

AUG 3 1983

MEMORANDUM FOR: Jane Axelrad, Acting Director of Enforcement, IE
FROM: Daniel J. Holody, Enforcement Specialist, Region I
SUBJECT: PROPOSED CIVIL PENALTY - GEORGE WASHINGTON UNIVERSITY
MEDICAL CENTER

On June 1-2, 1983, Region I conducted an inspection of activities authorized under NRC licenses issued to George Washington University. During the inspection, twelve examples of failure to comply with NRC requirements were identified.

Two of the examples fit Severity Level III violations as set forth in the appropriate Supplements of the NRC Enforcement Policy. These violations, however, which involve (1) an inadequate survey and a possible effluent release of Xenon-133 in excess of limits, and (2) unauthorized disposal of a small quantity of radioactive waste, in themselves are not significant and we believe they would be categorized at Severity Level IV.

Nonetheless, of the twelve violations which were identified during this inspection, two were similar to violations identified during previous inspections. Additionally, some of these violations had been identified by the licensee, but the licensee was less than prompt in initiating corrective action.

Accordingly, we consider these violations to collectively represent a breakdown in the management control of the radiation safety program. Therefore, we have categorized the violations collectively as a single severity level III violation and we recommend assessment of a civil penalty. Although the base civil penalty amount is \$2,000 for a severity level III violation, we propose a 25% increase of the penalty to \$2,500 because corrective actions were not taken promptly by the licensee when they identified some of the violations.

Original Signed By:

Daniel J. Holody
Enforcement Specialist

Enclosures:

1. Proposed "Notice of Violation and Proposed Imposition of Civil Penalty"
2. Applicable Pages of Inspection Report

cc w/encls:
Enforcement Coordinators, RII-V
J. Lieberman, ELD

8506110356 850109
PDR FOIA
ENGEL84-789 PDR

RI:ES
Holody/wb
7/26/83

7/27/83

RI:DETP
Martin
7/26/83

RI:ORA
Gutierrez
7/29

OFFICIAL RECORD COPY

RI:DRA
Allan
JMA's concern
uncompromised
8/1

RI:RA
Murley
8/3/83

22 AUG 1983

Docket Nos. 030-09049
030-19445
070-01795

License Nos. 08-00216-22 ✓
08-00216-23
SNM-1499

The George Washington University
Medical Center
ATTN: Fred Leonard, Ph.D.
Associate Dean for Research
2300 Eye Street, N.W.
Washington, D.C. 20037

Gentlemen:

Subject: Enforcement Conference Conducted July 19, 1983

This refers to the Enforcement Conference held at the NRC Regional Office in King of Prussia, Pennsylvania, on July 19, 1983, relating to activities authorized by your licenses. The meeting was attended by you and members of The George Washington University Medical Center staff and myself and other members of the NRC Staff. It is our view that this meeting was beneficial and improved your understanding of our concerns regarding operation of the Radiation Safety Committee and the violations identified in our inspection report dated June 30, 1983. The subjects discussed at this meeting are included in the enclosed Enforcement Conference Report. NRC Region I analysis of enforcement considerations for the items discussed at this meeting is continuing.

In accordance with 10 CFR 2.790(a), a copy of this letter and the enclosure will be placed in the NRC Public Document Room unless you notify this office, by telephone, within ten days of the date of this letter and submit written application to withhold information contained therein within thirty days of the date of this letter. Such application must be consistent with the requirements of 2.790(b)(1). The telephone notification of your intent to request withholding, or any request for an extension of the 10-day period which you believe necessary, should be made to the Supervisor, Files, Mail and Records, USNRC Region I, at (215) 337-5223.

No reply to this letter is required. Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By
E. H. Joyner

Thomas T. Martin, Director
Division of Engineering and Technical
Programs

Enclosure: Enforcement Conference Report

8309/20/40
2pp.

10

The George Washington University
Medical Center

2

22 AUG 1983

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

The George Washington University
Medical Center
ATTN: Dr. Mark Selikson
Radiation Safety Officer
Warwick Building
2300 K Street, N.W.
Washington, D.C. 20037

bcc:
Region I Docket Room (w/concurrences w/encl.)
Senior Operations Officer (w/o encl)
D. Holody
J. Gutierrez

for RI:DETP
Johansen/pja
8/16/83

RI:DETP
Glenn
8/19/83

JH
RI:DETP
Joyner
8/19/83

JH
for RI:DETP
Martin
8/19/83

U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Enforcement Conference Report No. 83-65

Docket Nos. 030-09049
030-19445
070-01795

License Nos.	08-00216-22	II	G1
	08-00216-23	III	E
	<u>SNM-1499</u>	<u>III</u>	<u>G</u>

Licensee: The George Washington University Medical Center

2300 K Street N.W.

Washington, D.C. 20037

Facility Name: The George Washington University Medical Center

Enforcement Conference At: Region I, King of Prussia, Pennsylvania

Enforcement Conference Conducted: July 19, 1983

~~8309/20145~~
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RP.

DETAILS

1. Persons Attending

For The George Washington University Medical Center:

Fred Leonard, Ph.D., Associate Dean for Research
Mario Werner, M.D., Chairman, Radiation Safety Committee
Mark Selikson, Ph.D., Radiation Safety Officer
Gary Good, Assistant Radiation Safety Officer

For the Nuclear Regulatory Commission:

Thomas E. Murley, Regional Administrator
James M. Allan, Deputy Regional Administrator
Thomas T. Martin, Director, Division of Engineering and Technical Programs
James H. Joyner, Chief, Nuclear Materials and Safeguards Branch
John E. Glenn, Chief, Nuclear Materials Section B
John D. Kinneman, Chief, Nuclear Materials Section A
Dan Holody, Enforcement Specialist
Teresa Hall Darden, Radiation Specialist

2. Conference Summary

- a. Introductions were made and the representatives of The George Washington University Medical Center were welcomed to Region I by Thomas E. Murley, Regional Administrator and James M. Allan, Deputy Regional Administrator.
- b. Thomas T. Martin, Director, Division of Engineering and Technical Programs explained the purpose and format of the Enforcement Conference. Mr. Martin expressed particular concern over the failure of The George Washington University Medical Center to take prompt or effective corrective action when violations of NRC regulations and License Conditions were identified by the Radiation Safety Office. In particular, the licensee's own evaluations indicated excessive concentrations of xenon-133 in effluent releases for a six-month period prior to effective corrective action being taken. Mr. Martin expressed concern that so many violations, including recurrent items, were identified by the regional inspectors. The licensee was asked to comment on the makeup and policies of the Radiation Safety Committee and to discuss the impact of having a large representation of the major isotope users on the committee.

Ms. Teresa Darden presented the findings of the June 1-2, 1983 inspection. Each apparent violation was discussed. The licensee had prepared, and presented to NRC representatives, a written summary of the causes of each violation and the corrective action taken or planned. The summary with attachments is enclosed as Appendix A to this report. During the discussion, NRC representatives noted that a report for two misadministrations which occurred during the last

quarter of 1982 had not been received as yet. (The required report was subsequently received with letter dated July 21, 1983.)

- c. Dr. Mario Werner, Chairman, of the George Washington University Medical Center Radiation Safety Committee responded to Mr. Martin's concerns. Dr. Werner acknowledged that the Committee had been slow to act and that an effective enforcement program to assure that individual users follow NRC rules and regulations had not been established. Dr. Werner pointed out that in an academic setting there was a tendency to discuss and require additional information rather than to act promptly and forcefully to assure that requirements were met. The Committee was now planning changes in policy in order to be able to discipline users who failed to meet requirements. The Radiation Safety Officer stated that he was unsure of his authority to stop activities which might be in violation of NRC requirements. Dr. Werner stated that the Committee would establish policy to make clear who had that authority and to assure that the authority could be exercised promptly.
- d. At the conclusion of the Enforcement Conference, Mr. Martin re-emphasized that the licensee must develop management controls over the Radiation Safety program to assure compliance with NRC Rules and Regulations and that future inspections could be expected on a more frequent basis. Mr. Martin stated that the NRC would transmit the enforcement action taken as the result of the June 1-2, 1983, inspection at a later date. Mr. Holody, Enforcement Specialist, discussed the NRC's enforcement policy as set forth in Part 2, Title 10, Code of Federal Regulations.

3. New Information Presented at and Subsequent to the Enforcement Conference

- a. Attachment #3 to the summary presented at the Enforcement Conference (Appendix A) included additional records of Dose Calibrator checks which were not available at the June 1-2, 1983 inspection. Records now indicate that dose calibrator checks were made during February 1982, November 1981, October 1981, March 1981, December 1982, and August 1982. The licensee is still unable to assure that any dose calibrator checks were made during the 3rd and 4th quarters of 1980, the 2nd quarter of 1981, and the 2nd quarter of 1982.
- b. Attachment #1 to the summary presented at the meeting indicated that the stack from which concentrations of Xenon-133 were released lies within a "secured" area. During a telephone conversation with Dr. Glenn, Chief, Nuclear Materials Section B, on July 20, 1983, Dr. Selikson stated that only individuals instructed in the precautions or procedures necessary to minimize exposure are given access to the secured area. Surveys by the licensee indicated that concentrations of xenon-133 at the stack were 3.5 times those permitted to be released to an unrestricted area but were only 7.5% of the limits permitted in a restricted area. Calculations of concentrations at the boundary of the secured area were presented in Attachment #1.

Additional information in a letter dated July 21, 1983, attached as Appendix B, indicates that concentrations at the boundary of the secured area were less than the limit of 3×10^{-7} microcuries per milliliter.

The finding that prior to June 1-2, 1983, the licensee had not evaluated concentrations of xenon-133 in effluent released at the boundary of the restricted area on the roof area surrounding the exhaust stack represents noncompliance with the requirements of 10 CFR 20.201(b).

- c. Additional written statements presented at the Enforcement Conference (Appendix A) indicated steps taken to identify and correct deficiencies in the Radiation Safety Program.

By letter dated July 21, 1983, the licensee documented the creation of an Executive Committee of the Radiation Safety Committee. This committee will administer enforcement and compliance on a day-to-day basis. The July 21, 1983 letter is attached as Attachment C.

APPENDIX A

SUMMARY OF CORRECTIVE ACTIONS PRESENTED BY THE
GEORGE WASHINGTON UNIVERISTY MEDICAL CENTER ON JULY 19, 1983

INFRACTION	CAUSE	COMMENT	ACTION
#1 Xenon Release (p10 item 15)	Failure of Nuclear Medicine to appreciate gravity of problem	Problem was discovered by Radiation Safety and brought to the attention of the Radia- tion Safety Committee(RSC). Release to unrestricted areas is actually less than MPC (See Att 1)	Enforcement program (ultimate authority revoke user privileges is being instituted
#2 Unauthorized Waste Disposal (p10 item 15)	See Att #2		
#3 Report on Misadministration (p10 item 16)	Improper procedures due to an oversight of one in a total of eight require- ments	None	In-house form for recording misadministra- tions has been changed to include notification requirements
#4 Leak Tests (p6 item 8)	A combination of: a) human error by safety office to include appropriate check sources in leak test program b) lost records due to lack of security	Error was noted and corrected, <u>all</u> sealed sources are now checked on a semi-annual basis. (See Att 3)	Records are being consolidated and secured.
#5 Dose Calibrator Linearity (p7 item 8)	Lost records due to lack of security	Linearity checks documented in most cases, but gaps exist in audits (See Att 3)	Records are being consolidated and secured
#6 Survey Meter Calibration (p7 item 11)	Human error by safety office occurred by inadequate staffing	An improved program for survey meter calibration instituted in spring of 1983. (See Att 4) Contamination survey meters have been put on semi- annual check source program.	No further action required
#7 Ring Badges (p8 item 13)	Human error of users (instructions contained in regulation guide 10.8)	Safety office does survey and written reprimands on record (See Att 5)	Same as #1
#8 Gloves (p8 item 13)	Human error on part of users	Safety office does survey and written reprimands on record (See Att 5)	Same as #1

INFRACTION	CAUSE	COMMENT	ACTION
#9 Eating, Drinking and Smoking (p11 item 18)	Human error of users (instructions in radioactive users guide)	Safety office does survey and written reprimands on record (See Att 5)	Same as #1
#10 Hot Waste in Cold Trash (p10 item 5)	Human error of users (separate hot and cold receptacles in place at all times)	No safety office records of inappropriate disposal of hot trash	Nuclear medicine has been reinstructed in writing to label and survey all trash. Safety office weekly survey has been expanded to include checks on all short lived waste. Violations will be handled as in #1.
#11 Mouth Pipetting (p11 item 18)	Human error of user (mechanical pipettes available)	Written reprimands on record, extensive counseling conducted (See Att 6)	Same as #1. Dr. Kumar's authorization has been placed on probation.
#12 Daily Surveys (p8 item 13)	Human error of user (survey equipment available)	Safety office surveys for this, written reprimands on record (See Att 5)	Same as #1

This plume calculation is based on "Workbook of Atmosphere Dispersion Estimates" PB - 191-482 by D. Turner, 1970. The roof of the hospital is secured and the stack from 4138 is not handled without prior notification of RSO. The concentrations were then evaluated at the 4 closest unrestricted areas. The results, shown below, demonstrate that no person in unrestricted areas would have been exposed to concentrations in excess of 1% M.P.C. averaged over the period of 1 year.

The following formation was used in making the calculation: Activity 3.9 Ci/year (1.7×10^{-7} Ci/sec), wind south at 6 mph (2.7 m/sec) Stability B (Table 3.1)

- 1) 22nd Street east 40 ft, down 80 ft

$$\sigma_y = 1$$

$$\sigma_x = 1$$

$$\text{Concentration} = 2.4 \times 10^{-24} \mu\text{Ci/cc}$$

- 2) Burns Building east 113 ft

$$\sigma_y = 1$$

$$\sigma_x = 1$$

$$\text{Concentration} = 1.9 \times 10^{-23} \mu\text{Ci/cc}$$

- 3) Air handler on roof north 114 ft, down 15 ft

$$\sigma_y = 9$$

$$\sigma_z = 4.5$$

$$\text{Concentration} = 4.9 \times 10^{-10} \mu\text{Ci/cc}$$

- 4) Air handler south west - 14ft, down 4ft (wind NW 25%)

$$\sigma_y = 1$$

$$\sigma_z = 1$$

$$\text{Concentration} = 2 \times 10^{-11} \mu\text{Ci/cc}$$

Radiation Safety Office
(202) 676-2630



THE
GEORGE
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UNIVERSITY
MEDICAL CENTER

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

June 20, 1983

John Glenn, Ph.D.
Chief, Nuclear Materials
Division of Engineering and Technical Programs
USNRC
Region I
631 Park Ave
King of Prussia, Pennsylvania 19406

Dear Sir:

This letter is a follow up to our telephone conversation on June 7, 1983 concerning the January 25, 1983 incident at The George Washington University and the possibility of a notice of violation severity level III. Since the incident concerned a loss of radioactive material we responded according to 10 CFR 20.402. I feel it is important to point out that the numbers listed in the memo to the file dated February 3, 1983 represent overestimates in order to clearly demonstrate that a "substantial hazard to persons in unrestricted areas" did not exist. A more realistic estimate of the I-125 unaccounted for would be closer to 20 uCi. I am therefore unclear as to the basis for a level III violation.

