



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Southfield and Outer Drive
Allen Park MI 48101

January 25, 1994

Weber
In Reply Refer To: 553/00A3

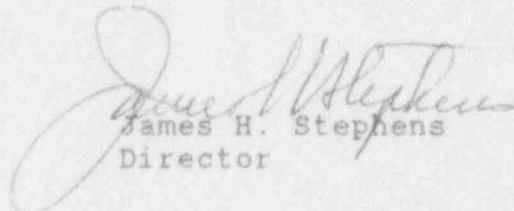
Nuclear Regulatory Commission
Region III
ATTN: John A. Grobe, Chief Nuclear
Materials Inspection, Section 2
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Mr. Grobe:

Enclosed is the reply to a notice of violation resulting from the inspection performed by Mr. M.F. Weber on November 15, through December 6, 1993.

Please address any questions regarding this reply to Mr. Steven D. Conatser, Radiation Safety Officer, at FTS 70C-378-3444.

Sincerely yours,


James H. Stephens
Director

Enclosure

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PDR ADOCK 03002050
C PDR

REPLY TO A NOTICE OF VIOLATION

1. Failure to measure non-fixed contamination levels of packages prior to offering the package for carrier shipment.

a. REASON:

(1) Packages containing syringes with pre-calibrated radiopharmaceutical doses are routinely shipped to our facility from commercial radiopharmacies. Our standing protocol was to conduct wipe tests of those packages to detect the presence of any removable contamination prior to the administration of the radiopharmaceutical. After the radiopharmaceutical was administered, the used syringes would be returned to the commercial radiopharmacy in their original shipping package.

(2) Shipping papers (see attached) provided by the commercial radiopharmacy for the purpose of our returning used syringes indicated that wipe tests of the package were required. Apparently, it was unclear to the nuclear medicine technologists that wipe tests of packages were to be conducted both prior to administration of doses from fresh syringes and prior to the return of used syringes. It was erroneously assumed that only a preliminary wipe test of packages containing fresh syringes was required.

b. CORRECTIVE ACTION: On November 18, 1993, the Radiation Safety Officer (RSO) provided training to the nuclear medicine technologists on how to use a Packard "Riastar" autogamma counter for counting wipe tests. The training provided information of how to assess the counting efficiency of the Riastar for determining the amount of disintegrations per minute per square centimeter. Effective this date, packages shipped to our facility are now being wipe-tested both upon arrival and prior to shipping packages containing used syringes back to the commercial radiopharmacy.

c. PREVENTION OF REPEAT VIOLATION: The RSO will ensure that nuclear medicine technologists continue to wipe-test packages both upon arrival and prior to returning the packages to the commercial radiopharmacy. Any newly assigned nuclear medicine technologists will be trained on this requirement either by the RSO or the nuclear medicine supervisory technologist, to ensure compliance with 10 CFR 71.5(a) and 49 CFR 173.443(a).

d. DATE OF COMPLIANCE: Compliance was met on November 18, 1993, when nuclear medicine technologists began the required wipe-testing (and documentation) of radiopharmaceutical packages.

FROM:

TO: Syncor International
21081 Melrose Avenue
Southfield, MI 48075

This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material limited quantity. N.O.S. 2910

RADIOACTIVE MATERIAL LIMITED QUANTITY

TABLE OF A_2 VALUES FOR TYPE A PACKAGING AND LIMITED QUANTITY SHIPMENTS

NUCLIDE	A_2 (Ci)	$10^{-4}A_2$ LIMITED QUANTITY (mCi)	TOTAL ACTIVITY RETURNED (mCi)
57-Co	90	9	_____
51-Cr	600	60	_____
67-Ca	100	10	_____
123-I	50	5	_____
125-I	70	7	_____
131-I	10	1	_____
111-In	25	2.5	_____
32-P	30	3	_____
75-Se	40	4	_____
99m-Tc	100	10	_____
201-Tl	200	20	_____
133-Xe	1000 $10^{-3}A_2$	1	Ci Uncompressed
169-Yb	80	8	_____

When shipping more than one type of radioactive material in the same package (cases), the limit on the quantity that may be shipped is determined by the smallest (most radiotoxic) A_2 value assigned to the most hazardous material.

1. THE AMOUNT OF RADIOACTIVITY IN THIS PACKAGE DOES NOT EXCEED THE SPECIFIED AMOUNT LISTED IN THE ABOVE TABLE.
2. NO POINT ON THE SURFACE OF THIS PACKAGE EXCEEDS 0.5 mR/hr THE READING AT 1 METER DOES NOT EXCEED BACKGROUND AS DETERMINED BY A LOW-LEVEL SURVEY METER.
3. REMOVABLE RADIOACTIVE SURFACE CONTAMINATION ON THE EXTERIOR OF THE PACKAGE DOES NOT EXCEED THE PRESCRIBED LIMITS, e.g. 6600 dpm/300 cm². [49 CFR subsection 173.443(a)]

Signed _____

Date _____

Case # _____