DEPARTMENT OF VETERANS AFFAIRS
Medical Center
2615 East Clinton Avenue
Fresno CA 93703

December 14, 1993

In Reply Refer To:
570/115

Docket No.: 030-01221
License No.: 04-01935-01

United States Nuclear Regulatory Commission
Region V
Attn: Gregory P. Yuhas
1450 Maria Lane
Walnut Creek, CA 94596-5368

Dear Mr. Yuhas:

We are in receipt of the notice of violation dated November 17, 1993 and regret the lapse in the regulatory requirements. Almost all the violations stated in the letter have been rectified and corrective actions were implemented as shown in the documents enclosed. The new Radiation Safety Officer began his employment on December 13, 1993.

We believe that we are in full compliance with regulations with our corrective actions. Please contact us if further clarification is necessary.

Sincerely

JAMES C. DENIRO
Director

Enclosures (6)

cc: United States Regulatory Commission
Attn: Document Control Desk
Washington, D.C.

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REPLY TO NOTICE OF VIOLATION

U.S. Nuclear Regulatory Commission
Region V
Attn: Gregory P. Yuhas
1450 Maria Lane
Walnut Creek, CA 94596-5368

Docket No.: 030-01221
License No.: 04-01935-01

Corrective action for each item in the Notice of Violation is listed below. As to the cause of the violations, we agree with Mr. Yuhas, who says in his letter of transmittal that "The root cause of the violations appears to be directly related to the lack of success in (our) efforts to replace the interim Radiation Safety Officer following the departure of the previous Radiation Safety Officer in June 1991." This situation has now been rectified with the hiring of Mr. Michael H. Farr, Ph.D., who began employment at this institution as of December 13, 1993. We are now in full compliance with all items listed in the Notice of Violation, with the exception of checking the Xe-133 trap. The trap will be checked the next time there is a patient exam using Xe-133, and a pending license amendment will propose an alternative schedule for checking the Xe-133 trap. The license amendment will be submitted within 30 days of the date of this reply.

Corrective Action to Individual Items:

A. Dose calibrator linearity will be tested at least quarterly, and after any service to the unit. The linearity of the dose calibrator was verified by the "decay method" between October 27, 1993 and October 30, 1993. Conditions for performing the linearity test by the "lineator method" were reviewed, and new initial factors for the "lineator method" were determined. One of the VAMC technologists was observed to perform the test by the "lineator method" with excellent results. A report of these tests is attached.

B. Dose calibrator accuracy will be tested, assaying at least two sealed sources, and after any service to the unit. Results of an accuracy test performed on October 27, 1993 are attached.

C. We propose to check the operation of the Xe-133 trap on the following schedule:

1. Each time there is a patient exam using Xe-133, the log will be checked to determined the most recent check of the trap.

2. If the time since the last check is greater than 30 days, the trap will be checked on that patient.

3. If the time since the last check is less than 30 days, the trap will not be checked on that patient.

We propose this schedule in an attempt to satisfy two contradictory requirements:

1. 10 CFR 35.205(e) requires that the trap be checked "each month."

2. On the other hand, the manufacturer's Operation Manual, (Biodex FN:90-189 4/93) page 8, specifies "Only perform the trap test when a patient is being tested on the system."

These two requirements are in conflict because it is common for several months to elapse without performing any Xe-133 exams. This proposed schedule is contained in a license amendment which is under preparation, and which will be submitted within 30 days of this letter.

In order to be sure that this schedule is adhered to, the instructions for the test, and the log of trap checks will be attached to the instrument. Furthermore, a 50 liter collection bag will normally be left, attached to the instrument exhaust, to remind the technologist to perform the test on each patient if needed.

There has not been a Xe-133 patient study since December 8, 1993, when the procedure for "acton level for checking Xe-133 trap effluent" was established. As soon as there is a patient exam using Xe-133, the trap will be checked. Instructions for performing the check, and the log sheet to be used, are attached to this reply.

D1. The detection efficiency and minimum detectable activity for the Iso-Data, Model 110 Gamma Counter was determined by the consulting physicist (report attached). A table is included in that report to convert CPM to DPM. Wipe samples from leak tests, and from area surveys will be counted in the Iso-Data, Model 110, and recorded in the appropriate units.

D2. The waste storage room will be surveyed weekly, including wipe tests for removable contamination. Wipe samples will be counted in the Iso-Data Gamma Counter, and reported in appropriate units.