It appears inappropriate to interpret this loss as an unauthorized disposal in violation of part 20.301 for several reasons. First, severity level III violations "comprises violations that are of significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public." The NRC's policy on RIA waste and/or the storage for decay program permit regular disposal of these quantities of RAM. Second, the management control on Room 657 was consistent with the amount of activity used there.

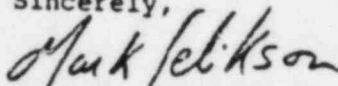
- A) The room is supervised during the day and secured during nighttime and weekend hours.
- B) Housekeeping does not enter Room 657. Cold trash is bundled and placed outside the locked doors at the end of each working day. A special housekeeping crew, which works closely with the Radiation Safety Office, is responsible for carrying out housekeeping chores.
- C) The in-house inventory did identify the missing bags and the appropriate response was initiated. The fact that only a single quantity of I-125 was lost was therefore not fortuitous. What happened was a failure of one management control mechanism appropriately backed up by another.

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43pp

It is my opinion that, given the general description of severity levels in the policy statements (P.S.- 33) and the specific examples in supplement IV (P.S.-37), this incident does not represent an overt act of improper disposal, but rather should be classified under supplement IV part E paragraph 2, "Any other matter including failure to follow procedures that has other than minor safety or environmental significance", or supplement IV paragraph F, "violations that have minor safety or environmental significance."

I therefore request that you reconsider the policy of classifying all loss of radioactive material as a violation of part 20.301.

Sincerely,



Mark H. Selikson Ph.D.
Radiation Safety Officer

cc: T Darden
J Johansen



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Radiation Safety Officer
(202) 676-2630

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

MEMO TO: Files

FROM: Martin Heyert *MH/gw*
Assistant Radiation Safety Officer

DATE: February 18, 1982

SUBJECT: Calibration Check - Capintec Dose Calibrator/Clinical
Nuclear Medicine

1. The new Capintec Dose Calibrator in Clinical Nuclear Medicine was checked for accuracy, linearity and geometrical variation during the period February 9 - 18, 1982.

2. Graphical analysis and a linear regression calculation (attached) demonstrated acceptable linearity characteristics up to the 105 mCi tested ($\pm 5\%$).

3. Satisfactory accuracy checks (less than $\pm 5\%$) were accomplished using calibrated sources traceable to NBS standards. Data follows:

- a. ^{137}Cs : 211 uCi in 20 ml calibrated 9-20-80; from NEN, Vial E series, serial no. 3560980A-10.

Averaged reading	206.7 uCi
Less background	(-) <u>.2</u>
Net activity	206.9
Calculated activity	204.5 uCi

- b. ^{57}Co : 5.2 mCi in 20 ml calibrated 11-10-80; from NEN, Vial E series, serial no. 2061100A-23.

Averaged reading	1.685 mCi
Less background	(-) <u>.002</u>
Net activity	1.687
Calculated activity	1.604 mCi

4. Tests for geometrical variation were performed using a 20 ml vial initially containing 4.86 mCi of ^{99m}Tc in 1 ml of isotonic saline. The liquid volume was increased in steps to 2, 4, 6, 8, 10, 15 and 20 ml and the activity measured. All readings held within $\pm 2\%$ of the original 4.86 mCi yielding an acceptable level of geometrical variation.

5. In addition, activity in a 10 ml syringe (2.36 mCi) was compared to the same activity and volume in a 20 ml vial (2.46 mCi). The calculated correction factor is less than $\pm 2\%$ and may be ignored.

cc: M. Cianci

Capintec
Dose Cal
99mTc
Clinical
Rm

9957 2116-211782

Clinical Nuclear Medicine
Rm 4138

31.00000	**
2.97000	**
19.00000	***
3.76000	***
17.70000	***
4.57000	***
16.00000	**
5.20000	***
15.70000	***
6.00000	***
14.00000	**
6.70000	**
13.00000	**



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(202) 676-2630

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

MEMO TO: Dr. Eckelman
Nuclear Medicine Research

FROM: Martin Heyert
Assistant Radiation Safety Officer *[Signature]*

DATE: December 8, 1981

SUBJECT: Dose Calibrator Check for ^{123}I Setting

Herewith a summary of the readings taken on November 4, 1981 of the ^{123}I sample vials furnished by your laboratory. The "NMR" dose calibrator is located in Ross Hall. The "Heart Station" and the "Hot Lab" units are located in Clinical Nuclear Medicine in the Hospital.

<u>Source</u>	<u>NMR</u>	<u>Heart Station</u>	<u>Hot Lab</u>
353-1	25.6 uCi	24.0 uCi	23.0 uCi
353-3	24.4	23.4	22.2
353-4	15.1	14.1	13.4
353-5	22.5	21.1	20.1
Unnumbered Test Tube	10.9	10.1	9.4
Time (11/4/81)	1:25 pm	1:45 pm	2:10 pm
Background	0.9 uCi	0.1 uCi	0
Cal. Setting	277	277	277



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MEDICAL CENTER

The University Hospital / 901 Twenty-Third Street, N.W. / Washington, D.C. 20037

Department of Radiology
Diagnostic Division
(202) 676-4600

MEMO TO: Dr. Eckelman
Nuclear Medicine Research

FROM: Martin Heyert *MH/ell*
Assistant Radiation Safety Officer

SUBJECT: Calibration of Dose Calibrator

DATE: October 30, 1981

1. The Nuclear Medicine Research Dose Calibrator (Capintec model #CRC-2N) was tested for accuracy, linearity and geometrical variations during the period October 28 to 30, 1981. Test protocols were based on appendix D "Methods for Calibration of Dose Calibrator" from the University Broad License.

2. Graphical analysis and a regression calculation (attached) demonstrate Capintec is accurate to within 7% at a reading of 90 mCi.

3. Accuracy checks were accomplished using calibrated sources traceable to NBS standards. Data follows:

a. ^{57}Co : 5.2 mCi in 20 ml calibrated 11-10-80; from NEN, Vial E series, serial no. 2061180A-23.

average reading	2.20 mCi
less background	0.00
net activity	2.20 mCi
calculated activity	2.098 mCi
correction factor	.954 mCi

b. ^{137}Cs : 211 uCi in 20 ml calibrated 9-29-80; from NEN, Vial E series, serial no. 350980A-10.

average reading	222 uCi
less background	0.00
net activity	226 uCi
calculated activity	205.822 uCi
correction factor	.912 uCi

4. Geometrical Variation: 0.1 ml of ^{99m}Tc was drawn up in a 1 ml tuberculin syringe and placed in dose calibrator - Reading 5.6 mCi. This volume was injected into a 30 ml vial and aliquots of normal saline added. The results are tabulated below:

<u>Volume of NS added</u>	<u>Total Volume</u>	<u>Dose Calibrator Reading</u>
0.0 ml	0.1 ml	5.28 mCi
0.9	1	5.20
1	2	5.18
2	4	5.13
2	6	5.10
2	8	5.09
2	10	5.07
10	20	4.97
5	25	4.94

All readings remained within $\pm 20\%$ of the original 5.28 mCi yielding an acceptable geometrical variation.

cc: B. Francis
G. Good
File

Linearity Check ^{99m}Tc

				<u>200 mCi Range</u>	<u>20 mCi Range</u>
0	:	10-28-81	10:00 a.m.	84.6 mCi	
1		10-28-81	11:00 a.m.	75.2 mCi	
2		10-28-81	12:00 noon	67.1 mCi	
3		10-28-81	1:00 p.m.	59.3 mCi	
5		10-28-81	3:00 p.m.	47.3 mCi	
6		10-28-81	4:00 p.m.	42.2 mCi	
6.75		10-28-81	4:45 p.m.	38.6 mCi	
23.1		10-29-81	9:05 a.m.	5.7 mCi	5.87 mCi
26.5		10-29-81	12:30 a.m.	3.7 mCi	3.95 mCi
29.0		10-29-81	3:00 p.m.	2.7 mCi	2.90 mCi
30.5	:	10-29-81	4:30 p.m.	2.3 mCi	2.46 mCi

10/30/81

Counter Data Calibrator
 Model CNE-2N
 Nuclear Medicine Research

Gi
 Tc

3 CYCLES X 10 DIVISIONS PER INCH

exponential
 regression

10.00	...
9.43	...
8.90	...
8.40	...
7.92	...
7.46	...
7.02	...
6.60	...
6.19	...
5.80	...
5.42	...
5.05	...
4.70	...
4.36	...
4.03	...
3.71	...
3.40	...
3.10	...
2.81	...
2.53	...
2.26	...
2.00	...
1.75	...
1.51	...
1.28	...
1.06	...
0.85	...
0.65	...
0.46	...
0.28	...
0.11	...
0.00	...

$r^2 = 1.0$
 $a = 90.25$
 $b = -0.12$

10/30/81

THE GEORGE WASHINGTON UNIVERSITY
INTERDEPARTMENTAL MEMORANDUM

TO: Michael Cianci, Technological Administrator
FROM: Martin Heyert, Assistant Radiation Safety Officer
DATE: March 20, 1981
SUBJ: Capintec Dose Calibrator
Linearity Check

Herewith a copy of the linearity plot done for the Capintec Calibrator in the Nuclear Medicine Laboratory during the period 3-9-81 through 3-12-81.

The linearity check was accomplished using a single 20 ml elution from the Union Carbide generator. Results show an acceptable linearity both on the graphic analysis as well as the linear regression calculation (also attached).

10.00 1.00
100.00 1.00

10.00 1.00
10.70 1.00

Linear
regression
calculation

11.00 1.00
12.00 1.00

14.00 1.00
11.00 1.00

16.00 1.00
15.00 1.00

Exponential
 $\frac{1}{1-t}$

17.00 1.00
17.00 1.00

41.00 1.00
17.00 1.00

Factor
 $\frac{1}{1-t}$

17.00 1.00
17.00 1.00

17.00 1.00
17.00 1.00

17.00 1.00
17.00 1.00

17.00 1.00
17.00 1.00

Hot Lab calibratorLinearity + accuracy

(23)

Date	H. L. Time	Elapsed Time	act.	Prod	% dev.
12.10.82	9:40 A.M.	0	276 mci	276	0
	2:18	4.63	161.8 mci	162.0	.13%
	6:35	8.92	98.4	98.8	.41%
12.11.82	12:39 A.M.	14.98	48.9	49.2	.61%
	10:29	24.82	15.73	15.84	.70%
	1:38	27.97	10.93	11.02	.82%

source checks

Isotope	Date	Decayed	measured	dev %
¹³⁷ Cs	12.10	200.6 μ ci	203	1.2% high
	12.11	200.6	203	1.2% high
⁵⁷ Co	12.10	c. 74 μ ci	0.776	4.7% high
	12.11	.739	.778	5.0% high
⁶⁰ Co	12.10	36.4 μ ci	36.0	1.2% low
¹³³ Ba		239.8 μ ci	251	4.6% high

H.S. Calibrator Linearity
 scales

So derivations

readings are
actual/bkg

by subtracted. ...

1.6390-

4.25.90-

2.390 -

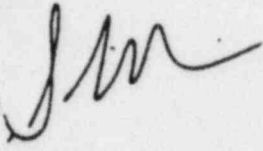


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Worwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

Radiation Safety Office
(202) 676-2630

MEMO FOR: File

FROM: Scott Matthews 

DATE: August 31, 1982

SUBJECT: Calibration of Nuclear Medicine Dose Calibrators

During the past month, the Radiation Safety Office has checked the dose calibrators in Clinical Nuclear Medicine (located in the 4th floor Hot Lab and the second floor Heart Station) for linearity, accuracy and geometric variation, as outlined in NRC Regulatory Guide 10.8, Appendix D, Section 2.

In both cases, the responses to ^{99m}Tc were linear for the maximum activity assayed (165 mCi for the Hot lab, 131 mCi for the Heart Station).

Samples of ^{57}Co , ^{60}Co , ^{137}Cs and ^{133}Ba , located in the Hot Lab and traceable to NBS standards, were assayed and all responses were within $\pm 5\%$ of the valued predicted by mathematical decay.

Finally, responses to samples of ^{99m}Tc assayed in varying amounts of saline (1-16 ml) showed a deviation due to geometrical variation of less than 2% from a median response.

cc: M. Cianci
D. Hixson



THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Washington, D.C. 20037 / (202) 676-6000

The University Hospital
901 Twenty-third Street, N.W.

DAILY MEMOS

12/9/82

Info to Eckelman

Meet with Rogers

Go over agenda in afternoon

Call Eileen on grade positions

VARMA

See Harisiadis

Sealed Swipe - Scott/done 12/17

Call Physics

12/9/82

In/o Billman
Meet with Rogers.

Go over Agenda in P/te noon

Call Billman on grade Positions

SEI/Vanna -
- STU Haruacatis
Lennard

Sealed swipe - Scott/Cone 12/17
{12/10/82
2.11.82

Speak to Leonard on letter to R.C. & Safety Office
Foster Memo to Rogers
334-2233

12/14
M.

MDH 20-25 system
linear tomography
CATSCAN

Larry Kemple (299-2700)
Physic Tech Health Physics
65-25-3000
40 Pts MS Health 35,40K
diagnosed at Pittsburgh
Tissue exposed.

20-25

Monty 20,420
23,490

3
\$2,698

Joseph Z Kelly
Bischoff & Helt

H/

Brinkas



2 sheets

USE OF Tc-99m FOR CALIBRATING SURVEY METERS

Scott Matthews
Mark H. Selikson
The George Washington University

Norman McElroy
USNRC

INTRODUCTION

Medical and academic institutions licensed to use sufficiently large quantities of radioactive materials must have radiation survey meters available for use. To show continued acceptable performance, a survey meter should be calibrated periodically. The protocol outlined in regulatory guide 10.8 specifies calibration every six months at two points on each scale, including .1mR/hr.. Commercial calibration of survey meters can be costly both in terms the charge for the service and the down time while the meter is off site.

For small institutions (20 to 30 survey meters) performing the calibrations in-house also presents problems:

- 1) The expense and inconvenience of purchasing and storing large sealed sources.
- 2) The space and time required to establish exposure stations and perform necessary measurements.
- 3) The difficulty in accurately establishing a .1 mR/hr. exposure station due to the amount of scatter at large distances from the calibration source.
- 4) The inconsistency of calibrating survey meters ~~with~~ at a high energy (662 keV) and then using the meter to evaluate exposure at a lower energy (140 keV).

The purpose of this paper is to address the fourth point by developing an in-house method for calibrating survey meters for use in nuclear medicine where the predominant nuclide is Tc-99m without adding to the expense or time already invested in our present Cs-137 in-house system.

Tc-99m is readily available in any hospital with a nuclear medicine department. In addition, most departments are required to maintain a dose calibrator for evaluating the quantity of activity. This calibrator is calibrated against an NBS traceable source. It was therefore decided to make use of these on-hand resources and to generate a known exposure field of 140 keV photons using the gamma exposure constant for Tc-99m. The method as it was

initially conceived consisted of the following:

- 1) Elute the Tc-99m generator.
- 2) Assay the amount of activity using the dose calibrator.
- 3) Using the gamma exposure constant for Tc-99m, to predict the exposure at a distance of .5 meters.
- 4) Measure the response of the survey meter at this position and calculate a correction factor for that scale.
- 5) Repeat the procedure with different activities sufficient to generate two calibration points on each scale.

