

Jaworski

YOUNGSTOWN ASSOCIATES IN RADIOLOGY, INC.

HITCHCOCK X-RAY • CRESTWOOD X-RAY • GENESIS

7250 WEST BLVD • P.O. BOX 3509
BOARDMAN, OH 44513
TELEPHONE (216) 758-8353
FAX (216) 758-3310

25 N. CANFIELD-NILES ROAD
YOUNGSTOWN, OH 44515
TELEPHONE (216) 793-5547
FAX (216) 793-7011

March 9, 1994

United States
Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60632-4351
Attn: Roy J. Caniano
Chief, Nuclear Safety Branch

Dear Mr. Caniano:

This letter is in response to the violations we have incurred during our recent routine safety inspection. We will address each violation and include 1) the reason for each violation, 2) corrective steps that have been taken and the results achieved, 3) corrective steps that will be taken to avoid further violations and 4) date when full compliance will be met.

We will review our entire nuclear program including PART 19, and PART 20. On January 5, 1994, the two nuclear technicians attended a training session conducted by Charles Wissuchek concerning the new PART 20.

The following pages include our violations.

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PDR ADOCK 03011343
C PDR

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MAR 30 1994

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Page 2

Violation 1 - Inadequate written quality management program.

Our previous quality management program had an oversight with 30 millicuries as the dose in which the program should be initiated, instead of 30 microcuries. At our office, we are not licensed to use 30 millicuries, so we felt that the QM Program did not apply to our situation.

We have now instituted a new QM Program, which has the corrected amount of 30 microcuries (1131). Since this regulation does apply to us, we will fully implement the QM procedures and policies as shown in our new QM Program. A written directive for each specific patient will be made and will be signed and dated by an authorized user prior to administration. All patients will be identified by more than one method.

We will be more careful to keep informed on all NRC policies by reading these policies more carefully to avoid these mistakes.

We will be in compliance on March 20, 1994.

Refer to attachment #1.

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Violation 2 Inadequate Survey Meter Calibration

Our Victoreen survey meter (MN 290 W 489-110B) with attached pancake probe (MN 489-110B) does not have the capabilities to do readings up to 1,000 millirem per hour and therefore, was not calibrated at that level.

A generator is no longer used at this facility which has significantly reduced the amount of radiation that we possess. Single unit doses are ordered daily and unused syringes are returned to Syncor, daily. We felt at these reduced levels, a pancake probe is adequate. If we do return to using a generator, a survey meter and/or probe can be obtained with the 1,000 millirem capabilities.

I spoke to Mr. Roy Caniano on March 9, 1994 about this particular issue. He mentioned that he will review this issue in reference to PART 35, 35.51. He is collecting additional information at this time.

Refer to attachment #2.

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Violation 3 - Geometry Dependency Test

- 1) According to PART 35, 35.50, a geometry test is necessary after a repair or an installation. We did not feel that moving the dose calibrator was either of these. Therefore, a geometry test was not done at that time.
- 2) On December 20, 1993, we did perform a geometry test with adequate results following Regulatory Guide 10.8, Page C-4.
- 3) We will read 10 CFR more carefully, as to not be in any violations.
- 4) We will be in compliance December 20, 1993.

Refer to attachment #3.

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Page 5

Violation 4 - Return Shipments of Radiopharmaceuticals.

Any spent radiopharmaceuticals are packaged by the technician approximately 4:00pm each day. These packages are not picked up until the following 7:45am. We had felt that any external radiation would be low because of the time element.

We will now take steps to measure all cases with any return shipment of radiopharmaceuticals to be sure they do not exceed .5mr/hr. If the readings exceed .5mr/hr, we will hold the case until such time that we will be in compliance.

A "limit quantity" poster is now taped to the area of pick-up and delivery so as to ensure we will be in compliance.

We will be in compliance December 20, 1993.

Refer to attachment #4.

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Page 6

Violation 5

During our recent move to West Boulevard, the required copies of PART 19, PART 20 were lost and not posted in our new nuclear room.

We have sent for new copies of these documents and they have been posted.

We are in compliance on January 1, 1994.

