 CFR 173.441.

8.6.27 Affix the tamper-indicating seal and record the seal number.

9 Records

Maintain records of package design, maintenance, and shipments in accordance with 10 CFR 71.91.

10 Change Record

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