EXPERIMENTAL PROTOCOL

A quantity of Tc-99m (approx. 150 mCi per 50 mR/hr) is drawn into a 3 cc BD syringe. A CRC 10 Capintec is then used to assay the exact amount of activity in the syringe. In addition to the standard checks for geometry, accuracy, reproducibility and linearity, the variation in the daily reproducibility check is factored into the final value for the activity.

The value for the exposure rate constant is evaluated using the equation

$$\Gamma = .156nE(10^5 u_a)$$

where Γ is in mR/hr/mCi @ 1 meter. Five lines are included in the computation for Γ . The contribution from the lower energy lines are scaled down by a factor of .75 to account for self-absorption in the source and absorption in the air between the source and the survey meter (Table I). The calculation for the self-absorption assumes a cylindrically symmetrical source ($d = .95$ cm) distributed in the water.

The source is suspended from the ceiling on a rigid polystyrene rod (fig. 1). The source-detector distance is .5 meters and except for the polystyrene rod and the cart supporting the survey meter all scattering surfaces are greater than one meter from either the source or the detector. With this geometry the portion of the signal due to scatter is less than 1%.

To validate the method, an MDH survey meter with a uniform energy response (+5%) from 20 to 1000 keV is used. The meter has been previously calibrated at a low energy (120 kvP) with a secondary x-ray source. A Cs-137 source calibrated at NBS is used to provide a check of the instruments accuracy at 662 keV. These two points,

which bracket the energy of interest (140 keV), combined with the uniform energy response of the meter serve as the calibration for the MDH at 140 keV. The predicted exposure, based on activity and the Γ , is then compared to the reading from the MDH. Several other survey meters are then evaluated and the calibration factors for Tc-99m versus Cs-137 are compared.

RESULTS AND DISCUSSION

The manufacturers' correction factors for the MDH vs. photon energy is plotted over the observed correction factors in fig. 2. The results indicate that the predicted exposure at 140 keV agrees with the measured exposure to within +5%. A precise measure of the error is difficult in the absence of a calibration standard at 140 keV. The Tc-99m method is then used to calibrate a number of other survey meters. The calibration factors at 140 keV are compared with their calibration factors at 662 keV (Table II). As expected there is a substantial difference in calibration factors for some survey meters for the two different energies. In the case of Victoreen 440 and 471 we observe differences consistent with the manufacturers' specifications on energy dependence. Energy dependence for the other instruments tested was not available.

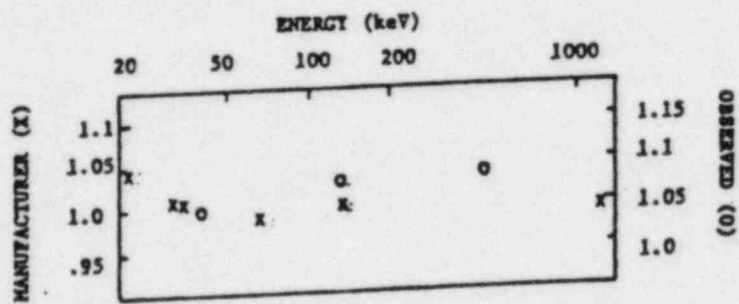
Eventually, the practice of eluting different amounts of Tc-99m in order to calibrate the different scales was changed. By starting with a high activity sample and using the physical decay of Tc-99m (6.02 hrs) all the different exposure rates are eventually generated. In the methods final form there is a single point calibration coupled with a linearity check on all scales. In carrying out the linearity test the position of the Tc-99m is at a fixed but arbitrary distance from the survey meter. Therefore, many survey meters can be processed simultaneously in a relatively small area. The single calibration and the linearity are then used to generate a calibration factor for all scales.

CONCLUSION

The method satisfied our expectations and produced some additional benefits. An in-house calibration of survey meters for 140 keV photons was developed and tested. The method is inexpensive and fairly convenient for institutions which maintain a dose calibrator and a Tc-99m generator. There is a considerable period of time required (40-50 hrs) to follow the decay curve through all scales. However, measurements are needed only once every three to six hours and the ability to process several meters simultaneously compensates for this inconvenience.

As predicted many survey meters used at this institution show a significant change between calibration factors at 662 keV vs. 140 keV. In addition, the single point-linearity approach can also be applied to the 662 keV calibration by using Cs-137 to calibrate a single point and then using Tc-99m to check linearity. Therefore, the calibration for both 140 keV and 662 keV are generated in less time than it used to take to perform single Cs-137 calibration. Also, the scatter problem at the low exposure rates is eliminated .

CORRECTION FACTOR for MDH



CALCULATING GAMMA

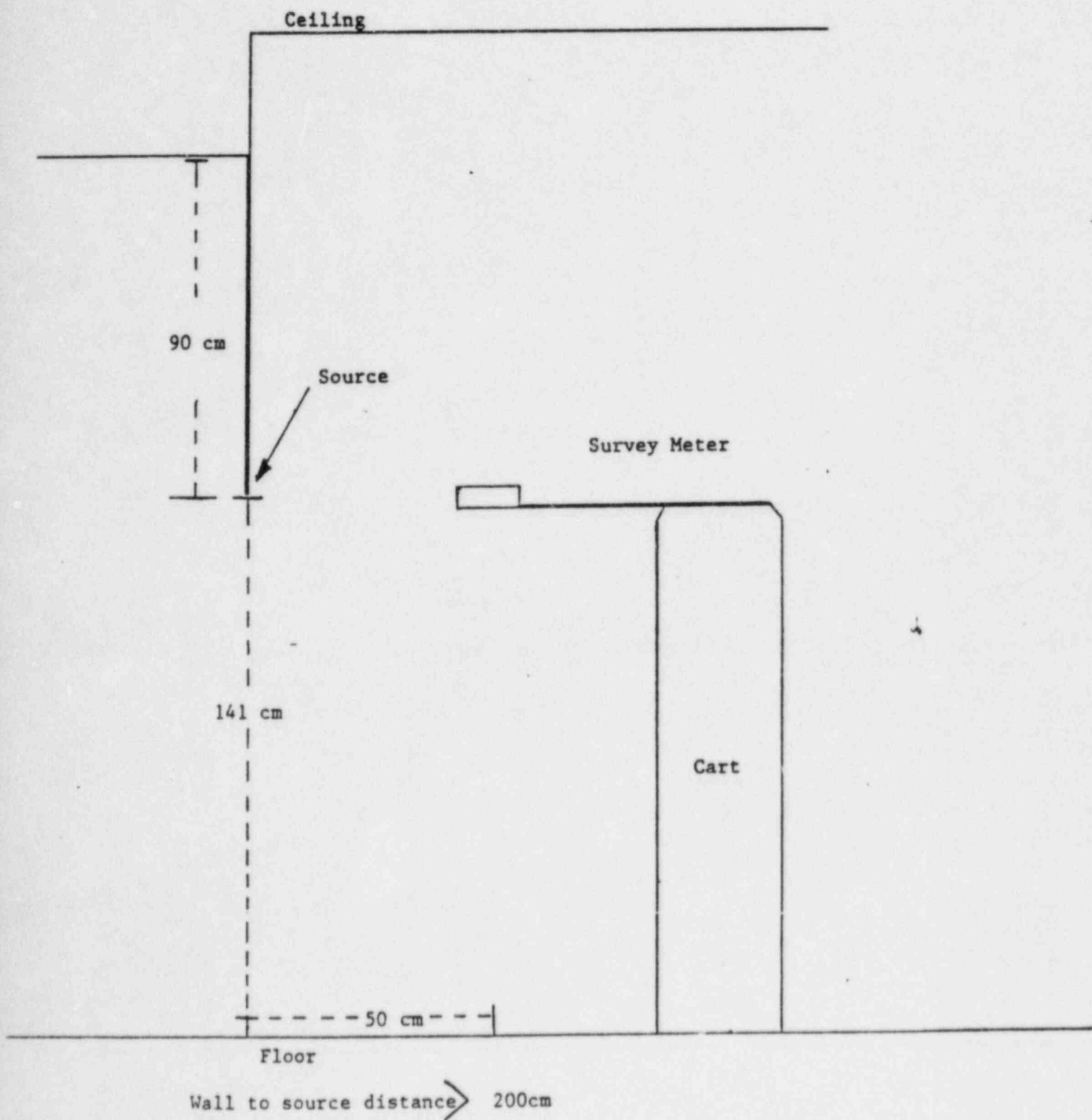
LINE	ENERGY (MeV)	EXPOSURE $\frac{\text{mR-cm}^2}{\text{HR-mCi}}$	WEIGHT
1	.1405	616	1
2	.1426	0.2	1
3	.0183	111	.75
4	.0182	55	.75
5	.0206	22	.75

WEIGHT=(SELF ABSORPTION)(AIR ABSORPTION)(SENSITIVITY)

$$\Gamma = 750 \frac{\text{mR - cm}^2}{\text{HR - mCi}}$$

CORRECTION FACTOR $\left[\frac{\text{pred.}}{\text{obs.}} \right]$

METER	CORRECTION FACTOR $\left[\frac{\text{pred.}}{\text{obs.}} \right]$	
	662 keV	140 keV
MDH	1.09	1.08
VICTOREEN 440	.78	.84
VICTOREEN 471	.89	.96
KEITHLEY	.96	.98
TEXAS NUCLEAR	1.7	2.1
NUCLEAR CHICAGO	1.04	.94



file

MEMORANDUM

TO: Mike Cianci
FROM: Mark Selikson *MS*
SUBJECT: Radiation Safety
DATE: May 25, 1983

*"IN"
Add OXINE
Studies*

Here is the list provided to me by your office. Be sure it includes all diagnostic and therapeutic procedures (no matter how infrequently) which are conducted in Nuclear Medicine.

Please find attached SOP's for I-131 Therapies, P-32 Therapies, Decontamination procedure (skin and surface) Radiation Safety practices, Receiving, xenon venting and Dose calibrator. *ok*

Also find attached a list of sealed sources assigned to your division. Please have them available so they may be swiped. Your assistance is appreciated. *done*

Finally, there continues to be a problem with ring badges in the injection areas. Please continue to bring this to the attention of your technologists. *?*

TO: Incident File
FROM: Eileen Strouse *el*
SUBJ: ^{131}I Spill in Hospital Room 4136, Nuclear Medicine
DATE: March 31, 1983

Personnel involved: , Staff Technologist

Time: Approximately 11:15 a.m., March 31, 1983

Place: Nuclear Medicine, Hospital Room 4136

Isotope, form: ^{131}I Isotope (Sodium Iodide)

Description: brought an ^{131}I source contained in a lead pig into Room 4136 in order to peak in the Med-X gamma camera. Because he had difficulty removing the ^{131}I source from the lead pig, he turned the pig upside down and tried to shake it out. Approximately 25-30 μCi ^{131}I spilled out of the vial, onto hands and the table top. told this to Mr. Donald Hixson, who was in the room at the time of the incident. Mr. Hixson got some chux and Radioac Wash to clear the contaminated areas. He also called the Radiation Safety office to notify us of the incident.

Action Taken: After the area had been cleaned with a decontaminant, Radiation Safety personnel took swipes of the affected area. The swipes showed that the floor immediately beneath the camera head and the table top were still contaminated. hands were surveyed with a single channel analyzer with sodium iodide scintillation probe and were found to be contaminated. thyroid gland was counted with the thyroid probe. There was no evidence of thyroid uptake.

Recommendation: All contaminated areas were to be thoroughly cleaned and decontaminated. would again wash his hands with Radioac Wash. He was reminded to wear gloves whenever handling radioactive materials.

Blocking agent was taken.
and 24 Thyroid assay showed no uptake. *MS.*

Channel F 100-600
A: 2 MeV, 100-750

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE June 22, 1983

HOT LAB TECH M. Daniel

HEART STATION TECH J. Rae

SWIPE SURVEY

(Survey results are listed in gross cpm
at 25-150 KeV/ 160-600 KeV)

1. Background 68/63
2. Wet Lab Sink 93/77
3. Wet Lab Work Area 113/61
4. Wet Lab Counting Room 105/58
5. Heart Station Floor 80/80
6. Heart Station Table 46/81
7. Heart Station Treadmill 59/75
8. Heart Station Prep Area 70/57
9. Hot Lab Floor 67/68
10. Hot Lab Dose Seat 66/49
11. Hot Lab Refrigerator 84/79
12. Hot Lab Hot Trash Container 122/95
13. Hot Lab Tables 64/69
- *14. Hot Lab Dose Calibrator 5949/1356
15. Hot Lab Hood 164/89
16. Hot Lab Phone 122/123
17. _____
18. _____
19. _____
20. _____

*Contaminations are defined as > 3 times
background.

COMMENTS _____

RADIATION SAFETY TECHNICIAN C. Stouzel

MONTHLY THYROID UPTAKES

Completed

DOSE CALIBRATOR ACCURACY CHECKS

O.K.

RADIOACTIVE PACKAGE RECEIPT

O.K.

^{99m}Tc WASTE STORAGE

O.K.

DAILY HOT LAB SURVEY

2nd Floor - not done since 6-16-83

Hot Lab O.K.

HOOD VENTILLATION

Maximum air flow is 325 linear feet
per minute.

¹³³Xenon Venting

DATE none vented

— mCi — MPC-hrs

— % of Regulatory Limits

Channel B: 1 MeV range 160-600
Channel A: 2 MeV range 100-750

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE June 6, 1983

HOT LAB TECH W. Kong

HEART STATION TECH W. Edwards

SWIPE SURVEY

(Survey results are listed in gross cpm at 25-150 KeV/ 160-600 KeV)

1. Background 49/63
2. Wet Lab Sink 65/71
3. Wet Lab Work Area 75/68
4. Wet Lab Counting Room 77/59
5. Heart Station Floor 85/58
6. Heart Station Table 60/65
7. Heart Station Treadmill 69/74
8. Heart Station Prep Area 72/81
9. Hot Lab Floor 51/79
10. Hot Lab Dose Seat 74/85
11. Hot Lab Refrigerator 60/73
12. Hot Lab Hot Trash Container 53/64
13. Hot Lab Tables 73/63
- * 14. Hot Lab Dose Calibrator 316/119
15. Hot Lab Hood 69/68
16. Hot Lab Phone 67/64
17. _____
18. _____
19. _____
20. _____

* Contaminations are defined as > 3 times background.

COMMENTS

1 Contamination

2 Violations - 2nd Floor Hot Dose Prep Area not surveyed 6/2/83 and 6/2/83

RADIATION SAFETY TECHNICIAN C. Strouse

MONTHLY THYROID UPTAKES

None

DOSE CALIBRATOR ACCURACY CHECKS

O.k.

RADIOACTIVE PACKAGE RECEIPT

O.k.

^{99m}Tc WASTE STORAGE

O.k.

DAILY HOT LAB SURVEY

2ND floor - not done since 6-1-83
HOT LAB O.K.