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D3. Training will be provided to security and housekeeping personnel on the radiation safety topics described in Appendix A of Regulatory Guide 10.8, on an annual basis. A training session was held on November 4, 1993; an outline of the material covered in that training session is attached.

JAMES C. DENIRO
Director

cc: United States Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

DOSE CALIBRATOR LINEARITY

Model: Atom Lab 200
Calibrator S/N: 212001
Chamber S/N: 217013

1. The linearity of the dose calibrator was verified by the Decay Method between 10/27/93 and 10/30/93. A "best fit" line was determined, with the half life constrained to be 6.05 hours. The measured data were compared to the "best fit" line and the maximum deviations were found to be + 3.4% and - 3.3%. These are acceptable, according to Reg Guide 10.8, Revision 2, Appendix C.

2. New "Initial Factors" were determined for the Atomic Products Lineator device. These are shown on the attached worksheet, dated 10/27/93.

3. When performing the Lineator test, the same conditions should be duplicated each time.
   a) Tc-99m activity (outside of lineator) in the range of 35 to 55 mCi.
   b) Tc-99m total volume between 0.5 and 3.0 ml, contained in a 20 ml glass vial.
   c) Place the glass vial directly on the bottom of lineator tube "0".

4. VAMC technologist Steven Smitha was observed to perform the lineator test on 11/2/93, using the newly determined Initial Factors. The results were acceptable; a maximum deviation of 1.2% was observed.

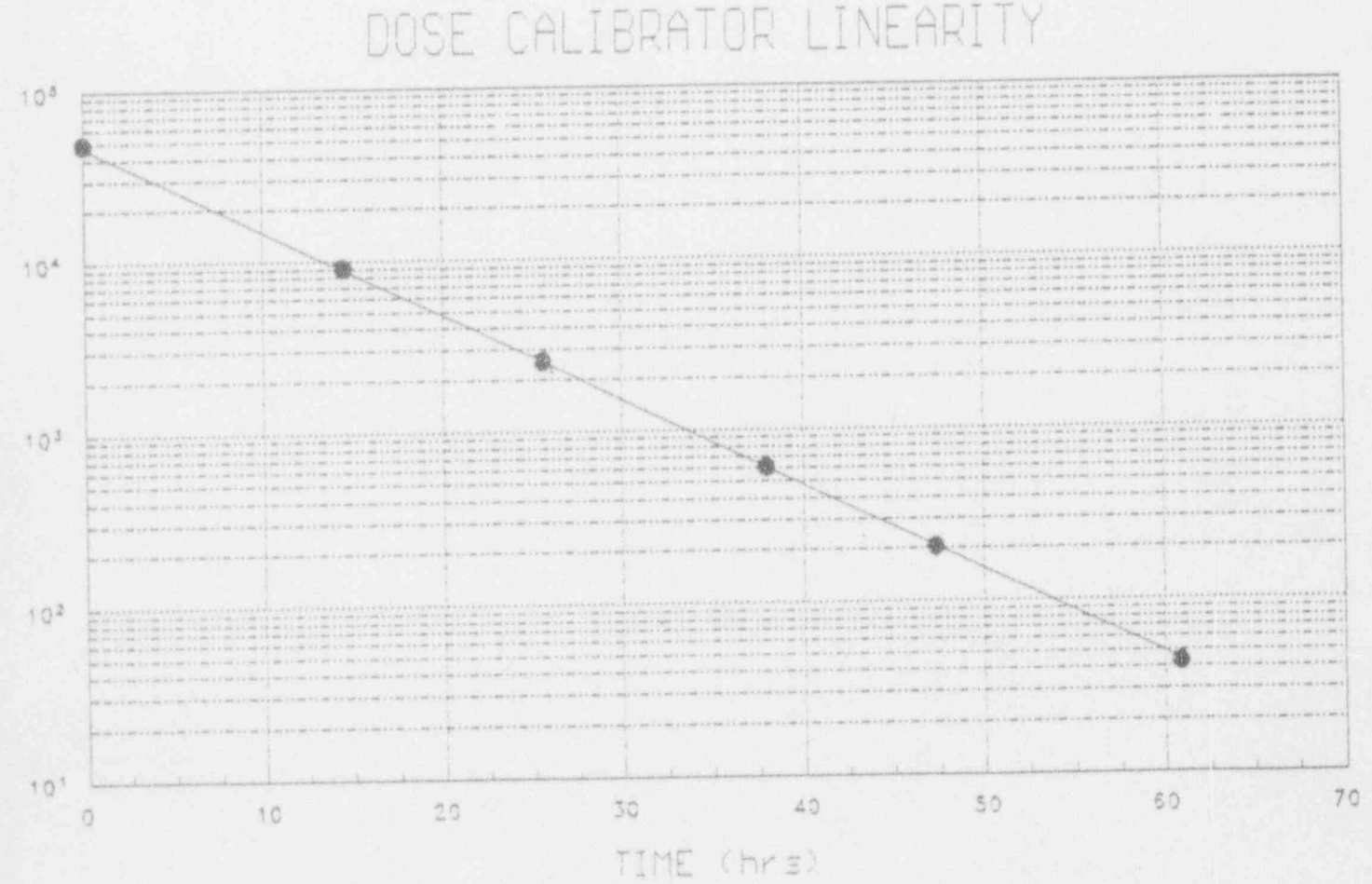
Wesley W. Wooten, Ph.D.
Consulting Physicist
11/8/93
date

