NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Lehigh Valley Hospital Center
1200 South Cedar Crest Blvd.
Allentown, PA 18105

TELEPHONE NO.: AREA CODE (215) 776 8100

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Carmine A. Pierno, M.S.

TELEPHONE NO.: AREA CODE (215) 776 8385

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 37-16238-01

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Donald E. Morel, M.D.
Stuart A. Jones, M.D.
Robert J. Rienzo, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Carmine A. Pierno, M.S.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	10
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	8000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	60
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	20
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

RECEIVED BY LFMB
Date 4/25/85
Log Apple 13 I
By Brown
Orig. To
Action Compl. 4/29/85

Applicant
Check No. 153895 #580-7C
Amount/Fee Category
Type of Fee Renewal
Date Check Rec'd 4/25/85
Received By Brown

"OFFICIAL RECORD COPY"
ML18 03697

NRC FORM 313M (9-81)

8510290513 850918
REG1 LIC30
37-16238-01 PDR

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: Oct. 1980

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments: on file license #37-01548-01 *(Check One)*
	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. & Co.	Monthly
		TLD		
	X	OTHER (Specify)	Pocket dosimeter, manufactured by Nuclear Associates, Inc.	See Below
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Co.	
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Pocket dosimeters with a range from 0 to 200 mR are used by the Nuclear Medicine technologists in addition to their film badges. Extra dosimeters are kept for emergency situations. The dosimeters are calibrated annually (procedure form attached under Item 24).

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: Human Use of Byproduct Material - Category C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Richard Manges

(2) TITLE
Vice President

c. DATE
4/12/85

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

ITEM 7·

A. Responsibility and Duties of the Radiation Safety Committee

As required under 35.11 of 10 CFR Part 35, the Hospital maintains a Radiation Safety Committee which conforms to the responsibilities and duties outlined in Appendix B of Regulatory Guide 10.8 Revision 1.

B. Meeting Frequency

The Radiation Safety Committee meets on a quarterly frequency.

C. Members of Radiation Safety Committee

Name	Specialty
Michael Geller, M.D. Chairman, Department of Radiology	Radiologist, Certified by The American Board of Radiology (Chairman of Radiation Safety Committee)
Donald E. Morel, M.D. Director of Nuclear Medicine	Internist, Nuclear Medicine Specialist, Certified by The American Board of Internal Medicine and The American Board of Nuclear Medicine
Carmine A. Pierno, M.S. Department of Radiology and Nuclear Medicine	Radiologic Physicist and Radiation Safety Officer
Paul Nurick Assistant Administrator	Representative of the Hospital's Management
Nancy O'Connor, R.N. Nursing Director for Cardiology	Representative of the Nursing Staff
Stephen Hiss, B.S. R.T. Radiology Administrative Coordinator	Representative of Department of Radiology
John Kohler, R.T. C.N.M.T. Chief Technologist, Nuclear Medicine	Representative of Department of Nuclear Medicine
Hugh Gallagher, M.D. Cardiologist	Representative of Cardiac Catheterization Lab
Sara Jane Parker Cardiac Catheterization Lab Administrative Coordinator	Representative of Cardiac Catheterization Lab

ITEM 8

Users

Donald E. Morel, M.D.

NRC Form 313M Supplement A and B on file under NRC Licenses 37-16238-01 and 37-01548-01.

Stuart A. Jones, M.D.

NRC Form 313M Supplement A and B on file under NRC Licenses 37-16238-01 and 37-01548-01. Please update Dr. Jones authorized use of groups IV and V of licensed material in accordance with the letter dated May 24, 1984, License Number 37-0154-01 Amendment Number 49.

Robert J. Rienzo, M.D.

NRC Form 313M Supplement A and B on file under NRC Licenses 37-16238-01 and 37-01548-01. Please update Dr. Rienzo authorized use of groups IV and V of licensed material in accordance with the letter dated May 24, 1984, License Number 37-0154-01 Amendment Number 49.

Radiation Safety Officer

Mr. Carmine A. Pierno, M.S.

NRC Form 313M Supplement A on file under NRC Licenses 37-16238-01 and 37-01548-01.

ITEM 9

1. Survey Meters

   a. Manufacturer's Name: Victoreen
      Manufacturer's Model No.: 6B
      Number of Instruments Available: 3
      Minimum Range: 0 mR/hr to 0.5 mR/hr
      Maximum Range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's Name: Victoreen
      Manufacturer's Model No.: 470A
      Number of Instruments Available: 1
      Minimum Range: 0 mR/hr to 3 mR/hr
      Maximum Range: 0 mR/hr to 1000 mR/hr

   c. Manufacturer's Name: EON
      Manufacturer's Model No.: 474173
      Number of Instruments Available: 2
      Minimum Range: 0 mR/hr to 0.5 mR/hr
      Maximum Range: 0 mR/hr to 50 mR/hr

   d. Manufacturer's Name: Texas Nuclear
      Manufacturer's Model: Log Seriers Ion Chamber
      Number of Instruments Available: 1
      Minimum Reading: 0.2 mR/hr
      Maximum Reading: 2000 mR/hr

   e. Manufacturer's Name: Mini Instruments
      Manufacturer's Model: Type 510 GM Meter
      Number of Instruments Available: 1
      Minimum Reading: 0 counts/second
      Maximum Reading: 2000 counts/second