HOOD VENTILLATION

Maximum air flow is 350 linear feet per minute.

¹³³Xenon Venting

DATE 6-3-83

25 mCi 39 MPC-hrs

23 % of Regulatory Limits

Hand 4: 2 Mar range 100 50

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE April 22, 1983

HOT LAB TECH W. Edwards

HEART STATION TECH S. Strecker

SWIPE SURVEY

(Survey results are listed in gross cpm at 25-150 KeV/ 160-600 KeV)

- | | <u>A/B</u> |
|--|--------------------|
| 1. Background | <u>53/67</u> |
| 2. Wet Lab Sink | <u>77/82</u> |
| * 3. Wet Lab Work Area | <u>193/72</u> |
| * 4. Wet Lab Counting Room | <u>298/77</u> |
| * 5. Heart Station Floor | <u>250/87</u> |
| 6. Heart Station Table | <u>129/94</u> |
| 7. Heart Station Treadmill | <u>—</u> |
| 8. Heart Station Prep Area | <u>70/68</u> |
| 9. Hot Lab Floor | <u>78/74</u> |
| 10. Hot Lab Dose Seat | <u>57/80</u> |
| 11. Hot Lab Refrigerator | <u>60/76</u> |
| * 12. Hot Lab Hot Trash Container | <u>5241/908</u> |
| 13. Hot Lab Tables | <u>114/81</u> |
| * 14. Hot Lab Dose Calibrator | <u>199/120</u> |
| 15. Hot Lab Hood | <u>117/88</u> |
| 16. Hot Lab Phone | <u>95/86</u> |
| * 17. Hot Lab Floor - Trash Container: | <u>1145/243</u> |
| * 18. Heart Station - Trash Container: | <u>675/138</u> |
| 19. Rest Room (women): | <u>85/59</u> |
| * 20. Rest Room (men): | <u>44,459/7263</u> |

* Contaminations are defined as > 3 times background.

COMMENTS Evidence of smoking in Wet Lab.

8 contaminations

4 Violations - 2nd Floor Dose Calibrator

3 Violations - 2nd Floor Hot Lab Survey

RADIATION SAFETY TECHNICIAN C. Thorne

MONTHLY THYROID UPTAKES

O.K.

DOSE CALIBRATOR ACCURACY CHECKS

OK; 2nd floor checked once

RADIOACTIVE PACKAGE RECEIPT

O.K.

^{99m}Tc WASTE STORAGE

O.K.

DAILY HOT LAB SURVEY

O.K.; 2nd floor checked twice

HOOD VENTILLATION

Maximum air flow is 325 linear feet per minute.

¹³³Xenon Venting

DATE 4-19-83

55 mCi 86 MPC-hrs

51 % of Regulatory Limits

Channel A .2 Mw range 100-750

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE April 14, 1983

HOT LAB TECH B. Edwards

HEART STATION TECH L. Meire

SWIPE SURVEY

(Survey results are listed in gross cpm at 25-150 KeV/ 160-600 KeV)

1. Background 56/26
2. Wet Lab Sink 84/48
- * 3. Wet Lab Work Area 320/209
4. Wet Lab Counting Room 110/45
5. Heart Station Floor 77/31
6. Heart Station Table 74/33
7. Heart Station Treadmill 56/29
8. Heart Station Prep Area 74/36
9. Hot Lab Floor 124/36
10. Hot Lab Dose Seat 60/32
11. Hot Lab Refrigerator 82/27
12. Hot Lab Hot Trash Container 121/44
13. Hot Lab Tables 58/22
- * 14. Hot Lab Dose Calibrator 367/48
- * 15. Hot Lab Hood 172/43
- * 16. Hot Lab Phone 322/64
17. Hot Lab Floor-Trash Container: 74/30
18. Heart Station-Trash Container: 61/21
19. Rest Room (Women): 68/35
20. Rest Room (Men): 49/25

* Contaminations are defined as > 3 times background.

COMMENTS

4 contaminations

2 Violations - 2nd Floor Dose Calibrator Daily Accuracy Check

2 Violations - 2nd Floor Hot Lab Daily Survey

RADIATION SAFETY TECHNICIAN C. Stouze

MONTHLY THYROID UPTAKES

O.K.

DOSE CALIBRATOR ACCURACY CHECKS

O.K. Hot Lab;

2nd H: done twice a week, not daily
RADIOACTIVE PACKAGE RECEIPT

O.K.

^{99m}Tc WASTE STORAGE

O.K.

DAILY HOT LAB SURVEY

O.K.

2nd H: done 4-7, 4-8, & 4-12, only
HOOD VENTILLATION

Maximum air flow is 300 linear feet per minute.

¹³³Xenon Venting

DATE 4-13-83

61 mCi 95 MPC-hrs

57 % of Regulatory Limits

Channel A: 0.2 MeV range 100 - 750
Chemical A: 0.2 MeV range 100 - 750

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE April 7, 1983

HOT LAB TECH B. Ault

HEART STATION TECH S. Streker

SWIPE SURVEY

(Survey results are listed in gross cpm at 25-150 KeV/ 160-600 KeV)

1. Background 60/60
2. Wet Lab Sink 158/79
3. Wet Lab Work Area 157/77
4. Wet Lab Counting Room 115/66
5. Heart Station Floor 81/87
6. Heart Station Table 79/78
7. Heart Station Treadmill 46/67
8. Heart Station Prep Area 68/53
9. Hot Lab Floor 123/73
10. Hot Lab Dose Seat 48/67
- * 11. Hot Lab Refrigerator 1326/264
- * 12. Hot Lab Hot Trash Container 1291/253
- * 13. Hot Lab Tables 370/109
- * 14. Hot Lab Dose Calibrator 1149/224
- * 15. Hot Lab Hood 388/121
- * 16. Hot Lab Phone 203/203
17. Hot Lab Floor - Trash Container: 132/112
18. Heart Station - Trash Container: 62/53
- * 19. Rest Room (Women): 200/118
- * 20. Rest Room (Men): 7306/1159

RADIATION SAFETY TECHNICIAN C. Stouze

MONTHLY THYROID UPTAKES

April done except S. Streker

DOSE CALIBRATOR ACCURACY CHECKS

2nd fl: done once this week; Hot Lab O.K.

RADIOACTIVE PACKAGE RECEIPT

✓ O.K.

^{99m}Tc WASTE STORAGE

✓ O.K.

DAILY HOT LAB SURVEY

2nd fl: not done since 2-28-83; batteries put in
Hot Lab O.K.

HOOD VENTILLATION

Maximum air flow is linear feet per minute. No air flow in hood

¹³³Xenon Venting

DATE 4-1-83 & 4-7-83
62 mCi 97 MPC-hrs
55 % of Regulatory Limits

* Contaminations are defined as > 3 times background.

COMMENTS After hood fan was fixed, the air flow was measured at
325 linear feet per minute.

8 contaminations
2 violations (2nd floor Dose Calibrator checks)
3 violations (2nd floor Hot Lab Surveys).

GW RADIATION SAFETY OFFICE INSPECTION - CLINICAL NUCLEAR MEDICINE

DATE 24 March 1983

HOT LAB TECH Steve Attker

HEART STATION TECH Janice Lee

SWIPE SURVEY

(Survey results are listed in gross cpm at 25-150 KeV/ 160-600 KeV)

1. Background 69
2. Wet Lab Sink 41
3. Wet Lab Work Area 36
4. Wet Lab Counting Room 40
5. Heart Station Floor 57
6. Heart Station Table 43
7. Heart Station Treadmill 39
8. Heart Station Prep Area 180
- *9. Hot Lab Floor 235
10. Hot Lab Dose Seat 50
11. Hot Lab Refrigerator 49
- *12. Hot Lab Hot Trash Container 246
13. Hot Lab Tables 51
14. Hot Lab Dose Calibrator 316
15. Hot Lab Hood 89
16. Hot Lab Phone 64
17. GENERATOR Top - 71
- *18. WOMEN Bathroom - 680
- *19. MEN Bathroom - 4567
20. _____

Contaminations are defined as > 3 times background.

* COMMENTS CONTAMINATED AREAS. THESE COUNTS WERE DONE IN
ROSS HALL - SEARLE DEEP WELL GAMMA COUNTER

RADIATION SAFETY TECHNICIAN Mary L. Galt

MONTHLY THYROID UPTAKES

okay

DOSE CALIBRATOR ACCURACY CHECKS

okay

RADIOACTIVE PACKAGE RECEIPT

okay

^{99m}Tc WASTE STORAGE

okay

DAILY HOT LAB SURVEY

NOT UP-TO-DATE

HOOD VENTILLATION

Maximum air flow is 375 linear feet per minute.

¹³³Xenon Venting

DATE 3-23-83

60 mCi 94 MPC-hrs
56 % of Regulatory Limits

Research

Date: 2/1/83

User

RSO

Yes

No

Yes

No

- (10) Use of authorized RAM only
- (10) Use of RAM in an authorized area only
- (10) No removal of RAM from GWU
- (10) All RAM received through the R.S.O. T
- (10) No RAM given to unauthorized user

AFRRI, WISCONSIN
TC-99, In-111

✓ RSO approval

1. 2) Door labels

- (5) User manual available
- (10) Personnel exposure records posted
- (10) Log book rcpt. and disposition entries complete
- (5) Log book use entries
- (10) In-house surveys
- (10) Sink disposal forms
- (10) Waste disposal record

- (10) All personnel have taken safety exam
- (5) Personnel wearing badges
- (5) Personnel wearing lab coat
- (5) Personnel wearing gloves
- (5) No evidence of eating, drinking or smoking
- (10) No mouth pipetting
- (10) Proper disposal of RAM
- (10) Survey meter available

(Handwritten notes in Hindi script)

Isotopes Authorized

<u>Isotope</u>	<u>Current Annual Limit (mCi)</u>	<u>Amount On Hand</u>	<u>Projected Annual Need (mCi)</u>
<u>Cl-36</u>	<u>5 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>Co-57</u>	<u>5 mCi</u>	<u>.2 3/14</u>	<u>Same</u>
<u>Cr-51</u>	<u>2 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>Fe-59</u>	<u>1 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>Ga-67</u>	<u>10 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>I-131</u>	<u>30 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>Tc-99</u>	<u>17 mCi</u>	<u>17 3/14</u>	<u>Same</u>

TO BE COMPLETED BY RADIATION SAFETY ONLY

Lab Conditions

(10) Floor	Acceptable	Clean	Waxed
(10) Countertop	Acceptable	Clean	Covered
(10) Hood	Acceptable	Clean	Proper opening

Comments: _____

Inspected by: _____

Date of Inspection: _____

You have been found to be in compliance. You are authorized to use the amounts of radioactive materials listed under the "Projected Annual Need" column.

The number of infractions found above has exceeded the trigger level established by the Radiation and Radioisotope Committee. These deficiencies should be corrected as soon as possible.

For each item circled above, please submit a written response (by _____) which includes the following:

- 1) any extenuating circumstances
- 2) corrective action taken or planned
- 3) the date when compliance will be achieved

Isotopes Authorized

<u>Isotope</u>	<u>Current Annual Limit (mCi)</u>	<u>Amount On Hand</u>	<u>Projected Annual Need (mCi)</u>
<u>In-111</u>	<u>36 mCi</u>	<u>3 3/14</u>	<u>Same</u>
<u>H-3</u>	<u>25 mCi</u>	<u>See back 20% 3/14</u>	<u>Same</u>
<u>I-125</u>	<u>150 mCi</u>	<u>3 3/14</u>	<u>Same</u>
<u>I-123</u>	<u>50 mCi (25 mCi on hand)</u>	<u>0 3/14</u>	<u>Same</u>
<u>Br-77</u>	<u>100 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>Br-82</u>	<u>5 mCi</u>	<u>0 3/14</u>	<u>Same</u>
<u>C-14</u>	<u>2.5 mCi</u>	<u>25 mCi</u>	<u>Same</u>

TO BE COMPLETED BY RADIATION SAFETY ONLY

Lab Conditions

(10) Floor	<u>Acceptable</u>	<u>Clean</u>	<u>Waxed</u>
(10) Countertop	<u>Acceptable</u>	<u>Clean</u>	<u>Covered</u>
(10) Hood	<u>Acceptable</u>	<u>Clean</u>	<u>Proper opening</u>

Comments: See attached Memo. Score 158 out of 178 possibleInspected by: Mark Selikson & Gary GoodDate of Inspection: 3/16/83

☒ You have been found to be in compliance. You are authorized to use the amounts of radioactive materials listed under the "Projected Annual Need" column.

☐ The number of infractions found above has exceeded the trigger level established by the Radiation and Radioisotope Committee. These deficiencies should be corrected as soon as possible.

For each item circled above, please submit a written response (by _____) which includes the following:

- 1) any extenuating circumstances
- 2) corrective action taken or planned
- 3) the date when compliance will be achieved

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5.
 - a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
 - b. Do not store food, drink, or personal effects with radioactive material.
6.
 - a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.
 - b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.
7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Always transport radioactive material in shielded containers.



THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

Radiation Safety Office
(202) 676-2630

TO: M. Cianci, Technical Administrator
FROM: Mark Selikson, Radiation Safety Officer
DATE: December 8, 1982
SUBJ: Safe Use of Radioactive Materials

During the annual inspection of your facility yesterday, a cup of coffee was found in the thyroid uptake room. As you are well aware, food or drink is strictly forbidden in any area where radioactive material is stored or used. A copy of Appendix G of the University's Broad License is attached for your information. Rule 5 spells out the details. You may wish to review this matter with your staff in order to insure future compliance.

TO: Files

FROM: Gary Good

DATE: April 19, 1983

RE: Annual Inspection of Nuclear Medicine Research.

An announced inspection of the Nuclear Medicine Research laboratories was conducted by the Radiation Safety Office on March 16, 1983. A routine annual inspection was performed with the following results noted:

- A. Approved User Practices - Satisfactory
- B. Posting - Satisfactory
- C. Records - Log book receipt and disposition entries were not complete. The materials not entered in the log were received from Clinical Nuclear Medicine. A procedure will be instituted where all radioactive materials will be logged in the inventory book.
- D. Personnel Practices - Evidence of eating and food storage in laboratories
 - 1. Coffee cups found in Room 660
 - 2. Food in radioactive material refrigerator in Room 660
 - 3. Food on window sill in Room 660
 - 4. Food storage refrigerator in a radioactive materials work area, Room 656.

The following changes will be instituted over the next year:

- A. ¹²³I shipments will be made by Nuclear Medicine Research to Georgetown University. These shipments will be made in accordance with new D.O.T. regulations to take effect July 1, 1983. These shipments will be coordinated with the Radiation Safety Office.
- B. New radioactive materials areas will be set up in rooms 649, 658, 659, and 661. All necessary signs and labels will be posted in these areas.