Vishnu Bobba, M.D.
Radiation Safety Officer
11-10-93
date

DOSE CALIBRATOR LINEARITY TEST - DECAY METHOD

Model: Atom Lab 200
Calibrator S/N: 212001
Chamber S/N: 217013

Date	Time	Elapsed Time	Bkgnd	Assay	Fit	Deviation
10/27/93	5:14 pm	0.00 hr	.02 uCi	48.8 mCi	47.2 mCi	+.034
10/28/93	7:47 am	14.55 hr	.01 uCi	9.08 mCi	8.91 mCi	+.019
10/28/93	6:45 pm	25.52 hr	.02 uCi	2.56 mCi	2.54 mCi	+.009
10/29/93	7:11 am	37.95 hr	.04 uCi	606 uCi	610 uCi	-.007
10/29/93	4:30 pm	47.27 hr	.01 uCi	205 uCi	210 uCi	-.023
10/30/93	6:01 am	60.79 hr	.04 uCi	43.1 uCi	44.6 uCi	-.033



Wesley W. Wooten, Ph.D.
Consulting Physicist

11/8/93
date

Vishnu Bobba, M.D.
Radiation Safety Officer

11-10-93
date

NEW INITIAL FACTORS

APPENDIX C: WORK SHEET

Date: 10/27/93

Calibrator Serial No: 212001
Chamber Serial No 217013

Operator: Wesley Worten

Source: Tc-99m

ZERO (Background) Reading: 0.03 μCi

Range: Auto Ranging

Start Time: 5:07 PM

TUBE(S)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only	41.4 mCi	1	1	100
0 + A	12.20 mCi	3.393	3.393	—
0 + B	7.84 mCi	5.281	5.281	—
0 + AB	2.29 mCi	18.08	18.08	—
0 + C	1.226 mCi	33.77	33.77	—
0 + AC	0.368 mCi	112.5	112.5	—
0 + BC	0.235 mCi	176.2	176.2	—
0 + ABC	0.0701 mCi	590.6	590.6	—

Completion Time: 5:10 PM

Reviewed By
Raouf Bouha, MD
11-10-93

NOTES:

(1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.

(2) Values determined from intial calibration.

(3) % Ratios of entries: 100 x Col. (1)/Col. (2) If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

APPENDIX C: WORK SHEET

Date: 11/2/93

Calibrator Serial No: 212001 (Capintec S/N 217013)

Operator: Steven J. Smith

Source: ^{99m}Tc ~50.0 mCi in .63mL

ZERO (Background) Reading: 0.01 nCi

Range: Auto-Range

Start Time: 1255 Am

TUBE(S)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only	49.9	1	1	100
0 + A	14.64	3.408	3.393	100.4
0 + B	4.44	5.286	~~5.408~~ 5.281	~~97.7~~ 100.1
0 + AB	2.75	18.145	18.079	100.3
0 + C	1.460	34.178	33.772	101.2
0 + AC	0.443	112.641	112.486	100.1
0 + BC	0.281	177.580	176.056	100.8
0 + ABC	0.0841	593.341	590.667	100.4

Completion Time: 1258 Am

Reviewed By
Rao-Bolha
11-10-93

NOTES:

(1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.

(2) Values determined from intial calibration.