2. Dose Calibrators

   a. Manufacturer's Name: Capintec
      Manufacturer's Model No.: CRC 30
      Number of Instruments Available: 1

   b. Manufacturer's Name: Medotopes
      Manufacturer's Model No.: 238-2 Assay Unit
      Number of Instruments Available: 1

3. Instruments Used for Diagnostic Procedures

	Type of Instrument	Manufacturer's Name	Model No.
a.	Dual Probe Rectilinear Scanner	Ohio Nuclear	Series 84
b.	Gamma Camera	Technicare	Sigma 438 HR
c.	Whole Body Gamma Camera	Technicare	Sigma 438 HR
d.	Gamma Camera with Computer	Baird	Model 77
e.	Portable Gamma Camera	Technicare	Sigma 420
f.	Thyroid Uptake Probe	Canberra	Series 35
g.	Multi-Channel Analyzer and Well	Canberra	Series 35
h.	Computer	Technicare	Model 560
i.	Computer	Digital	Gamma 11/PDP 11/34

4. Area Monitor

Manufacturer's Name: Victoreen
Manufacturer's Model No.: 808D Area Monitor
Number of Instruments Available: 1
Minimum Reading: 0.1 mR/hr
Maximum Reading: 100 mR/hr

ITEM 10

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

__X__ First elution from new Mo-99/Tc-99m generator

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	4.9	±3.9%
Ba-133	0.1-0.5	0.163	±5%
Cs-137	0.1-0.2	0.195	±4.0%
Ra-226	1-2		

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

__X__ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

D. Dose Calibrator: 1. Capintec
Model CRC-30

2. Medotopes
Model 238-2

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III. METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to a accuracy of ± 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument Linearity (at installation and quarterly thereafter).

2. Geometrical variation (at installation).

3. Instrument Accuracy (at installation and annually thereafter).

4. Constancy (at installation and daily thereafter).

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. TEST OF INSTRUMENT LINEARITY

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of ^{99m}Tc whose activity is equivalent to the maximum anticipated activity to be assayed (e.g.; the first elution from a new generator).

USE EITHER OF THE FOLLOWING TWO METHODS

METHOD #1

1. Assay the ^{99m}Tc vial in the dose calibrator and subtract background level to obtain net activity in millicuries.

2. Repeat Step #1 at time intervals of 6, 24, 30 and 48 hours after the initial assay. Record all results on the 'Quarterly Instrument Linearity Check' sheet (See Page #6A for the work sheet).

3. Using the 30 hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24 and 48 hours using the following table:

Assay Time (hrs.)	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

4. Plot the measured net activity for each time interval and the ± 5% predicted activity versus the time interval on semi-log graph paper.

5. The activities plotted should be within the ± 5% activity range if the instrument is linear and functioning properly. Errors greater than ± 5% indicate the need for repair or adjustment of the instrument.

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NUCLEAR MEDICINE &/OR NUCLEAR CARDIOLOGY

QUARTERLY INSTURMENT LINEARITY CHECK

Instrument: _____ Date: _____

Assay Time	Measured Activity	Correction Factor	Predicted Activity	- 5% Predicted Activity	+ 5% Predicted Activity
0		32			
6		16			
24		2			
30		1			
48		0.125			

Check performed by: _____

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METHOD #2

Linearity will be checked with the Model #086-507 'Lineator' manufactured by Atomic Products Corporation. Test results will be maintained on forms similar to those provided in the manufactures instruction manual. The test will be performed as per the instruction manual. Calculated ratios should by within ± 5% of the initial factor. Ratios outside of 0.95 - 1.05 indicate the need for repair or adjustment of the instrument. If the instrument linearity cannot be corrected, it will be necessary to apply a correction factor (CF) for the amount of activity being measured.

1. Using the 'Lineator Device' by Atomic Products and a vial of ^{99m}Tc whose activity is equivalent to the maximum anticipated activity to be assayed (i.e.: the first elution from a new generator), follow the instructions in the procedure manual and record all results on the 'Linearity Work Sheet' (See Page #7A for the Work Sheet).

D. TEST FOR GEOMETRICAL VARIATION

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e.; greater than ± 2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, a 30cc vial containing 2 mCi of ^{57}Co or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20 and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake the vial to mix the contents and repeat the assay as in Step #1.

3. Select one volume as a standard, and calculate the ratio of measured activities for each volume to the reference volume activity. The answer represents the volume correction factor (CF) to be utilized.