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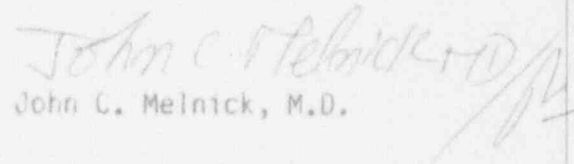
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If there are any further questions concerning these violations, please contact, Janet Sainato. Thank you.

Sincerely,


John C. Melnick, M.D.


Janet Sainato, R.T.

JS:rd

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QUALITY MANAGEMENT PROGRAM

Please fill out this form on all patients receiving 30 microCuries or more. Have the authorized user sign and date.

PATIENT NAME _____ DATE _____

DOCTOR _____ has ordered a

I131 DOSE OF _____

FOR PATIENT _____

TO BE GIVEN ON _____

Physician's Signature

Date

This dose was ordered by _____ R.T.

Dose _____

Patient's name _____

To be given on _____

R.T.

This dose was calibrated and administered.

Patient's name _____

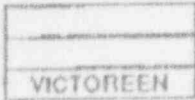
Date _____

Calibrated _____

Signature

Date

VICTOREEN, Inc.



6000 Cochran Road, Cleveland, Ohio 44139-3395
(216) 248-9300 FAX (216) 248-9301

**Fax Transmission
Please Deliver Immediately**

Date: 12-21-93 Ref. No. : _____

This fax contains 1 pages including
this cover sheet.

Fax No. : 216-258-3310

Company : Youngstown Rad

Attention : Janet Sainato

From : CONNIE BENHAM Ext. : 307

Title : CUSTOMER SERVICE ADMINISTRATOR

Message :

*The 489-110B cannot be calibrated
with the Model 290 on the X1000 range
It exceeds the parameters of the probe*

*Therefore the 489-110B probe is not
applicable on the X1000 range of the Model 290*

Dose Calibrator Geometry

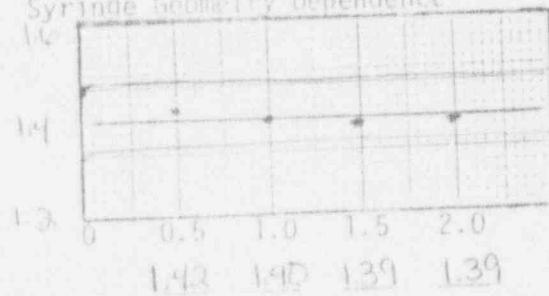
for

Youngstown Associates In Radiology

Manufacturer: Squibb CRC-6A
 Model Number: BDC.VI
 Serial Number: 62613
 Date: 12/20/93
 Performed by: Janet Sainato, R.T.
 RSO Dr.: Dr. J.C. Melnick

<u>1.42 mCi of Tc^{99m}</u>	first assay: <u>1.42 mCi</u>
Model: <u>BDC.VI</u>	second assay: <u>1.40 mCi</u>
SN: <u>62613</u>	third assay: <u>1.39 mCi</u>
Calibration date:	average: <u>1.40 mCi</u>
<u>12-20-93</u>	<u>1.40 mCi dev: $\pm .01$</u>
	Average

Syringe Geometry Dependence



TO: SYNCOR CORP.
 1601 Motor Inn Dr.
 Suite 270
 Girard, OH 44420

This package conforms to the conditions and limitations specified in 49 CFR 173 for excepted radioactive material limited quantity, N.O.S. UN-2910

RADIOACTIVE MATERIAL
 LIMITED QUANTITY
 N.O.S. UN-2910

Table of A Values for
 Type A Packaging and Limited Quantity Shipments

ISOTOPE	A (Ci)	LIMITED QUANTITY (mCi)
57-Co	90	9
58-Co	20	2
51-Cr	600.....	60
67-Ga	100.....	10
123-I	50	5
125-I	70	7
131-I	10	1
111-In.....	25	2.5
99-Mo	20	2
32-P	30	3
75-Se	40	4
99m-Tc.....	100.....	10
201-Tl.....	200.....	20
133-Xe (uncompress)	1000.....	100
169-Yb.....	80	8

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

1. THE AMOUNT OF THE 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 mRem/hr AS DETERMINED BY A LOW-LEVEL SURVEY METER.

SIGNED _____

DATE _____