(3) % Ratios of entries: 100 x Col. (1)/Col. (2) If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

DOSE CALIBRATOR ANNUAL ACCURACY CHECK

Atomlab 200 Dose Calibrator
Model: 086-270
Serial No: 212001
Chamber Serial No: 217013

Source	Calib. Date	Calib. Activity	Current Activity	Dial Set	Bkgd	Assay	Error
Co-57	6/28/93	5.4 mCi	3.96 mCi	preset	0.2 uCi	4.05 mCi	+2.3%
Cs-137	7/19/83	204 uCi	160.9 uCi	preset	.07 uCi	158.2 uCi	-1.7%
Ba-133	3/19/81	251 uCi	110.6 uCi	7.7	.02 uCi	110.3 uCi	-0.3%

List of sources used:

Co-57:	DuPont	NES-206	S/N S206071-042 (borrowed from Syncor)
Cs-137:	New England Nuclear	NES-356	S/N 3560783A-12
Ba-133:	New England Nuclear	NES-358	S/N 3580381A-03

Calibration:
Wesley W. Wooten, Ph.D.
Consulting Physicist
date: 10/27/93

Reviewed:
Vishnu Bobba, M.D.
Radiation Safety Officer
date: 10-27-93

ACTION LEVEL FOR CHECKING Xe-133 TRAP EFFLUENT

Date of measurements: December 8, 1993

Camera used to measure bag: El Scint portable, model 409
Collimator removed

Acquisition parameters: 80 Kev, 5% window
Preset time 60 seconds

Preparation of standard:

1. 50 liter plastic bag filled with air and measured amount of Xe-133.

2. syringe before: 107 uCi
   syringe after: 21 uCi
   activity in bag: 86 uCi

   concentration in bag = 86 uCi / 50,000 ml
   = 1.72 x 10-3 uCi/ml

Observed counts:

1. Background counts: 8K

2. counts from standard: 1,590K

Calculation of action level:

The action level is based on the air being discharged from the trap reaching 1×10^{-5} uCi/ml

$$\text{Action level} = \frac{1 \times 10\text{-}5 \text{ uCi/ml}}{1.72 \times 10\text{-}3 \text{ uCi/ml}} \times 1{,}590\text{K counts}$$

= 9,000 CPM above background

Calibration:

Wesley W. Wooten, Ph.D.
Consulting Physicist
date: 12/11/93

Reviewed:

Vishnu Bobba, M.D.
Radiation Safety Officer
date: ~~Radv. Bobba~~ 12-13-93

V.A. Medical Center
Fresno, CA

Xe-133 TRAP CHECK

1. During a patient exam, collect the trap exhaust in a 50 liter plastic bag.

2. Count the bag directly in front of the El Scint, model 409 portable camera, with collimator removed and window set for 80 KeV, 5%. Use preset time = 60 seconds.

3. Count the room background with the same settings.

4. ACTION LEVEL:
   Net counts = (exhaust bag counts) - (room background counts)
   If the net counts exceeds 9,000 CPM the trap must be replaced.

Date	Background (a)	50 Liter Bag from patient (b)	Net counts (b) - (a)	Initial

V.A. Medical Center
Fresno, CA

REVIEW OF Xe-133 SPILLED GAS CLEARANCE TIME

Genesis Camera Room

V = mixing volume
= Genesis camera room + El Scint camera room + hot lab
= 6,460 ft^3
= 1.83×10^8 ml

Q = exhaust rate
= flow thru vents F, G, and half of the hood flow
= 75 + 120 + 1490/2 CFM
= 940 CFM
= 2.66×10^7 ml/min

A = maximum activity in spilled dose
= 7000 uCi

C = maximum permissible concentration in a controlled area
= 1×10^{-5} uCi/ml

t = clearance time

$$t = \frac{-V}{Q} \times \ln (C \times V/A)$$
= 9 minutes

Orbiter Camera Room

V = mixing volume
= Orbiter camera room + Treadmill room + hot lab
= 6,324 ft^3
= 1.79×10^8 ml

Q = exhaust rate
= flow thru vents L, P, and half of the hood flow
= 80 + 65 + 1490/2 CFM
= 890 CFM
= 2.52×10^7 ml/min

A = maximum activity in spilled dose
= 7000 uCi

C = maximum permissible concentration in a controlled area
= 1×10^{-5} uCi/ml

t = clearance time

$$t = \frac{-V}{Q} \times \ln (C \times V/A)$$
= 10 minutes

Wesley W. Wooten, Ph.D.
Consulting Physicist
Date 12/13/93

Vishnu Bobba, M.D.
Radiation Safety Officer
date 12-13-93

EMERGENCY PROCEDURES FOR Xe-133 SPILL

Leakage or Spill in the Radiopharmacy

1) Leave the radiopharmacy immediately.

2) Close the radiopharmacy door as you leave.