   Example: If activities of 2.04, 2.02 and 2.00 mCi are measured for 4, 8 and 10 ml volumes and 10 ml is the reference volume selected,

$$4 \text{ ml volume CF} = \frac{2.00}{2.04} = 0.98$$

LINEATOR WORK SHEET

DATE: _____

CALIBRATOR SERIAL #: _____

TECHNOLOGIST'S NAME: _____

SOURCE: _____

ZERO (Background) Reading: _____

Range: _____

Start Time: _____

Tube(s)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only		1	1	100
0 + A				
0 + B				
0 + AB				
0 + C				
0 + AC				
0 + BC				
0 + ABC				

Completion Time: _____

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 the initial 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.

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4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x CF

   where the correction factor (CF) used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of ^{57}Co in a syringe may be compared with that of 10ml in a 30cc vial and a correction factor may be calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides, such as, ^{125}I. Hence, adequate correction factors must be established for this type of syringe.

   An alternate to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

E. TEST FOR INSTRUMENT ACCURACY

Check the accuracy of the dose calibrator for several radionuclides such as ^{137}Cs, ^{57}Co and ^{133}Ba using appropriate reference standards whose activity is traceable to NBS. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower-energy reference standards (^{99m}Tc, ^{133}Xe and ^{125}I) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain net activity.

2. Repeat Step #1 for a total of three (3) determinations, and average the results.

3. The average activity determined in Step #2 should agree with the certified activity of the reference source within ± 5% after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Record all results on the 'Yearly Instrument Accuracy Check' sheet. (See Page #8A for work sheet).

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NUCLEAR MEDICINE &/OR NUCLEAR CARDIOLOGY

YEARLY INSTRUMENT ACCURACY CHECK

Instrument: _____ Date: _____

^{133}Ba Check Source:

Count #	Net Measured Activity	Average for the 3 counts
1		
2		
3		

Average Activity	Predicted Activity	- 5% Predicted Activity	+ 5% Predicted Activity

^{137}Cs Check Source:

Count #	Net Measured Activity	Average for the 3 counts
1		
2		
3		

Average Activity	Predicted Activity	- 5% Predicted Activity	+ 5% Predicted Activity

^{57}Co Check Source:

Count #	Net Measured Activity	Average for the 3 counts
1		
2		
3		

Average Activity	Predicted Activity	- 5% Predicted Activity	+ 5% Predicted Activity

Check performed by: _____

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6. Calibration checks that do not agree within ± 5% indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated with NBS-traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (^{137}Cs, ^{131}I, ^{99m}Tc, ^{125}I, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more NBS-traceable standards. Keep a log of these initial and subsequent readings.

F. TEST FOR INSTRUMENT CONSTANCY

1. Daily, before using the instrument, measure and record the activity of at least one reference source. This check should be repeated during the day whenever sample readings are not within ± 10% of the anticipated assay. Variations greater than ± 5% in this test will indicate the need for instrument repair, adjustment or recalibration.

   a.) In the Nuclear Medicine and Nuclear Cardiology laboratories, we measure and record (in the Dose Calibrator Log Book) the activity of the following reference sources:

   i.) ^{57}Co
   ii.) ^{133}Ba
   iii.) ^{137}Cs

2. Measure and record the apparent activity of a long-lived standard radionuclide at all the commonly used radionuclide settings. Choose a source with activity in the 100 uCi range.

   a.) In the main laboratory, measure and record (in the Dose Calibrator Log Book) the apparent activity of the ^{133}Ba reference standard at the following settings:

   i.) ^{99m}Tc
   ii.) ^{67}Ga
   iii.) ^{131}I
   iv.) ^{133}Xe
   v.) ^{201}Tl
   vi.) ^{111}In

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b.) In the Nuclear Cardiology laboratory, measure and record (in the Dose Calibrator Log Book) the apparent activity of the ^{133}Ba reference standard at the following settings:

i.) ^{99m}Tc

ii.) ^{201}Tl

3. Variations greater than ± 5% from the predicted activity indicates the need for instrument repair or adjustment.

4. Repeatedly throughout the day investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

5. Repeatedly throughout the day inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacture's instructions).

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ITEM 11

A. The Mo-99/Tc-99m generator systems, which are being utilized, are stored in a recessed lead lined counter in the Hot Lab. The generator systems are surrounded by a cylindrical lead shield 13/16" thick and placed in a recessed counter that is shielded with 1/16" of lead. The generator systems are eluted by means of an evacuated vial which is placed in a lead container. The Tc-99m is removed from the lead container for assay by means of a remote handling service. This procedure takes place behind a 12/16" lead wall which provides protection for the technologist.

B. All radiopharmaceuticals are stored in lead storage vials. The radiopharmaceuticals which do not require refrigeration are placed behind a 2" lead cove located in the fume hood of the Hot Lab. The radiopharmaceuticals requiring refrigeration are placed in a 1/18" lead lined refrigerator in the Hot Lab.