Generally, this laboratory area was found to be in compliance with most NRC regulations. More emphasis, however, should be placed on personnel practices, i.e., prohibiting eating, drinking, and food storage in radioactive materials areas.

cc: Dr. Eckelman



THE
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Radiation Safety Office
(202) 676-2630

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

TO: Dr. A. Kumar, Ph.D

FROM: Mark Selikson, Ph.D *MS*

DATE: April 28, 1983

RE: Survey Results

I have been requested to present an update on your authorization at the next meeting of the radiation and radioisotopes committee (July 83). A large portion of this report will be generated from the weekly surveys and these results have recently been getting worse. For example:

- April 1, 1983 - (a) 6 unlabeled areas of contamination were noted.
- (b) No in-house contamination surveys had been performed since 3/10/83.
 - (c) No bioassays had been performed for personnel using > 5 mCi of unbound ^{32}P .

- April 11, 1983 - (a) 8 unlabeled areas of contamination were noted.
- (b) Only one in-house contamination survey had been performed the previous week.
 - (c) No bioassays had been performed for personnel using > 5 mCi of unbound ^{32}P .
 - (d) Radioactive waste storage drums were filled beyond capacity.
 - (e) Coffee cups, water jugs, hot pots were found in Room 228, a radioactive materials work area.
 - (f) Coffee cups and ash trays were found on lab benches in Room 232, a radioactive materials work area.
 - (g) Laboratory personnel were not wearing lab coats and were observed pipetting by mouth.

- April 19, 1983
- (a) 3 unlabeled areas of contamination were noted.
 - (b) Only one in-house contamination survey had been performed the previous week.
 - (c) No bioassays had been performed for personnel using > 5 mCi of unbound ^{32}P .
 - (d) Food dishes, coffee cups, and a thermos were found in Room 228, a radioactive materials work area.
 - (e) Personnel were not wearing lab coats.
 - (f) Radioactive materials inventory log was incomplete - 5 shipments of radioactive materials were never entered, 5 additional shipments did not show any disposal records.

- April 26, 1983
- (a) 10 unlabeled areas of contamination were noted.
 - (b) Only one in-house contamination survey had been performed the previous week.
 - (c) No bioassays had been performed for personnel using > 5 mCi of unbound ^{32}P .
 - (d) Radioactive materials inventory log was incomplete.

It will be pointed out that as one of the largest users at the university a flawless survey is difficult. However, such things as mouth pipetting, eating, drinking and smoking in a restricted area are inappropriate. I also need a bioassay program initiated, if only to document that there is no need for bioassays. In a lab your size it is important that one individual take time each week to review safety practices. Let us get the system moving again and go into the July meeting with a clean report.

In a related manner, the estimates on the core storage facility have been returned for final consideration by Dean Birnbaum.

APPENDIX B

LETTER DATED JULY 21, 1983
REGARDING ATMPSHERIC DISPERSION CALCULATIONS



THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Washington, D.C. 20037 / (202) 676-6000

The University Hospital
901 Twenty-third Street, N.W.

July 21, 1983

John Glenn, Ph.D.
Chief, Nuclear Materials
Division of Engineering and Technical Programs
USNRC
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

Dear Sir:

Per your request, I have enclosed the graphs I used from "Workbook of Atmospheric Dispersion Estimates". Linear extrapolation was used to estimate dispersion coefficient for distances less than 100 meters. Looking at on axis concentrations for 35 meters down wind gives a concentration of 5×10^{-10} uCi/cc. ($\sigma_y = 7.2$, $\sigma_z = 4$).

As you suspected, evaluating the dilution along a cone seems more appropriate. If we assume that the rate at which air is coming up the stack is equal to the rate at which the wind is pulling it away, then the cross section area of the plume at the stack, A, is

$$A = \frac{\text{Stack Rate (volume/time)}}{\text{Air Velocity (distance/time)}} = \frac{1251 \text{ cfm} \times 1/60 \text{ min/sec} \times .028 \text{ M}^3/\text{ft}^3}{2.7 \text{ M/sec}} = .22 \text{ M}^2$$

At 35 m down wind the plume cross section area (from the graph) is 90.5 M^2 which corresponds to a dilution ration of 1:400.

There our results show that no public areas (inside or outside the hospital) were exposed to concentrations of Xe-133 in excess of 10% MPC when averaged over a year.

Sincerely,

Mark H. Selikson, Ph.D.
Radiation Safety Officer

MF S/nmk
Enclosure

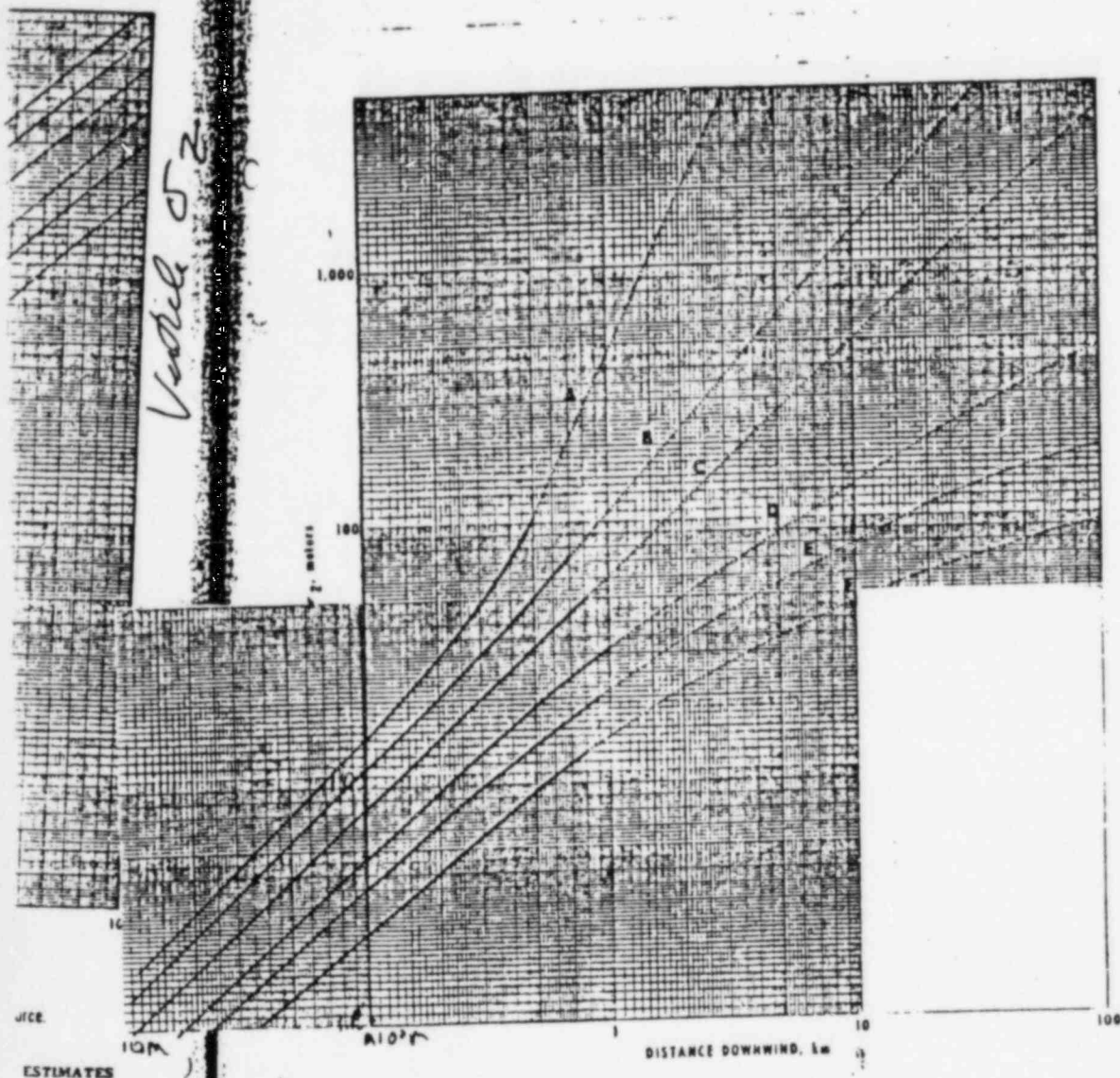


Figure 3-3. Vertical dispersion coefficient as a function of downwind distance from the source.

Estimates

100-100 10-10-10

REFERENCE NOTES APPLYING TO TABLES APPEAR ON THE PAGE FOLLOWING LAST TABLE.
(Caution: Letters and symbols may have different meanings in 1941-1970 tables than in earlier tables. See notes.)

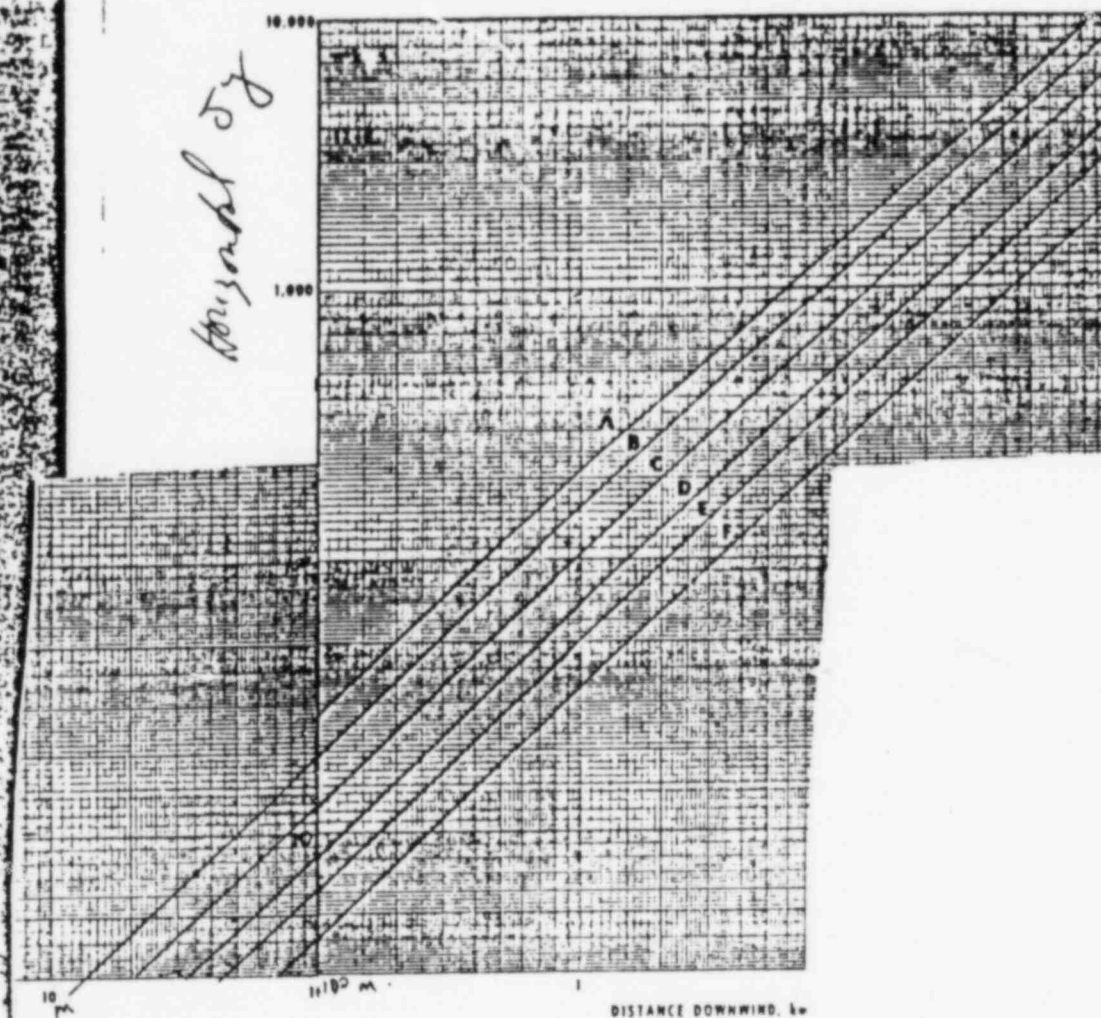


Figure 3.2. Horizontal dispersion coefficient as a function of downwind distance from the source.

ATMOSPHERIC DISPERSION ESTIMATES

Estimate
10-400

APPENDIX C

LETTER DATED JULY 21, 1983
REGARDING IMPLEMENTATION OF A NEW MANGEMENT ENFORCEMENT PROGRAM



THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Warwick Building / 2300 K Street, N.W. / Washington, D.C. 20037

Radiation Safety Office
(202) 676-2630

July 21, 1983

John Glenn, PhD.
Chief, Nuclear Materials
Division of Engineering and Technical Programs
USNRC
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

Dear Sir:

In regard to our effort to establish a management enforcement program we have now established an Executive Committee of the Radiation Safety Committee. This Executive Committee will administer enforcement and compliance on a day to day basis while the full committee continues to meet only quarterly. The major user is to complete safety inspection schedule which is subsequently verified on site and unannounced by the Radiation Safety Officer. This is to insure safety of the operation through self education of the users. Infractions detected during the inspection will be assigned a point value. If infractions exceed a trigger level, the user will have two weeks to institute corrections, otherwise the radioactive material destined for the particular user will be withheld by the Radiation Safety Office until the user has proven to the Executive Committee that he is in compliance. Repeat infractions on subsequent inspections will double the penalty points.

Attached, as an example, is the draft for a quarterly inspection report together with a point by point schedule. We expect the final version will differ somewhat but we thought you would be interested that we have made a formal start.

Sincerely,

Mark H. Seliksman, Ph.D.
Radiation Safety Officer

MFS/nmk

Enclosure

QUARTERLY INSPECTION REPORT

1. Use of unauthorized RAM. (5)
2. Use or storage of RAM in an unauthorized area. (5)
3. Removal of RAM from GWU. (10)
4. RAM ordered/received directly from supplier. (10)
5. RAM provided to unauthorized staff. (10)
6. Failure to provide training/ALARA sessions. (10)
7. NRC-3 form not posted. (2)
8. Radioactive material sign not posted. (2)
9. Radiation area sign not posted. (2)
10. High radiation area sign not posted. (2)
11. Radioactive User's Guide inaccessible. (5)
12. Personnel exposure records inaccessible. (2)
13. Log book records inadequate. (10)
14. Laboratory survey records inadequate (where applicable). (10)
15. Waste disposal records inadequate. (5)
16. Personnel working with RAM prior to passing safety exam. (10)
17. Personnel not wearing monitors as assigned. (5)
18. Evidence of personnel eating, drinking, smoking in area where RAM is used. (5)
19. Personnel mouth pipetting RAM. (10)
20. Personnel not wearing gloves and/or protective clothing while working with RAM. (5)
21. Failure to use hood/glove box as required. (5)
22. Food/drink and RAM stored together. (10)
23. Absorbent pads not properly used. (2)
24. Unmarked and unattended labware containing RAM. (2)
25. RAM inadequately shielded. (5)
26. RAM not secured against theft. (5)
27. Improper disposal of RAM waste. (10)
28. Appropriate survey meter not accessible. (5)

Explanation of Inspection Form

1. Use of unauthorized RAM

Deficiencies include the use or presence of a radionuclide not included in the list of authorized materials of the designated authorized user of the lab.

2. Use or storage of RAM in an unauthorized area

Deficiencies include the use or storage of RAM in an area not designated by the authorized user in the most recent application involving the radionuclide(s), or in a memo to Radiation Safety requesting authorization of the new site.