3) Ask a nearby person to call the Radiation Safety Officer, or place the call yourself if no one else is available.

4) Block the door to the radiopharmacy with tape, until the RSO arrives.

5) Because of the small size of the radiopharmacy, and high exhaust rate through the hood, the room need only be closed for about 5 minutes.

6) The RSO will monitor the room before re-entering.

Leakage or Spill in the Orbiter, or Genesis Camera Room

1. Evacuate the patient as soon as possible to the corridor.

2. Leave the Pulmonex running and switch to "washout" to draw contaminated air into the trap.

3. If possible, close off any other imaging rooms, but BE SURE TO LEAVE DOORS OPEN, LEADING TO THE HOT LAB HOOD. This will allow the hood to pull contaminated air out of the room where the spill occurred.

4. Call the RSO.

5. Use tape to warn other personnel from entering the area of the spill.

6. The air clearance time for either the Orbiter, or the Genesis camera room is 10 minutes. The RSO will monitor the room before personnel are allowed to re-enter.

DETECTION EFFICIENCY OF GAMMA COUNTER

Manufacturer: Iso-Data
Model: 110
Serial No: 8804020
Window: 15 - 1000 KeV

Date of Measurements: 11/24/93

1. Parameter settings on gamma counter
   Window: 15 - 1000 KeV
   Preset time: 1 minute
   Background limit: automatic

2. Sources used to determine detection efficiency

   A. I-129 (New England Nuclear)
      Serial No. NES-223-051485
      Calibration activity: 0.0147 microcuries (14 May 1985)
      Current activity: 0.0147 microcuries (24 November 1993)

   B. Cs-137 (Beckman Instruments)
      Serial No. 41119049
      Calibration activity: 0.1 microcurie (1 November 1984)
      Current activity: 0.081 microcurie (24 November 1993)

3. Measured Detection Efficiency

Source	Energy (KeV)	Dis/min	Photons/dis	Photons/min	Observed Cts/min	Detection Efficiency
I-129	35	32,600	0.78	25,400	16,950	0.67
Cs-137	662	180,000	0.90	162,000	43,350	0.27

4. Table of Conversion Factors
   Based on the measured detection efficiency at 35 KeV and 662 KeV, detection efficiencies are assumed at intermediate energies to prepare the attached table of conversion factors (disintegration per count).

5. Examples of How to Use the Table of Conversion Factors
   In all cases, the window must be the same as the window used for calibration (15 - 1000 KeV). On this machine, the background is subtracted automatically, and should be updated just prior to counting samples.

DETECTION EFFICIENCY OF GAMMA COUNTER

Manufacturer: Iso-Data
Model: 110
Serial No: 8804020
Window: 15 - 1000 KeV

Date of Measurements: 11/24/93

A. Consider a wipe from a sealed source of Co-57, which reads 150 CPM. Use the conversion factor for Co-57 from the table and multiply:

150 CPM x 2.13 disintegrations/count = 319 DPM

B. Consider a wipe from a counter top in one of the imaging rooms, which reads 250 CPM. In this case, you do not know which isotope might have caused the contamination, and you should use the highest value from the table. If the contamination could be either Tc-99m or Ga-67, you should use the conversion factor for Ga-67.

250 CPM x 2.70 disintegrations/count = 675 DPM

6. Minimum Detectable Activity

Minimum detectable activity is based on the updated background. We normally assume that the minimum detectable count rate is 3 standard deviations above the background countrate. The minimum detectable countrate in CPM can be converted to minimum detectable DPM, by the appropriate conversion factor from the table.

A typical background this instrument and this window is 500 CPM. For a 1.0 minute counting time the standard deviation is the square root of 500 = 22 CPM. Three standard deviations is 66 CPM, and for any isotope, this can be converted to DPM by using the appropriate conversion factor from the table. Two examples are given below:

Isotope	Minimum Detectable CPM	Minimum Detectable DPM	Minimum Detectable uCi
Cs-137	66	244	0.00011
Ba-133	66	49	0.000022

Calibration:
Wesley W. Wooten, Ph.D.
Consulting Physicist
date: 12/11/93

Reviewed:
Vishnu Bobba, M.D.
Radiation Safety Officer
date: 12-13-93

TABLE OF CONVERSION FACTORS
(DISINTEGRATIONS / COUNT)