C. All radioactive waste, used Mo-99/Tc-99m generators, old calibration sealed sources, and gamma camera flood sources are stored in the Decay Storage Room, which is next to the Hot Lab. All radioactive solid waste is held until decay to background levels, and the waste is surveyed to assure background levels before being disposed. Liquid radioactive waste is generally decayed to background prior to disposal to the sanitary sewer system and disposal through the sewer system will be in accordance with regulations set by 10 CFR 20. The Decay Storage area is approximately 50 square feet which provides sufficient storage space for accumulation of used Mo-99/Tc-99m generators and radioactive waste.

D. Preparation of kit radiopharmaceuticals and the dispensing of radiopharmaceuticals are conducted behind an L-shaped protective lead barrier equipped with lead glass for viewing. This barrier is located in the fume hood of the Hot Lab. Remote handling tools, lead vials, and syringe shields.

E. The Nuclear Medicine Department is located on the ground floor of the Hospital. The ceiling is provided with approximately 6" of concrete which provides sufficient shielding to the rooms above. The outside walls of the Decay Storage area, Hot Lab and Camera Rooms are provided with 12" of concrete. The inside walls of the Decay Storage area and the Hot Lab (including door of Hot Lab) are constructed with 1/16" of lead which provides sufficient shielding. The imaging rooms are provided with adequate space to allow the technologists a distance of 6' between themselves and the patient.

F. All diagnostic studies requiring the use of Xe-133 are performed in the camera rooms. The camera rooms are kept under a constant negative pressure. The exhaust flow rates in these rooms exceed the required flow rates needed to keep the release of Xe-133 below the requirements of 10 CFR Parts 20.103 and 20.106. Item 21 provides detailed information on the airflow rates and use of Xe-133.

G. The Nuclear Cardiology Department is located on the third floor of the Hospital. The floors and ceiling are provided with 4" of concrete which provides sufficient shielding to the rooms above and below. The imaging room is provided with adequate space to allow the technologist a distance of 1 meter between themself and the patient.