3. Removal of RAM from GWUMC

Use of RAM as authorized by the institutional broad license is limited to locations specified in the license, i.e., GWU and GWUMC. Thus, RAM obtained under the authorization of the license must be used only at locations specified in the license. Proper transfer of RAM can be achieved by adherence to the requirements specified in 10 CFR Part 30.41. All transfers of RAM to other institutions, or from campus to campus, must be accomplished with the assistance of the Radiation Safety Staff.

4. RAM ordered/received directly from supplier

License condition requires that all research RAM including free samples, etc., be processed through Radiation Safety Office (X2630) and shipped to George Washington University Medical Center, Receiving Department, Corner 24th and I Streets, N.W., Washington, D.C. 20037,

5. RAM provided to unauthorized staff

License condition requires users to be approved by specified Committees for each radionuclide needed. Transfer between users is permitted if each is approved for use of the radionuclide and if they indicate the transfer in their logbooks.

6. Failure to provide training/ALARA sessions

Definition: Training/ALARA session is a lecture given by the principal investigator for the purpose of instructing personnel in all phases of radiation safety pertaining to the RAM used in their lab. Deficiencies include: 1) failure to provide a training/ALARA session each year, 2) failure to keep records of: date; personnel attending; personnel absent; dates of follow-up sessions and names of attendees.

7. NRC-3 form not posted

Federal regulation requires that the form be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe it on their way to or from work.

8. Radioactive material sign not posted

Sign is to be conspicuously posted for each room in which RAM is used or stored.

9. Radiation area sign not posted

Federal regulation requires posting to indicate radiation areas, i.e., areas where a major portion of the body could receive a dose in excess of 5 millirems in any one hour or in excess of 100 millirems in any 5 consecutive days.

10. High radiation area sign not posted

Federal regulation requires posting of areas where a major portion of the body could receive a dose in excess of 100 millirems in one hour.

11. Radioactive User Guide Inaccessible

One manual per authorized user is sufficient if all labs are on one floor. All personnel should know where the manual is and have access to it at all times.

12. Personnel exposure records not accessible

All personnel should know where to find the dosimetry report.

13. Log book records inadequate

Lab portion or receipt record which includes use, transfer, and date of final disposal, must be completely filled out.

14. Laboratory survey records inadequate

Deficiencies include:

1. No survey or record of non-use during period for surveys, i.e., weekly or monthly.
2. No record of: radionuclides being used; date; and signature.
3. No indication of remedial action where contamination is found (must indicate result of re-wipe numerically).

15. Waste disposal records inadequate

Deficiencies include NOT having: 1) sink disposal form posted, 2) a record posted for amounts of activity in liquid waste and investigator (in a common area), 3) a record of disposal amounts and investigators for scintillation vials stored in a common area.

16. Personnel working with RAM prior to passing safety exam

Deficiencies include individuals: 1) seen using RAM prior to passing exam, 2) who do not show up for the test and do not sign up again.

17. Personnel not wearing monitors as assigned

Deficiencies include personnel: 1) not wearing his badge in a RAM area, 2) wearing someone else's badge/or the control badge, 3) not wearing a ring or other type badge while working with RAM (as appropriate).

18. Evidence of personnel eating, drinking, smoking in area where RAM is used

Deficiencies include: 1) coffee cups, 2) ashtrays, 3) cigarette butts, 4) plates with food, and 5) soda cans in RAM areas. (If people are collecting aluminum, the container should be in a non-RAM area with its own sign on it.)

19. Personnel mouth pipetting in a RAM area

Deficiencies include: 1) those people who were observed mouth pipetting by the inspector, 2) those people who reported an accident while mouth pipetting, and 3) finding a "hot" mouth pipette in a lab.

20. Personnel not wearing gloves and/or protective clothing while working with RAM

As stated.

21. Failure to use hood/glove box as required

Deficiency includes failure to use hood/glove box when using unbound iodine in non basic or oxidizing conditions.

22. Food/drink and RAM stored together

Deficiencies include food or drink stored together with RAM anywhere (refridgerator, cabinet, or shelf, etc.)

23. Absorbent pads not properly used

24. Unmarked and unattended labware containing RAM

Deficiencies include unattended labware containing RAM without the following identification:

Radionuclide
date
amount uCi or mCi
caution radioactive materials and warning symbol label

25. RAM not adequately shielded

This category applies to RAM in use or storage. Radiation levels should not exceed 0.2 mR/hr at one foot beyond shield, and Beta contribution should be completely shielded when RAM is in storage. Deficiencies include: 1) shielding of mCi amounts of high energy Beta emitter with lead only, 2) insufficient shielding of Gamma emitters so that exposure rates in occupied areas are significantly higher than those that could be achieved with a reasonable amount of additional shielding, 3) lack of or insufficient shielding when handling high energy Beta emitters in mCi amounts.

26. RAM not secured against theft

Deficiencies include failure to lock RAM or RAM waste left

A. Improper disposal:

1. improper labeling packaging of animal carcasses
2. vials containing liquid in dry waste
3. Radiation symbols in decayed trash unobliterated
4. dry waste in bags with animal carcasses
5. corrosive liquid put in metal cans
6. non-RAM waste in RAM waste can

B. Improper labeling:

Deficiencies include: 1) inadequate or incomplete information on the waste transfer card. 2) failure to label RAM waste container with "Caution Radioactive Materials" sign or tape.

28. Appropriate survey meter not accessible

Deficiencies include failure to provide a survey meter that reads exposure rates in mR/hr with the minimal capability or reading 0.1 mR/hr must be in the lab or near vicinity and available when needed by lab personnel.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
831 PARK AVENUE
KING OF PRUSSIA, PENNSYLVANIA 19406

September 1, 1983

Docket Nos. 030-09049
030-19445
070-01795
License Nos. 08-00216-22
08-00216-23
SNM-1499

EA No. 83-73

The George Washington University Medical Center
ATTN: Fred Leonard, Ph.D.
Associate Dean of Research
2300 Eye Street, N.W.
Washington, D. C. 20037

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES
(NRC Inspection 83-01)

This refers to the NRC safety inspection conducted on June 1-2, 1983, of activities authorized by NRC License Nos. 08-00216-22, 08-00216-23, and SNM-1499. The report of this inspection was forwarded to you on June 30, 1983. During the inspection, twelve examples of failure to comply with NRC requirements were identified. On July 19, 1983, we held an enforcement conference with you during which these failures, their causes, and your corrective actions were discussed.

These examples, two of which are similar to violations identified during previous NRC inspections, are described in the enclosed Notice and they collectively represent a significant breakdown in management oversight and control of the radiation safety program. These examples demonstrate the need for improvement in the administration and control of the program to assure adherence to NRC requirements, and safe performance of licensed activities.

To emphasize the importance of adequate control of the radiation safety program, I have been authorized, after consultation with the Director, Office of Inspection and Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of Two Thousand Five Hundred Dollars (\$2,500) for the violations set forth in the enclosed Notice. The twelve violations have been categorized in the aggregate as a Severity Level III problem in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C, 47 FR 9987 (March 9, 1982)).

The base civil penalty for a Severity Level III problem is normally \$2,000. However, since corrective actions were not taken promptly when some of the

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RETURN RECEIPT REQUESTED

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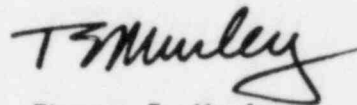
violations were identified previously, the proposed civil penalty has been increased to \$2,500 to further emphasize the importance of prompt and effective corrective action for identified deficiencies.

You are required to respond to the enclosed Notice and, in preparing your response, you should follow the instructions specified in the Notice. Your reply to this letter and the results of future inspections will be considered in determining whether further enforcement action is appropriate.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,



Thomas E. Murley
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalties

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

The George Washington University Medical Center
ATTN: Dr. Mark Selikson
Radiation Safety Officer
Warwick Building
2300 K Street, N.W.
Washington, D.C. 20037

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

The George Washington University
Medical Center
2300 Eye Street, NW
Washington, D.C. 20037

Docket Nos. 30-09049
30-19445
70-01795
License Nos. 08-00216-22
08-00216-23
SNM-1499

EA 83-73

An NRC inspection of activities authorized under NRC License Nos. 08-00216-22, 08-00216-23, and SNM-1499 was conducted on June 1-2, 1983. During the inspection, multiple examples of failure to comply with NRC requirements were identified. Two of the examples, involving failure to wear TLD finger badges, and failure to dispose of radioactive waste in a designated container, were also identified during a previous NRC inspection in 1980. Collectively, these failures represent a significant breakdown in the management of the radiation safety program.

To emphasize the importance of adequate control of the radiation safety program, the Nuclear Regulatory Commission proposes the imposition of cumulative civil penalties in the amount of Two Thousand Five Hundred Dollars for this matter. In accordance with the NRC Enforcement Policy (10 CFR Part 2, Appendix C) 47 FR 9987 (March 9, 1982), and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended ("Act"), 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205, these particular violations and the associated civil penalties are set forth below:

- A. 10 CFR 20.106(a) requires that no licensee release radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR 20, Appendix B, Table II, when averaged over one year. 10 CFR 20, Appendix B, Table II, specifies the effluent release limit for airborne xenon-133 to be 3.0×10^{-7} microcuries per milliliter.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20 and that each licensee make or cause to be made such surveys that are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of June 2, 1983, an adequate survey had not been performed to assure compliance with 10 CFR 20.106(a) in that no evaluation of the concentrations of xenon-133 were made at the boundary of the restricted area to determine the concentration of xenon-133 resulting from releases made during the one-year period ending March 31, 1982, even

83-0270644
5pp

though surveys at the release point within the restricted area showed xenon-133 in concentrations of 7.5×10^{-7} microcurie per milliliter when averaged over one year.

- B. 10 CFR 20.301 requires that no licensee dispose of licensed material except in accordance with certain authorized methods which are specified in 10 CFR 20.301(a), (b) and (c).

Condition 22 of License No. 08-00216-22 requires a survey to be made of material placed in normal trash.

Contrary to the above, on January 25, 1983, a bag of waste consisting of disposable protective clothing and plastic-backed absorbent pads, containing approximately 70 microcuries of iodine-125, was removed from a restricted laboratory and placed in the normal trash without a survey. As a result, this waste was subsequently removed and transported to a public landfill near Lorton, Virginia, a method of disposal not authorized by 10 CFR 20.301(a), (b), or (c).

- C. 10 CFR 35.43 requires diagnostic misadministrations be reported to the NRC Regional Office within 10 days after the end of the calendar quarter in which the misadministration occurred.

Contrary to the above, misadministrations which occurred on October 13, 1982, and November 16, 1982, were not reported to the NRC Regional Office within 10 days after the end of the 4th quarter 1982 (December 31, 1982), and had not been reported as of June 2, 1983.

- D. Condition 13 of License No. 08-00216-22 requires that sealed sources containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, sealed sources containing millicurie quantities of cesium-137 for brachytherapy use were not leak tested during the first six months of 1981, or during the entire twelve months of 1982.

- E. Condition 21 of License No. 08-00216-22 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in applications dated March 21, 1978, and January 31, 1979; letters with attachments dated March 27, 1979, and April 18, 1979; Items A (ALARA Program), D, and E of letter dated May 15, 1981; and letters dated January 28, 1982, July 1, 1982, and July 13, 1982.

1. Item No. 10 of an attachment to the letter dated March 27, 1979, requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8 (January 1979).

Procedure E of Appendix D, Section 2, requires dose calibrators to be tested quarterly for linearity.

Contrary to the above, as of June 1, 1983, although records of linearity tests were maintained, no records were available to demonstrate that linearity tests were performed on a dose calibrator for the 3rd and 4th quarters of 1980, the 1st quarter of 1981, and the 2nd quarter of 1982.

2. Item No. 10 of the attachment to the letter dated March 27, 1979, requires that survey meters be calibrated every 6 months.

Contrary to the above, on June 1 and 2, 1983, an NRC inspector identified that several survey meters located in the research laboratories had not been calibrated since March 1982, an interval in excess of 6 months.

3. Item No. 15 of the attachment to the letter dated March 27, 1979, requires adherence to the "General Rule for Safe Use of Radioactive Materials" contained in Appendix G of Regulatory Guide 10.8.

- a. Rule 2 of Appendix G requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, on June 1, 1983, an NRC inspector observed personnel in the Nuclear Medicine Department who were not wearing disposable gloves while handling and injecting radiopharmaceuticals.

- b. Rule 5 of Appendix G requires that there be no eating, drinking, smoking, or application of cosmetics in any area where radioactive materials are stored or used.

Contrary to the above, on June 2, 1982, an NRC inspector observed an individual smoking in Room 407AB, Ross Hall, where radioactive materials are stored, and found evidence of eating and drinking, namely eating utensils and cups, in several other of the research laboratories where radioactive materials are stored.

- c. Rule 8 of Appendix G requires that TLD finger badges be worn during elution of generators, and during preparation, assay, and injection of radiopharmaceuticals.

Contrary to the above, on June 1, 1983, an NRC inspector observed a student technologist who was not wearing a TLD ring badge while preparing radiopharmaceuticals.

- d. Rule 9 of Appendix G requires that radioactive waste be disposed of only in specifically designated receptacles.

Contrary to the above, on June 2, 1983, a receptacle designated as non-radioactive "cold trash" contained radioactive materials in that a radiation level of 7 milliroentgen per hour was identified by the NRC inspector at the surface of the receptacle.

- e. Rule 10 of Appendix G requires that there be no pipetting by mouth.

Contrary to the above, on June 2, 1983, an NRC inspector observed evidence (hose) of mouth pipetting in Room 234, Ross Hall, and an individual admitted pipetting quantities of phosphorous-32 by mouth.

- f. Rule 11 of Appendix G requires surveys of generator, kit preparation, and injection areas after each procedure or at the end of the day.

Contrary to the above, as of June 1, 1983, documentation reviewed by an NRC inspector demonstrated that surveys were not performed on May 9 and 10, 1983 in the Nuclear Medicine areas and between June 18 to August 2, 1982, October 10 to November 8, 1982 and December 18, 1982 to January 31, 1983 in the Nuclear Cardiology areas.

Collectively, the above twelve violations have been evaluated as a Severity Level III problem (Supplements IV and VI.)

(Cumulative Civil Penalty - \$2,500 - assessed equally among the violations.)

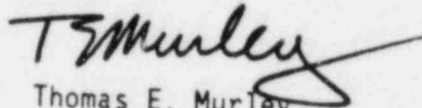
Pursuant to the provisions of 10 CFR 2.201, The George Washington University Medical Center is hereby required to submit to the Director, Office of Inspection and Enforcement, USNRC, Washington, DC 20555, with a copy to this office, within 30 days of the date of this Notice, a written statement or explanation in reply, including for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation, if admitted; (3) the corrective steps that will be taken and the results achieved; (4) the corrective steps that will be taken to avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, The George Washington University Medical Center may pay the civil penalties in the amount of Two Thousand Five Hundred Dollars or may protest imposition of the civil penalties in whole or in part by a written answer. Should The George Washington University Medical Center fail to answer within the time specified, the Director, Office of Inspection and Enforcement, will issue an order imposing the civil penalties in the amount proposed above. Should The George Washington University Medical Center elect to file an answer in accord-

ance with 10 CFR 2.205 protesting the civil penalties, such answer may: (1) deny the violations listed in this Notice in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalty. In requesting mitigation of the proposed penalties, the five factors contained in Section IV.B of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of The George Washington University Medical Center is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282.

