

September 8, 1989

U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Rd.
King of Prussia, PA 19406

ATTN: Mohamed M. Shanbaky, Chief Nuclear
Material Safety Section A
Division of Radiation Safety & Safeguards

Dear Mr. Shanbaky:

In response to the routine safety inspection on June 8, 1989, pertaining to docket #003-11944, license #18-16956-01. Also, please see attached.

Item A: As stated in 10 CFR 35.21 (A) the RSO does insure all radiation safety activities are performed in accordance with approved procedures. Wipe testing of radioactive shipments received will be continued. (See attached policy.)

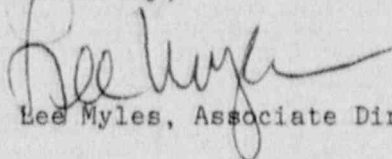
Item B: All syringes containing radiopharmaceuticals intended for patient use will be labeled in accordance 10 CFR 35.60 (b). (See attached policy.)

Item C: Dose calibrators upon being installed new or replacement will be tested for linearity and geometric function. (See attached policy.)

Item D: Wipe testing of radioactive shipments will be done on packages. (See attached policy.)

Should you need further assistance in this response please contact me. Thank you.

Sincerely,



Lee Myles, Associate Director

xc: Terry Jandreau, Nuclear Medicine Technologist
Dr. Madjid Yaghmai, RSO

enc:

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RECEIVED-REGION 1

8911150016 891101
REG 1 LIC 30
18-16956-01 PDC

CARY MEDICAL CENTER
DEPARTMENT OF RADIOLOGY,
NUCLEAR MEDICINE & ULTRASOUND

31-016-03
Radiation Safety Committee

PURPOSE: To conspicuously label each syringe with a radiopharmaceutical.
POLICY: 31-016-03 Labeling Radioactive Syringes
PROCEDURE: Each syringe that contains a radiopharmaceutical be labeled to show the radiopharmaceutical name, or its abbreviation, or clinical procedure to be performed or pt's name in accordance with 10 CFR 35.60 (b)

EFFECTIVE DATE: 9/1/87

REVIEW DATE: _____

Madjid Yaghmai, M.D.
Madjid Yaghmai, M.D.
Director of Radiology

Wanda Hale R.T.
Wanda Hale, R.T., RDMS
Radiology Manager

Lee Myles
Lee Myles
Associate Director

CARY MEDICAL CENTER
DEPARTMENT OF RADIOLOGY,
NUCLEAR MEDICINE & ULTRASOUND

31-020-04
Radiation Safety Committee

PURPOSE: To test new and replacement Dose Calibrators.
POLICY: 31-020-04
PROCEDURE: Dose Calibrators new and replacement will be tested for linearity, geometric function upon installation, prior to being utilized for patient doses.

EFFECTIVE DATE: 9/1/89
REVIEW DATE: _____

Madjid Yaghmal, M.D.
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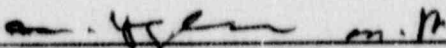
31-011-010
Radiation Safety Committee

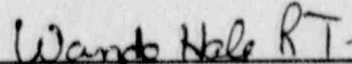
PURPOSE: To establish a procedure to wipe test Generator packages, and other Radioactive shipments to Manufacturer to ensure that packages do not exceed contamination levels -- 2,200 DPM/100cm², as stated in 10 CFR 71.5(A), 49 CFR Part 173.411.

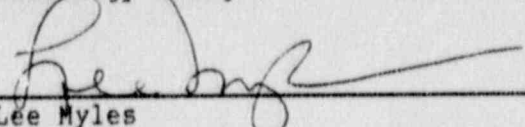
POLICY: 31-011-010
Wipe Testing of Generators sent back to manufacturer for disposal.

PROCEDURE: Put rubber gloves on, and with an alcohol swab wipe external surface, internal surface of package then container, the area wiped should have no more than 2,200 DPM/100cm² of contamination, to be safe to ship. All wipes will be counted in the Dade Isolect #5600-1, #12479 machine.

EFFECTIVE DATE: 9/1/89


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31-013-01C

NUCLEAR MEDICINE TECHNOLOGIST INSTRUCTIONS :
RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Receive and examine the package. Look for obvious evidence of external damage to the package; wet, puncture, crushing, etc.
2. Put on a pair of rubber disposable gloves and measure 1 meter (3 feet) from package then measure surface of package. Record the readings on the Record of Package Receipt/Disposal.
 - a. Surface reading should not exceed 200 Mr/Hr.
 - b. The 1 meter (3 foot) reading should not exceed 10 Mr/Hr.
 - c. Should readings exceed above, follow procedure Reg. Guide 10.8, App. F.
3. Wipe the surface of the package with a damp material and measure the activity of the wipe. Record on the Package Receipt/Disposal Record.
4. Compare the identity and strength of the material as noted on the shipping label, bill of lading and purchase order. Confirm the P.O. # on the bill of lading.
5. Open the package and examine the contents visually for evidence of damage. If acceptable, remove contents and perform wipe test on actual container holding the material.
 6. Perform survey of inner package and packing material. If no evidence of radioactivity (above room background), dispose of package and record disposition on Record of Package Receipt/Dispensing Record.
7. Measure the activity of the material at the appropriate range in the dose calibrator. Record the results in the appropriate section of the Isotope Receipt/Dispensing Record.
8. Remove and dispose of the rubber gloves in the prescribed manner as for contaminated materials.
9. The radioactivity label on the shipping package should be removed/obviated prior to disposal of the package.

Terry Jandreau 12/12/86
Terry Jandreau, R.T. (R)

Madjid Yaghmaei, M.D.
Madjid Yaghmaei, M.D.
Chief of Radiology
Radiation Safety Officer

ITEM 13, April 1, 1986

MANUFACTURER: _____

DATE OF CALIBRATION: _____ TIME: _____

DATE OF EXPIRATION: _____ TIME: _____

DATE RECEIVED: _____ TIME: _____

TOTAL ACTIVITY: _____ MCI _____

SPECIFIC ACTIVITY: _____ MCI/ml _____

GM READINGS: 3 FEET FROM PACKAGE _____ MR/hr

SURFACE OF PACKAGE _____ MR/hr

PACKAGE INTACT _____ IF NO, EXPLAIN ON REVERSE

DADE ISO-LECT #5600-1 12479

WIPE TEST: SURFACE OF OUTSIDE SOURCE CONTAINER _____ DPM BKG _____ CPM

SURFACE OF INSIDE SOURCE CONTAINER _____ DPM WIPE _____ CPM

GM READING OF PACKING MATERIAL PRIOR TO DISPOSAL _____ MR/hr EFF. 1.04 DPM

TECHNOLOGIST _____

DATE REMOVED TO STORAGE: _____

TECHNOLOGIST: _____

DATE DISPOSAL: _____

MODE: _____

TECHNOLOGIST: _____

GM READING ON LEAD @ TIME OF DISPOSAL: _____

DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. RADIONUCLIDE _____ yes _____ no difference _____

b. AMOUNT _____ yes _____ no difference _____

c. CHEM FORM _____ yes _____ no difference _____