ITEM 11
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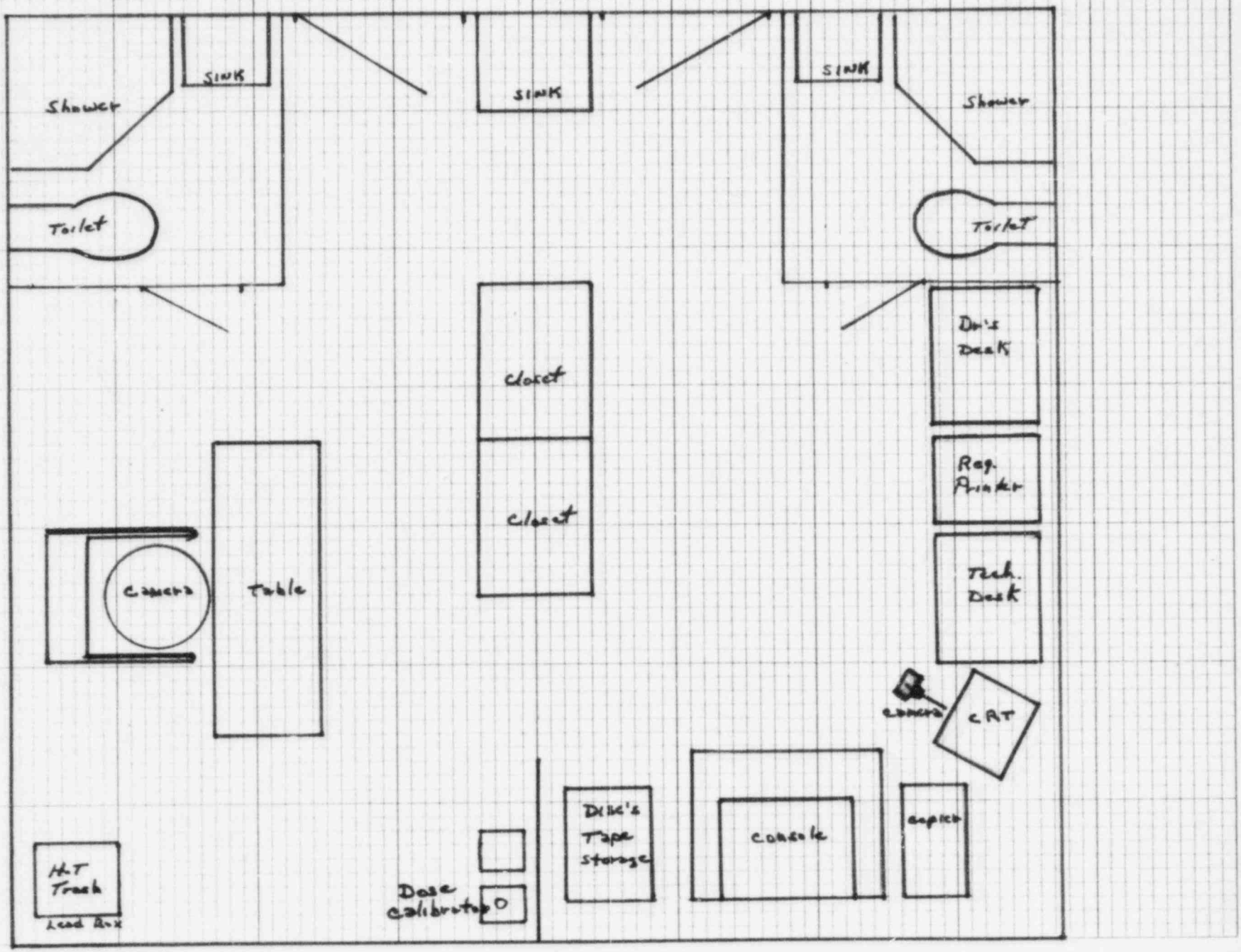
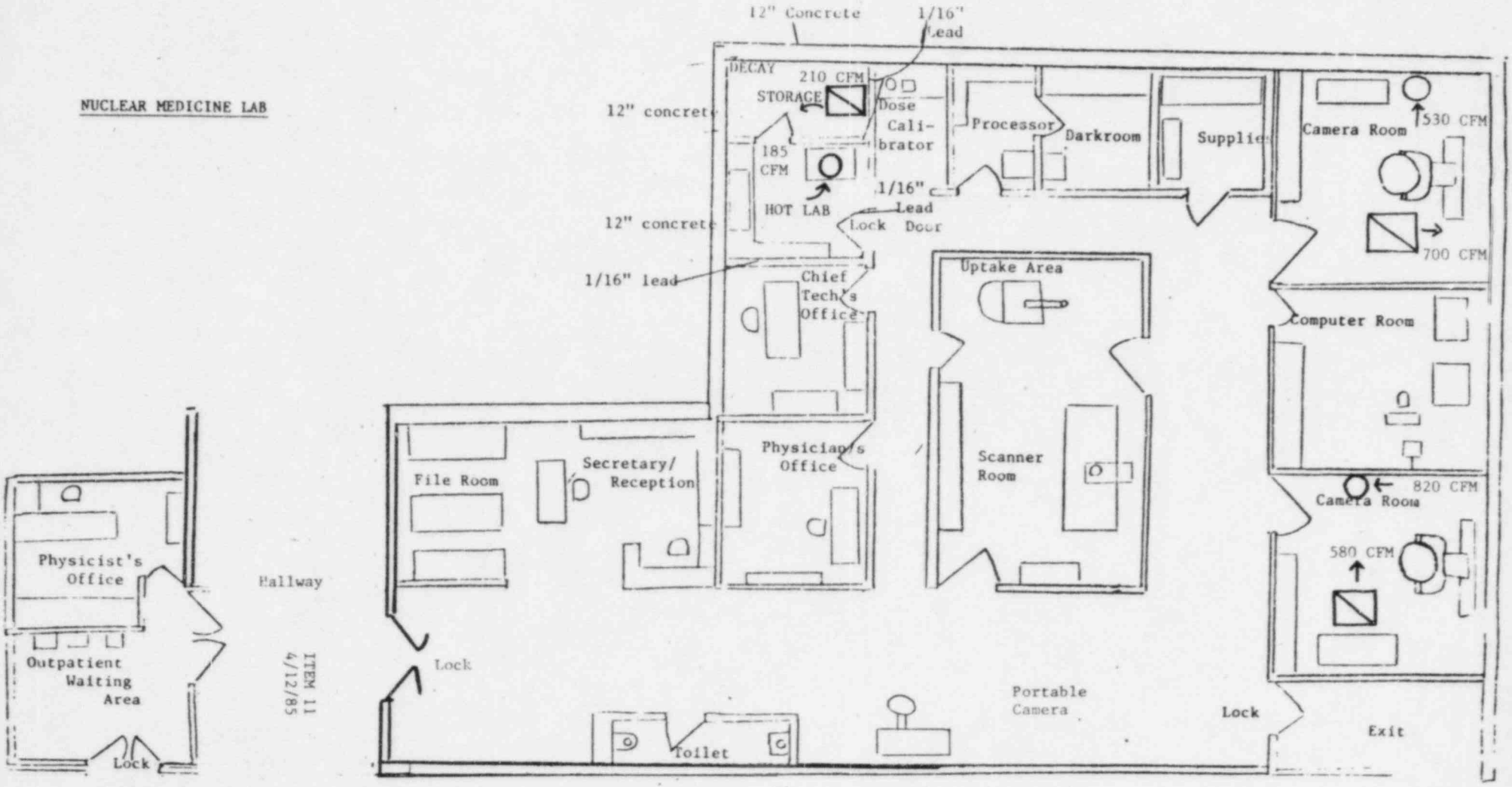
scale
0' 1' 2' 3' 4' 5' 6' 7' Approximate (+-6")

Nuclear Cardiology 3C-01,02



ITEM 11
4/12/85

NUCLEAR MEDICINE LAB



ITEM 12

PERSONNEL TRAINING PROGRAM

Radiation workers are instructed in storage, transfer, and use of radioactive materials on annual basis or whenever significant changes in regulations, duties, or license conditions occur. All aspects of 10 CFR 19 are covered including storage, potential radiation hazards, safety procedures, limitations and conditions of our license, obligations for reporting unsafe conditions, workers rights for requesting an NRC inspection, response to emergencies or unsafe conditions, areas where licensing conditions and pertinent regulations are posted, and employee protection. Sections of 10 CFR 20 and a general review of radiation protection principles are also covered.