FOR THE NUCLEAR REGULATORY COMMISSION


Thomas E. Murley
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 1st day of September 1983

08-00216-22



THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Washington, D.C. 20037

Office of the Associate Dean for Research
2300 Eye Street, N.W.
202-676-2995

Thomas B. Murley
Regional Administrator
Region I
USNRC
King of Prussia, PA

September 26, 1983

Dear Mr. Murley:

This letter is in response to the Notice of Violation EA No. 83-73 dated 9/1/83.

The letter is divided into 4 sections

- I. General comments concerning NRC conclusions.
- II. Specific comments for each alleged violation in accordance with instructions in the Notice.
- III. Policy actions that have been taken.
- IV. Conclusions

I. GENERAL COMMENTS

- A. The NRC conclusions that there has been a "significant breakdown in management oversight and control of the Radiation Safety Program," when considered in the light of our overall radiation program, is unwarranted. The following specific examples reflecting a meritorious Radiation Safety Program are presented:

1. Program Growth/Lower Personnel Exposure : Since our last inspection in 1980, the size of the George Washington University program rose from 37,300 mCi of activity to 362,600 mCi of activity in 1982 plus 2,100,000 mCi Cs sealed source. During that period of time, the number of personnel with exposures exceeding the low ALARA trigger levels (10% MPD as approved by NRC in 1981.) decreased from 27 in 1981 to 12, in 1982 to 2 in the first half of 1983. Eight hundred (800) thyroid bioassays were performed during the same three year period and only once (12% MPD) was the ALARA trigger level exceeded. This record is not one which reflects a program which is an "actual or high potential risk" to the public, the patients, or personnel at the George Washington University or one in which there is a "significant breakdown in management oversight of the Radiation Safety Program."

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2. Radiation Safety Education Program: There is an active educational program in radiation safety for both students and workers. Since the beginning of 1983, over 410 workers have attended on the job radiation safety education inservices. Three radiation safety courses have been given for credit in our Allied Health Program. In addition, research personnel who work with radioactive materials are required to take, and pass, a radiation safety examination.
3. Radiation Safety Development Program: a.) Recently, a double energy calibration technique has been developed and implemented by the Radiation Safety Office at the George Washington University. The technique was presented at the Annual meeting of Campus Radiation Safety Officers, June 1983, Columbia, Missouri. This procedure exceeds requirements. As a result of this new calibration protocol, investigators have a more accurate indication of exposure levels when working with a variety of isotopes. b.) The Radiation Safety Office has developed a method for converting oil-soluble radioactive waste to stable oil in water emulsions so that they may be disposed of in a similar manner as water soluble radioactive waste. The method was presented at the annual meeting of the Health Physics Society, June 1983, Baltimore, Maryland, and a paper is being submitted for publication to Health Physics.

The George Washington University is very supportive of the educational and development efforts of the Radiation Safety Office for travel and attendance at meetings, for exchange and dissemination of information developed by the Radiation Safety Office, and for specialized courses in Radiation Safety to train the radiation safety personnel working at the University.

4. Salutory Comments on the Latest Inspection: In a recent licensing inspection on September 13, 1983 the University was commended by a NRC representative for the security and safety precautions that have been taken for our 2.1 kCi Cesium irradiator.

- B. The characterization by the NRC of the violations cited at a collective severity level III is inappropriate.

This is the first time that the George Washington University has been inspected since the establishment of the severity level concept for academic institutions and therefore there is little past experience. However, in its policy statements the NRC defines severity level III as violations which have "actual or high potential impact on the public." (PS-33). The main concern expressed in your letter, "breakdown in management oversight control" appears to be analogous to the definition of a level IV problem

- "degradation of...management control systems." (PS-33). It also states that "severity level IV in themselves are not cause for concern, they are the sort of violations that, if left uncorrected, could lead to matters of significant concern." Many of the violations cited in EA No., 83-73 had been identified and corrected prior to the NRC inspection. Most of the remaining items had been identified and were being worked on by the Radiation Safety Committee. Even the need for a new streamlined administrative structure in Radiation Safety was being initiated as early as January 1983. In view of the foregoing, and as specified below, a severity level III in our opinion is unwarranted.

- C. Allegations are made by NRC that corrective actions were not promptly taken when previous violations had been noted by NRC.

These allegations are incorrect. All of the violations cited in the NRC inspection in May 1980 were promptly corrected. (see letter June 3, 1980) Nuclear Medicine was promptly instructed to handle all waste containers as radioactive. Temporary film badges were immediately ordered so that anyone working in the hot lab would get a ring badge. The importance of wearing ring badges has been stressed in annual "inservices" and individual memoranda. An additional corrective action identified in the May 1980 inspection was the need for more frequent surveys in Dr. Kumar's research laboratory. Such weekly surveys were promptly initiated. In addition, persistent problems with decontamination in his laboratory led the Radiation Safety Office to recommend, and the University to proceed with, refinishing all the working surfaces in his laboratory. Since that time, the contamination rate has dropped dramatically. Therefore there is no basis for the NRC contention that corrective actions were not taken promptly.

II. SPECIFIC COMMENTS FOR EACH ALLEGED INFRACTION

As requested we now respond to each alleged violation. These are:

- A. Inadequate survey to insure compliance with 10 CFR 20.106 (a).
- B. Disposal of RAM not authorized by 10 CFR 20.301.
- C. Reporting diagnostic misadministrations 10 CFR 35.43
- D. Sealed source leak test (License condition 13)
- E.
 - 1. Dose calibrator linearity tests (10.8 App D sec 2).
 - 2. Survey meter calibration tests. (License condition 21, item 10 3-27-79)
 - 3.
 - a. Wearing gloves (10.8 App G Rule 2)
 - b. Eating, drinking and smoking (10.8 App G Rule 5)

- c. Finger badges (10.8 App G Rule 8)
- d. Radioactive waste designated containers (10.8 App G Rule 9)
- e. Mouth pipetting (10.8 App G Rule 10)
- f. Daily surveys (10.8 App G Rule 11)

The citations A,B,D,E1,E3f were first discovered by the Radiation Safety Office and made part of University documentation. They were not discovered by the NRC and they did not exist at the time of the NRC inspection. The remaining citations had previously received attention of the Radiation Safety Office and corrective action by the Radiation Safety Committee.

Reasons for Violations

- A. There was varying hypotheses between personnel in Nuclear Medicine and Radiation Safety as to what assumptions were appropriate when performing the survey.
- B. The principal investigator, who was following appropriate guidelines, nevertheless lost a small amount of sealed I-125. An exposure estimate, made by the Radiation Safety Office as required by NRC for the purpose of the calculation, assumed that the unaccounted for activity ended up in a land fill although there is no actual evidence for this loss (estimated to be less than 70 uCi). It is clearly the intention of the University to properly dispose of all radioactive waste at all times.
- C. This is a self inspection program initiated just after our May, 1980 inspection by the NRC. Since its inception, only zero (0) therapeutic misadministrations and (2) diagnostic misadministrations have occurred. As required, in both cases the referring physician was notified, and an investigation was conducted and recorded. As required, the following was determined: the referring physician's name, the patient's name, social security number, the Nuclear Medicine physician's name, the technologist's name, the chronology of events that led to the diagnostic misadministration, and the effect on the patient. The misadministration report was reviewed by the Radiation Safety Committee and corrective action was implemented. As required, the entire record was kept on file for review by the NRC. This is the first time this program has been inspected. In setting up and carrying out the new program, the additional quarterly reporting requirement for diagnostic misadministrations was overlooked.

- D. Sealed sources of byproduct material which were less than 100 uCi (check sources) and exempt under License Condition 13, Amendment #12, May 4, 1979 were not included in the semiannual sealed source swipe program. Recently several check sources slightly over the 100 uCi exemption limit were purchased by Nuclear Medicine and inadvertently left off the list of sources to be swiped every 6 months. This error, by the Radiation Safety Office, was discovered and corrected prior to the NRC inspection.
- E1. The central file on dose calibrator linearity tests and sealed source therapy swipes was missing at the time of the NRC inspection. Copies of most of the missing documents have been recovered and forwarded to the NRC. Dose calibrator linearity and sealed source swipes have been performed. Also additional tests exceeding requirements have been done. These include extra accuracy and geometry checks. In addition, we calibrate against I-123 NBS standards.
- E2. A new calibration procedure which both improved the accuracy of the lower exposure stations and evaluated energy dependence was under development during the past year. Because of the development of this program, we were a few months behind in our routine checks of instrument calibration. This new method exceeds regulatory requirements and eliminated what we felt are gross inaccuracies in the standard two point calibration method widely used.
- E3a. Gloves are supplied by the University. University policy of wearing gloves is stressed in "inservices" and by supervisors. Disregard on the part of the worker for University established practice led to the citation.
- E3b. Eating, drinking, and smoking in restricted areas is against University established policy. Disregard for that policy on the part of the worker led to the citation.
- E3c. As required from our last NRC inspection, extra dosimeters are being kept on site so that new employees are "badged" as soon as they start working. In addition, "inservices" by the Radiation Safety Office and instruction from the immediate supervisors stress the importance of wearing ring badges. One student technologist out of seven was observed not wearing a ring badge. She did, however, have it in her pocket. This citation was due to disregard on the part of the student to follow established protocol and Radiation Safety's failure to survey for compliance.

- E3d. In response to the May 1980 inspection, University policy was changed to have all receptacles in Clinical Nuclear Medicine handled as radioactive. In addition, housekeeping access to several laboratories in Ross Hall was eliminated and cold trash was placed outside the doors for pick up. This citation was due to disregard on the part of personnel in Nuclear Medicine to follow established protocol.
- E3e. University policy prohibiting mouth pipetting of RAM has been included in annual inservices. Special lectures with this group covered in detail the hazards of mouth pipetting RAM and the mechanical alternatives available. This citation was due to disregard of established University policy on the part of the researcher.
- E3f. Daily surveys for contamination in the Nuclear Medicine areas is standard procedure since 1979. Radiation Safety does surveys for compliance. This infraction represents disregard of established University policy.

Corrective Steps Taken and Date of Full Compliance

- A. The "inadequate surveys" problems cited by the NRC, had been previously identified by the Safety Committee, reviewed by the Radiation Safety Committee, and corrected by Nuclear Medicine a year before the NRC inspection. (We have been, and are now in compliance.)
- B. The loss of RAM was reported by the user, investigated by Radiation Safety, and reviewed by the Radiation Safety Committee. The existing protocol was found to contain adequate safeguards. Educational efforts were intensified including new labeling on doors and "inservices". The entire event was kept on record. This incident represents a Radiation Safety program at its best. (We are in compliance and were at the time of the inspection).
- C. The quarterly reporting requirement has been added to the inhouse University form. (We are now in compliance).
- D. As a matter of inhouse policy, all sealed sources are now being swiped semiannually except for those which are not in use and stored in Radiation Safety's unused inventory areas. (We are now in compliance and were at the time of inspection).

- E1. Records of linearity tests are in a single notebook and maintained securely. (We are now in compliance and were at the time of the inspection).
- E2. The dual energy calibrator program has been instituted. A semiannual check of contamination meters has been implemented. New meters have been purchased. (We are now in compliance.)
- E3a. An enforcement program has been instituted which requires workers to utilize the safety equipment which the University provides under penalty of sanctions. (We are now in compliance.)
- E3b. An enforcement program has been instituted which requires workers to utilize the safety equipment which the University provides under penalty of sanctions. (We are now in compliance.)
- E3c. An enforcement program has been instituted which requires students to utilize the safety equipment which the University provides. (We are now in compliance.)
- E3d. A survey of waste container labels has been added to the Radiation Safety Inspection form for Nuclear Medicine. (We are now in compliance.)
- E3e. An enforcement program has been instituted which requires the principal investigator to utilize the safety equipment which the University provides. (We are now in compliance.)
- E3f. An enforcement program has been initiated to insure that user surveys are made on a daily basis under penalty of sanction. (We are now in compliance.)

III. POLICY ACTIONS THAT HAVE BEEN TAKEN

To minimize the time between identification and correction of a radiation safety problem, a quarterly inspection and enforcement program supplementing our monthly, weekly and daily survey program has been implemented. The time limit allowed for corrective action is specified and sanctions will be imposed to insure compliance. In addition, an Executive Committee of the Radiation Safety Committee has been constituted to insure that the enforcement program is in place and that all policy questions receive immediate attention.

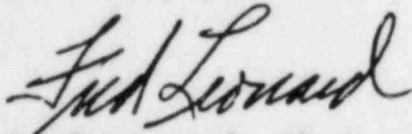
IV. CONCLUSIONS

In view of the foregoing documentation in regard to the George Washington Radiation Safety Program, we respectfully request that the NRC reconsider their initial conclusions, viz

1. That there has been a significant breakdown in management oversight and control of the Radiation Safety Program.
2. That the violations comprise a collective severity level III.
3. That corrective action was not promptly taken.

and rule in favor of reducing the severity level to level V and waiving the fine imposed upon the George Washington University.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Fred Leonard".

Fred Leonard, Ph.D.
Associate Dean of Research
Medical Center
The George Washington University



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

*Region 1
Docket Room*

NOV 13 1983

Docket Nos. 030-09049
030-19445
070-01795
License Nos. 08-00216-22
08-00216-23
SNM-1499
EA No. 83-73

The George Washington University Medical Center
ATTN: Fred Leonard, Ph.D.
Associate Dean of Research
2300 Eye Street, N.W.
Washington, D.C. 20037

Gentlemen:

This refers to your letter dated September 26, 1983, in response to the Notice of Violation and Proposed Imposition of Civil Penalties sent to you with our letter dated September 1, 1983. Our letter and Notice described violations identified during NRC Inspection 83-01 on June 1 - 2, 1983.

After careful consideration of your response, we have concluded for the reasons given in the enclosed Order and Appendix that a sufficient basis for mitigation of the proposed penalty was not provided in your response. Accordingly, we hereby serve the enclosed Order on The George Washington University Medical Center imposing a civil penalty in the amount of Two Thousand Five Hundred Dollars.

In your September 26, 1983 response, you express disagreement with the NRC conclusion that a significant breakdown in the management control and oversight of the radiation safety program had occurred at the George Washington University Medical Center. Rather, your response characterizes the program as meritorious, emphasizing that many of the violations were caused by the failure of individual personnel to adhere to established policies and procedures. The University is not only responsible for development of a satisfactory program, establishment of adequate procedures to implement the program, and training of personnel in the use of procedures, but is also responsible for maintaining adequate control and oversight of the program to ensure adherence to procedures, identification of procedural deviations, and prompt correction of procedural deviations including actions to prevent recurrence.