Manufacturer: Iso-Data
Model: 110
Serial No: 8804020
Window: 15 - 1000 KeV

Date of Measurements: 11/24/93

Isotope	Energy (KeV)	Photons/dis	Assumed Detection Efficiency	Conversion Factor (Disintegrations per Count)
I-125	27-35	1.46	0.71	1.00
Tl-201	69-83	0.938	0.54	
	167	0.100	0.46	1.82
Co-57	122-136	0.962	0.49	2.13
Tc-99m	140	0.891	0.47	2.38
Gd-153	41-48	1.19	0.62	
	97-103	0.472	0.51	1.02
In-111	23-27	0.146	0.75	
	171	0.902	0.45	
	245	0.940	0.38	1.15
Ga-67	91-93	0.400	0.52	
	184-209	0.227	0.43	
	300	0.166	0.36	2.70
Ba-133	31-36	1.19	0.70	
	79-81	0.364	0.54	
	276-303	0.255	0.37	
	356-384	0.710	0.32	0.74
I-131	30	0.040	0.71	
	80	0.026	0.54	
	284	0.061	0.37	
	364	0.812	0.32	
	637	0.073	0.27	2.94
Cs-137	32	0.057	0.70	
	662	0.848	0.27	3.70

OUTLINE OF MATERIAL COVERED BY VIDEOTAPE AND LECTURE
Presented to Environmental Services, and Police
VAMC, Fresno, CA 11/4/94

A. Types of radiation
    1. Electromagnetic spectrum
    2. Ionizing and non-ionizing
    3. Natural background
    4. Difference between "radiation" and "radioactive material"

B. Where is ionizing radiation found in the hospital
    1. Exposure rate from all sources stored in radiopharmacy
    2. Exposure rate around portable x-ray machines
    3. Other areas of the hospital

C. Radioactive Materials License
    1. Contents of the license
    2. Available for inspection
    3. ALARA program
        a. Action levels
        b. Committment by hospital administration
        c. Committment by radiation safety committee
        d. Committment by radiation safety officer

D. Effects of ionizing radiation
    1. Tasteless, odorless, cannot be felt
    2. Radiation injury from massive doses
    3. Cancer risk about 1/10,000 per rem of radiation

E. Three ways to protect yourself from radiation
    1. Time
    2. Distance
    3. Shielding

F. The radiation symbol,
    1. "Radiation Area"
    2. "Radioactive Material"
    3. Shipping labels

G. Radiation accidents
    1. What to do if you find something with the radiation symbol in the trash, or other location
    2. If contamination is suspected, keep people from leaving or coming into the area. Get help
    3. In case of medical emergency or other disaster, treat the emergency or disaster first, then get help to evluate the radiation problem
    4. How to contact the Radiation Safety Officer, Nuclear Medicine Technologist on call, Radiologist on call.

H. Obligation to report unsafe conditions, to supervisor, Radiation Safety Officer, and to state Rad Health Branch if unresolved.

Wesley W. Wooten, Ph.D. — 11/11/93 date
Consulting Physicist

Vishnu Bobba, M.D. — 11-12-93 date
Acting RSO

SURVEY METER COMPARISON

Date of Measurements: 10/27/93

Technique:

1) 5 GM survey meters belonging to the VA Medical Center, Fresno, California, and 1 GM survey meter belonging to Saint Agnes Medical Center, were compared.

2) The source geometry was a 10 mCi of Co-57 in a 50 cm disk (normally used for camera flood field evaluation).

Model: NES 8012
S/N: 8012483-03
Calibration Activity: 10 mCi
Calibration Date: 8/31/93
Current Activity : approx 8.7 mCi

3) Meters were placed, one by one, at a distance of 1.0 meter from the center of the disk source and read.

Results:

Meter	Model	S/N	Probe	S/N	mR/hr
1) Ludlum	2	87767	44-9	083938	2.0
2) Ludlum	3	73009	44-9	067468	3.0
3) Nuclear Chicago	2650	2236	-----	-------	1.5
4) Dosimeter Corporation	3700	2919	-----	-------	2.0
5) Technical Associates	TBM-3	099087	-----	-------	1.8
6) Victoreen Thyac III	490	4819M	-----	-------	1.8

Conclusion:

1) Meters 2) and 3) should be taken out of service and sent for calibration. A dedicated check source should be sent with the meter. The calibration laboratory should label the instrument with the check source reading at the time of calibration.

2) The other meters are acceptable for use until the next scheduled recalibration for each meter. Each meter was labelled with the check source reading at the time of the intercomparison.

Wesley W. Wooten, Ph.D.
Consulting Physicist

11/4/93
date

Rao Bohba

Vishnu Bohba, M.D.
Radiation Safety Officer

11-10-93
date