Access to the Hot Lab and Decay Storage area is restricted to Nuclear Medicine personnel. Clerical, nursing, housekeeping, and security personnel are prohibited from these areas.

IV. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

A. Ordering of Radioactive Materials

1. The Chief and/or Senior Technologist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded (See NRC and PA State licenses).

2. For therapeutic material, a written request will be obtained from the Physician who will perform the procedure. This request will indicate Radionuclide, compound and activity. This request will be referenced when placing the order, receiving and before administration of the radionuclide.

B. Receiving Radioactive Material

1. During Normal Working Hours

a.) Carriers will be instructed to deliver radioactive packages to either the Storeroom and/or the Nuclear Medicine department.
b.) The Storeroom personnel and/or the Nuclear Medicine department personnel will sign for the delivery of the package(s).

2. During Off-duty Hours

a.) Security personnel will accept delivery of the radioactive package(s) in accordance with the following procedures:
i.) Any package(s) containing radioactive materials that arrive between 5:00 p.m. and 7:00 a.m. or on weekends shall be delivered directly to the Nuclear Medicine department by the carrier accompanied by security.
ii.) If the package(s) is wet and/or damaged, immediately contact the following personnel at the telephone numbers listed below.
iii.) Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.
iv.) If the package(s) are <u>not</u> wet and/or damaged, then deliver the package(s) to the Nuclear Medicine department.
v.) Unlock the door, place the package(s) on the counter-top in the Secretary/Reception area. When leaving relock the laboratory.

The first person to contact is the:
RADIATION SAFETY OFFICER: Mr. Carmine Pierno
Home Phone Number -- 261-1503

The second person to contact is the:
CHIEF TECHNOLOGIST: Mr. John Kohler
Home Phone Number -- 821-8582

<u>or the:</u>
SENIOR TECHNOLOGIST: Mr. Bernard Valasek
Home Phone Number -- 797-0594

C. Procedures for Safely Opening Packages Containing Radioactive Material (Record all information on the RADIONUCLIDE SHIPMENT RECEIPT REPORT form - See Page # 12A)

1. PUT ON DISPOSABLE GLOVES !

2. Visually inspect the package(s) for any sign of damage (i.e.; wetness, crushed, etc.). If damage is noted, stop the procedure and notify the Radiation Safety Officer and the Chief and/or Senior Technologist at the following telephone numbers:

   RADIATION SAFETY OFFICER: Mr. Carmine Pierno
   Home Phone Number -- 261-1503
   Pager Number -- 160

   CHIEF TECHNOLOGIST: Mr. John Kohler
   Home Phone Number -- 821-8582
   Pager Number -- 547

   SENIOR TECHNOLOGIST: Mr. Bernard Valasek
   Home Phone Number -- 797-0594

3. Measure the exposure rate at 1 meter (approximately 3 feet) from the package surface. If the exposure rate is 10 mR/hr, stop the procedure and notify the Radiation Safety Officer and the Chief and/or Senior Technologist.

4. Measure the exposure rate at the package surface. If the exposure rate is 200 mR/hr, stop the procedure and notify the Radiation Safety Officer and the Chief and/or Senior Technologist.

5. Open the outer package and remove the packing slip. Open inner package to verify the contents (compare the packing slip and the label on the vial), and check integrity of the final source container (inspecting for breakage of seals or vials, loss of liquid or discoloration of packaging material). Check also that the shipment does not exceed our possession limits.

6. Wipe the external surfaces of the shipping carton and the final source container with a cotton swab moistened with alcohol. Count the swipes in the well counter and record the results.

7. Monitor the packing material and package for contamination before discarding.

   a.) If contaminated, treat as radioactive waste.

   b.) If not contaminated, obliterate the radiation labels before discarding to the regular trash.

IN ALL THE ABOVE PROCEDURES, TAKE PRECAUTIONS AGAINST THE SPREAD OF CONTAMINATION AS NECESSARY !