We recognize that the program at George Washington University Medical Center has expanded substantially in the last few years without significant personnel exposure in excess of NRC requirements. Nevertheless, we are concerned that the number of violations which were identified during this inspection, including several which were repetitive, indicate that the oversight of your program may

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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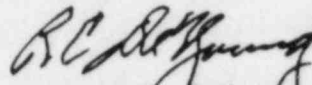
George Washington University
Medical Center

2

not have expanded concurrently. Specifically, personnel failures to adhere to procedures were not identified, identified deficiencies were not promptly and effectively corrected, and previously identified deficiencies recurred. These deficiencies represent a significant breakdown in management control and oversight of the radiation safety program.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,



Richard C. DeYoung, Director
Office of Inspection and Enforcement

Enclosures:

1. Order Imposing Civil Monetary Penalties
2. Appendix - Evaluations and Conclusion

cc:

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia

The George Washington University Medical Center
ATTN: Dr. Mark Selikson
Radiation Safety Officer
Warwick Building
2300 K Street, N.W.
Washington, D.C. 20037

The George Washington University
Medical Center

2

bcc:
Region I Docket Room (w/concurrences)
Senior Operations Officer (w/o encls)
SECY
Congressional Affairs
R. C. DeYoung, IE
J. Axelrad, IE
T. E. Murley, RI
J. Lieberman, ELD
V. Stello, DED/ROGR
Enforcement Coordinators
RI, RII, RIII, RIV, RV
F. Ingram, PA
J. Crooks, AEOD
B. Hayes, OI
G. Messenger, OIA
L. Cobb, IE
E. Flack, IE
V. Miller, NMSS
D. Nussbaumer, OSP
IE/ES File
IE/EA File
EDO Rdg File
DCS

11/17/83

RI:ES Holody/gcb 11/17/83	RI:DETP Glenn	RI:DETP Joyner	RI:DETP T. Martin	RI:RC Gutierrez
RI:DRA Allan 11/ /83	RI:RA Murley 11/ /83	IE:ES Flack 11/ /83	ELD Lieberman 11/5/83	IE:DP Axelrad 11/13/83
				IE:RC JTaylor 11/13/83
				IE:RC DeYoung 11/15/83

bcc:
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B. Hayes, OI
J. Cummings, OIA
L. Cobb, IE
E. Flack, IE
V. Miller, NMSS
D. Nussbaumer, OSP
IE/ES File
IE/EA File
EDO Rdg File
DCS

RI:ES
Holody/as
10/24/83

RI:DBA
10/25
with addition
of statement in
transmission
JTH

RI:DETP
Glenn
10/24/83

RI:RA
Murley
10/26

RI:DETP
Joyner
10/24/83

HQ:IE
Flack

RI:DETP
T. Murley
10/25/83

HQ:ELD
Lieberman

RI:RC
Gutierrez
10/26/83

HQ:IE
Axelrad

HQ:IE
DeYoung

1099

violated, and the amount of civil penalty for each violation. A response dated September 26, 1983 to the Notice of Violation and Proposed Imposition of Civil Penalties was received from the licensee.

III

Upon consideration of the answers received, the statements of fact, explanations, and arguments for remission or mitigation of the proposed civil penalties contained therein, and as set forth in the Appendix to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalties should be imposed.

IV

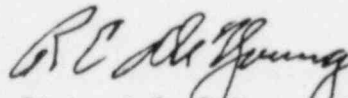
In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282, PL 96-295), and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay civil penalties in the amount of Two Thousand Five Hundred Dollars (\$2,500) within thirty days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director of the Office of Inspection and Enforcement, USNRC, Washington, D.C. 20555.

The licensee may, within thirty days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection and Enforcement. A copy of the hearing request shall also be sent to the Executive Legal Director, USNRC, Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. Upon failure of the licensee to request a hearing within thirty days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection. In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

- (a) whether the licensee violated NRC requirements as set forth in the Notice of Violation and Proposed Imposition of Civil Penalties; and
- (b) whether, on the basis of such violations, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION



Richard C. DeYoung, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 5th day of November 1983

APPENDIX

EVALUATIONS AND CONCLUSIONS

Although the licensee essentially admits the twelve violations, the licensee's September 26, 1983 response to the Notice of Violation and Proposed Imposition of Civil Penalties dated September 1, 1983 requests that the Severity Level of the aggregate problem be reduced from Level III to Level V, and that the proposed fine be waived. The response provides the reasons why the licensee believes reduction of the Severity Level and waiving of the penalties are appropriate. Provided below are (1) restatement of each violation, (2) the licensee's assertions in support of their requests, and (3) the NRC response to each of the licensee's assertions.

Restatement of Violations:

- A. 10 CFR 20.106(a) requires that no licensee release radioactive material to an unrestricted area in concentrations which exceed the limits specified in 10 CFR 20, Appendix B, Table II, when averaged over one year. 10 CFR 20, Appendix B, Table II, specifies the effluent release limit for airborne xenon-133 to be 3.0×10^{-7} microcuries per milliliter.

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20 and that each licensee make or cause to be made such surveys that are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of June 2, 1983, an adequate survey had not been performed to assure compliance with 10 CFR 20.106(a) in that no evaluation of the concentrations of xenon-133 was made at the boundary of the restricted area to determine the concentration of xenon-133 resulting from releases made during the one-year period ending March 31, 1982, even though surveys at the release point within the restricted area showed xenon-133 in concentrations of 7.5×10^{-7} microcurie per milliliter when averaged over one year.

- B. 10 CFR 20.301 requires that no licensee dispose of licensed material except in accordance with certain authorized methods which are specified in 10 CFR 20.301(a), (b) and (c).

Condition 22 of License No. 08-00216-22 requires a survey to be made of material placed in normal trash.

Contrary to the above, on January 25, 1983, a bag of waste consisting of disposable protective clothing and plastic-backed absorbent pads, containing approximately 70 microcuries of iodine-125, was removed from a restricted laboratory and placed in the normal trash without a survey. As a result, this waste was subsequently removed and transported to a public landfill near Lorton, Virginia, a method of disposal not authorized by 10 CFR 20.301(a), (b), or (c).

- C. 10 CFR 35.43 requires diagnostic misadministrations be reported to the NRC Regional Office within 10 days after the end of the calendar quarter in which the misadministration occurred.

Contrary to the above, misadministrations which occurred on October 13, 1982, and November 16, 1982, were not reported to the NRC Regional Office within 10 days after the end of the 4th quarter 1982 (December 31, 1982), and had not been reported as of June 2, 1983.

- D. Condition 13 of License No. 08-00216-22 requires that sealed sources containing byproduct material be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, sealed sources containing millicurie quantities of cesium-137 for brachytherapy use were not leak tested during the first six months of 1981, or during the entire twelve months of 1982.

- E. Condition 21 of License No. 08-00216-22 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in applications dated March 21, 1978, and January 31, 1979; letters with attachments dated March 27, 1979, and April 18, 1979; Items A (ALARA Program), D, and E of letter dated May 15, 1981; and letters dated January 28, 1982, July 1, 1982, and July 13, 1982.

1. Item No. 10 of an attachment to the letter dated March 27, 1979, requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8 (January 1979).

Procedure E of Appendix D, Section 2, requires dose calibrators to be tested quarterly for linearity.

Contrary to the above, as of June 1, 1983, although records of linearity tests were maintained, no records were available to demonstrate that linearity tests were performed on a dose calibrator for the 3rd and 4th quarters of 1980, the 1st quarter of 1981, and the 2nd quarter of 1982.

2. Item No. 10 of the attachment to the letter dated March 27, 1979, requires that survey meters be calibrated every six months.

Contrary to the above, on June 1 and 2, 1983, an NRC inspector identified that several survey meters located in the research laboratories had not been calibrated since March 1982, an interval in excess of six months.

3. Item No. 15 of the attachment to the letter dated March 27, 1979, requires adherence to the "General Rule for Safe Use of Radioactive Materials" contained in Appendix G of Regulatory Guide 10.8.
 - a. Rule 2 of Appendix G requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, on June 1, 1983, an NRC inspector observed personnel in the Nuclear Medicine Department who were not wearing disposable gloves while handling and injecting radiopharmaceuticals.
 - b. Rule 5 of Appendix G requires that there be no eating, drinking, smoking, or application of cosmetics in any area where radioactive materials are stored or used.

Contrary to the above, on June 2, 1982, an NRC inspector observed an individual smoking in Room 407AB, Ross Hall, where radioactive materials are stored, and found evidence of eating and drinking, namely eating utensils and cups, in several other of the research laboratories where radioactive materials are stored.
 - c. Rule 8 of Appendix G requires that TLD finger badges be worn during elution of generators, and during preparation, assay, and injection of radiopharmaceuticals.

Contrary to the above, on June 1, 1983, an NRC inspector observed a student technologist who was not wearing a TLD ring badge while preparing radiopharmaceuticals.
 - d. Rule 9 of Appendix G requires that radioactive waste be disposed of only in specifically designated receptacles.

Contrary to the above, on June 2, 1983, a receptacle designated as non-radioactive "cold trash" contained radioactive materials in that a radiation level of seven milliroentgens per hour was identified by the NRC inspector at the surface of the receptacle.
 - e. Rule 10 of Appendix G requires that there be no pipetting by mouth.

Contrary to the above, on June 2, 1983, an NRC inspector observed evidence (hose) of mouth pipetting in Room 234, Ross Hall, and an individual admitted pipetting quantities of phosphorous-32 by mouth.

- f. Rule 11 of Appendix G requires surveys of generator, kit preparation, and injection areas after each procedure or at the end of the day.

Contrary to the above, as of June 1, 1983, documentation reviewed by an NRC inspector demonstrated that surveys were not performed on May 9 and 10, 1983 in the Nuclear Medicine areas and between June 18 to August 2, 1982, October 10 to November 8, 1982 and December 18, 1982 to January 31, 1983 in the Nuclear Cardiology areas.

Collectively, the above twelve violations have been evaluated as a Severity Level III problem (Supplements IV and VI).

(Cumulative Civil Penalty - \$2,500 - assessed equally among the violations.)

Evaluation of Licensee's Response

Licensee's Assertion: The NRC conclusion that there has been a significant breakdown in management oversight and control of the Radiation Safety Program (RSP) is unwarranted. Rather, a meritorious RSP exists, as demonstrated by the following:

- (1) Although the size of the program increased in the past three years, the number of personnel with radiation exposures exceeding low ALARA trigger levels decreased during that time. Also, of 800 thyroid bioassays performed during the same three-year period, only once was the ALARA trigger level exceeded.
- (2) An active radiation safety program exists for both students and workers, including on the job radiation safety training, three radiation safety courses for credit, and exams for research personnel who work with radioactive materials.
- (3) The Radiation Safety Office (RSO) has developed a calibration technique to provide more accurate indications of exposure levels when working with various isotopes. Further the RSO has developed a method of converting oil-soluble radioactive waste to stable oil-in-water emulsions so they may be disposed in a similar manner as is water-soluble radioactive waste.
- (4) An NRC licensing representative commended the security and precautions taken for the cesium irradiator.

NRC Response:

The NRC expects that individuals who work with radioactive materials will be appropriately educated and trained. Further, the NRC expects that licensees will take appropriate measures to ensure adherence to ALARA principles. Such actions on the part of a licensee are not considered extraordinary.

While the NRC recognizes the stated development of calibration techniques and waste-disposal methods as positive factors, the violations described in the Notice of Violation and Proposed Imposition of Civil Penalties cannot be considered reflective of a meritorious RSP.

The NRC staff maintains that the twelve violations do represent a significant breakdown in the control and oversight of the RSP. The staff's conclusions are based on the facts that:

- (1) Of the twelve violations described in the Notice, eight were identified by the NRC (Violations C, E2, E3a-E3f), demonstrating that management's monitoring of the RSP was not adequate to identify existing deficiencies.
- (2) Six of the violations involved program personnel disregarding program requirements (Violations E3a-E3f), demonstrating that adequate supervision to ensure acceptable personnel performance was not provided.
- (3) One of the violations (Violation A), involving failure to perform an adequate survey to determine the xenon-133 release in March 1982, at the boundary of a restricted area, was identified by the licensee in March, 1982, but was not adequately corrected until after the NRC inspection and enforcement conference, when an adequate survey was then performed, demonstrating that prompt and appropriate corrective action was not taken.
- (4) Three of the violations (Violations B, E3c, E3d) were similar to violations identified during an NRC inspection conducted in May 1980, demonstrating that actions to prevent recurrence were not effective.

Management is responsible for proper development of the RSP, including procedures and training, proper supervision of program implementation, and proper actions to correct improper program implementation, including actions to correct identified deficiencies, and actions to prevent recurrence including disciplinary actions.

Licensee's Assertion: The NRC's characterization of the violations in the aggregate as Severity Level III is inappropriate. The NRC Enforcement Policy defines Severity Level III as violations which have an actual or potential impact on the public. The NRC's characterization of the violations as a breakdown in management oversight and control appears to be analagous to the definition of a Severity Level IV violation, namely, degradation of management

control systems. The NRC Enforcement Policy further states that Severity Level IV problems are the sort of violations that, if left uncorrected, could lead to matters of significant concern.

NRC Response: Contrary to the licensee's assertions, the NRC Enforcement Policy (10 CFR 2, Appendix C) does not define a Severity Level III violation as one having a high actual or potential impact on the public. Rather, that is the definition of a Severity Level I or II violation, as defined in Section III of the NRC Enforcement Policy. In Section III, Severity Level III violations are defined as cause for significant concern. The twelve violations, representing a significant breakdown in management control of the RSP, are cause for significant concern since personnel failures to adhere to procedures were not identified, identified deficiencies were not promptly and effectively corrected, and previously identified deficiencies recurred. The problem is appropriately classified as Severity Level III and civil penalties are appropriate.

The NRC staff further notes that Violation B, involving improper disposal of radioactive waste, could itself be classified as Severity Level III in accordance with Section C.6 of Supplement IV of the NRC Enforcement Policy. However, the staff has decided to consider all twelve violations in the aggregate as Severity Level III, so that the emphasis of the civil penalty is placed on the underlying cause of the violations.

Licensee's Assertion: The NRC's allegations that corrective actions were not promptly taken when previous violations were noted by the NRC are incorrect. All violations identified during the NRC inspection conducted in May 1980, were promptly corrected.

NRC Response: Although the specific violations identified in May 1980 were corrected, the actions taken at that time to prevent recurrence were not effective since three of the violations (B, E3c, E3d) recurred. The staff's concerns are increased because one of the violations identified in 1980, involving placement of radioactive trash in the wrong containers, recurred not once, but twice, in January 1983 and again in June 1983.

Licensee Assertion: Many of the violations had been identified and corrected prior to the NRC inspection. Most of the remaining items had been identified and were being worked on by the Radiation Safety Committee.

NRC Response: Only four of the twelve violations were identified by the Licensee (Violations A, B, D, E1). The remaining eight violations were identified by the NRC. Additionally, Violation A, which occurred in March 1981, was not adequately corrected at the time of the inspection in June 1983. Further, three violations (B, E3c, E3d) were recurrences of previous violations, indicating that actions to prevent recurrence were not effective.

NRC Conclusion:

The violations did occur as originally stated and are appropriately classified in the aggregate as Severity Level III. Assessment of a \$2,500 civil penalty for these violations is appropriate. The information provided in the licensee's response does not provide a basis for modifying the enforcement action.