ITEMS 13 and 14
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RADIONUCLIDE SHIPMENT RECEIPT REPORT

1. P.O. # _____ Survey Date: _____ Time: _____

   Technologist's Name: _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ Punctured _____ Wet _____ Other

   If 'Other' - describe: _____

3. RADIATION UNITS ON LABEL: _____ uCi / mCi / Ci (circle one)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mRem/hr

   b. 1 meter (3 feet) from surface _____ mRem/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide: _____ yes _____ no, difference: _____

   b. Amount: _____ yes _____ no, difference: _____

   c. Chemical form: _____ yes _____ no, difference: _____

6. WIPE RESULTS FROM: EFFICIENCY = _____%

   a. Outer: _____ CPM = _____ DPM = _____ uCi

   b. Final source container: _____ CPM = _____ DPM = _____ uCi

   FOR $^{99}Mo/^{99m}Tc$ GENERATORS ONLY: ^{99}Mo EFFICIENCY = _____%

   c. ^{99}Mo outer: _____ CPM = _____ DPM = _____ uCi

   d. ^{99}Mo final source container: _____ CPM = _____ DPM = _____ uCi

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS: _____ mRem/hr

8. DISPOSITION OF PACKAGE AFTER INSPECTION: _____

9. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED:
   _____ Yes (Use other side of this form)

10. LOCATION OF PACKAGE: _____ Outside Hot Lab; _____ Inside Hot Lab

    _____ Outside Bathroom; _____ On counter @ Sec/Recep. Area

    _____ Other - describe: _____

ITEMS 13 and 14
4/12/85

_____ _____
Signature Date

LEHIGH VALLEY HOSPITAL CENTER

M E M O R A N D U M

DATE: March 18, 1985

TO: William Huber

RE: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrives between 5 p.m. and 7 a.m. or on weekends shall be signed for by the security guard on duty and the guard should immediately escort the delivery person to the Nuclear Medicine Department. The security guard should unlock the Nuclear Medicine Department and let the delivery person place the package on top of the counter to the left side of the room. Upon leaving the Nuclear Medicine Department, the door should be relocked.

If the package is wet or damaged upon delivery, immediately contact the Radiation Safety Officer or Chief Technologist at the telephone numbers below. Ask the carrier to remain at the Hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Radiation Safety Officer: Mr. Carmine A. Pierno
Home Telephone Number: 261-1503

Chief Technologist: Mr. John Kohler
Home Telephone Number: 821-8582

Carmine A. Pierno
Radiologic Physicist

cc: Donald Morel, M.D.
John Kohler, R.T.
Paul Nurick

CAPled

ITEMS 13 and 14
4/12/85

LEHIGH VALLEY HOSPITAL CENTER

M E M O R A N D U M

DATE: March 18, 1985

TO: William Dieruff

RE: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrives at the storeroom during the day shall be signed for and immediately transported by hand truck or cart (not carried) to the Nuclear Medicine Department. The package should be left outside the Hot Lab, and one of the technologists should be notified that the material has arrived.

If the package is wet or damaged, immediately contact the Nuclear Medicine Department at extension 8383. Ask the carrier to remain at the Hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Carmine A. Pierno
Radiologic Physicist

cc: Donald Morel, M.D.
John Kohler, R.T.

CAPled

ITEMS 13 and 14
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V. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

A. All Personnel

1. Wear long sleeve 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. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as a pediatric patient, when their use would compromise the patient's well-being.

4. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored and/or used.

5. 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%.

6. Wear personnel monitoring devices (film badges and pocket dosimeters) at all times while in areas where radioactive materials are used and/or stored.

7. Wear TLD finger badges during the elution of generators and preparation, assay and injection of all radiopharmaceuticals.

8. Dispose of radioactive waste only in specially designated receptacles.

9. Never pipette by mouth.

10. Survey generator, kit preparation and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

11. Confine radioactive solutions in covered containers plainly identified and labeled with the name of the radionuclide, date, activity at time of assay, time of assay and radiation level, if applicable.

12. Always transport radioactive material in shielded containers.

13. Monitor hands for contamination when leaving the 'Hot Lab' after elution of the generators, drawing up of doses and after preparation of kits.

VI. EMERGENCY PROCEDURES

A. Minor Spills

1. NOTIFY: Notify all personnel that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves ! Carefully fold the absorbent paper and place it in a plastic bag. Using paper towels and Radiacwash, clean the area. Place all paper towels and the gloves into the plastic bag.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, your hands and clothing for contamination. If contamination is present, repeat Step #3 until radiation readings approximate background readings for that area.

5. REPORT: Report the incident to the Radiation Safety Officer and the Chief and/or Senior Technologist.

B. Major Spills

1. CLEAR THE AREA: Notify all personnel that a major spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel that are potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer and the Chief and/or Senior Technologist immediately.

6. PERSONNEL CONTAMINATION: Contaminated clothing should be removed and placed in a plastic bag for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash the area with mild soap and lukewarm water.

7. CLEAN UP & SURVEY: The Radiation Safety Officer and/or the Chief and/or Senior Technologist will direct the clean-up and surveying of the area and any contaminated personnel.

RADIATION SAFETY OFFICER: Mr. Carmine Pierno
Home Phone Number -- 261-1503
Pager Number -- 160

CHIEF TECHNOLOGIST: Mr. John Kohler
Home Phone Number -- 821-8582
Pager Number -- 547

SENIOR TECHNOLOGIST: Mr. Bernard Valasek
Home Phone Number -- 797-0594

VII. AREA SURVEY PROCEDURES

A. Daily

1. All elution, preparation and injection areas will be surveyed daily with a low-range, thin-window G-M survey meter and decontaminated if necessary.

2. The trash can in the 'Hot Lab' will be monitored at the end of the day, before the trash is disposed of. If the reading is higher than background, the trash will be placed in the decay locker until it decays to approximately background level.

B. Weekly

1. All laboratory areas will be surveyed weekly.

2. The weekly survey will consist of the following:

a.) A measurement of the radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

b.) A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 cts/min/100 cm^2 above background count for the contaminate involved.

3. A permanent record will be kept of all survey results, including negative results. The record will include:

a.) Location, date and type of equipment used.

b.) Name of person conducting the survey.

c.) Drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

d.) Measured exposure rates, keyed to location on the drawing (point out rate that require corrective action).

e.) Detected contamination levels, keyed to locations on the drawing.

f.) Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

4. An area will be decontaminated if the the contamination level exceeds 100 counts/100 cm^2 above the background count.

NOTE: For daily surveys where no abnormal (approximately background) exposures are found, only the date, the identification of the person performing the survey and a statement "All Other Areas Are Within BKGD Range" will be recorded.

VIII. WASTE DISPOSAL

A. Liquid Waste

1. Liquid waste will be disposed of in the sanitary sewer system in accordance with *20.303 of 10 CFR - Part 20.

B. $^{99}Mo/^{99m}Tc$ Generators

1. $^{99}Mo/^{99m}Tc$ generators will be held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached approximate background levels. All radiation labels will be removed or obliterated and the generator disposed of as normal trash.

C. Other Solid Waste

1. Other solid waste will be held for decay until the radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached approximate background levels. All radiation labels will be removed or obliterated and will be disposed of as normal trash.

ITEM 21

PROCEDURE AND PRECAUTIONS FOR USE OF RADIOACTIVE GAS

1. Quantities to be Used

a.1. Patient Information: The maximum anticipated patient load is 5 patients per week.

2. The average activity administered per patient is 20 mCi.

b. Desired possession limit is 200 mCi.

2. Use and Storage Areas

Use: Studies requiring the use of Xe-133 will be performed in the camera rooms of the Nuclear Medicine Department. The proximity to unrestricted areas and the ventilation areas are indicated in the diagram in Item 11. This diagram also indicates the air supply and exhaust rates in the camera rooms and the hot lab. Both camera rooms in which Xe-133 is used is kept under negative pressure. The exhaust system is vented directly to the roof top without and recirculation of the air.

Storage: Xe-133 will be obtained in precalibrated unit dose vials. These vials are stored behind lead shielding in the fume hood of the hot lab. The Xenon gas trap is located inside the decay locker when not in use.

3.a. Procedure for Routine Use

The Xenon delivery unit, function unit, and charcoal trays including the carbon dioxide absorber and dessicant will be checked for proper function befor use. The patient will be instructed on the details of the procedure and the proper use of the equipment. Just prior to the study, one or more practice runs will be accomplished. Only necessary personnel wearing whole body and finger badges will be in the room at the time of the study. For cooperative patients, face masks will be used to minimize leakage during the procedure. If a mouth piece is employed, a nose clip will be used to minimize leakage. Following completion of the washout phase, the system will be flushed into the charcoal tray using room air and oxygen. To ensure that the trays are working properly, an Xenalarm Xenon-133 gas trap monitor is attached to the charcoal trap. Concentration approaching 1 MPC are indicated by an alarm on the monitor.

b. Special Apparatus for Administration and Collection of Xe-133

Manufacturer's Name: Atomic Products Corp.

Model No.: Xenon Delivery System Model 130-500
Xenon Gas Trap Model 127-318
Xenon Trap Monitor Model 136-250

Description of Characteristics

The Xenon delivery unit is composed of a rubber breathing bag, a Co_2 absorber, a moisture absorber, and a network of gas conduits and valves. The delivery system is designed to operate in three positions. In the first position, the delivery system is filled with oxygen. In the second position, it forms a closed circuit to allow for equilibration of Xe-133 and the patient's breath. In the third position, it permits the washout of radioactive gas to the charcoal trap. The Xenon gas traps are replacable and shielded with lead. The cartridge traps approximately 95% of the Xenon. Placed at the exhaust port of the xenon gas trap is the trap monitor. This monitor automatically trips a visual and oral alarm when concentration of radioactive Xenon exceeds 1×10^{-2} uCi/ml.

A brochure describing the above systems is attached.

4. Emergency Procedure

In the veent of an inadvertant release of Xe-133, the supply of air to the room would be shut off. The exhaust vents in the hot lab and camera room vent to the rooftop without and recirculation of air. The patient and personnel inside the room will be immediately evacuated and the door to the room will be closed. After adequate time, approximately 10 exchanges of room air, a survey meter will be used to determine if the room is cleared of Xe-133 before use.

Air Concentration of Xe-133 in Restricted and Unrestricted Areas

LEHIGH VALLEY HOSPITAL CENTER

MEMORANDUM

DATE: APRIL 4, 1985

TO: File

RE: Air Flow Measurements in the Nuclear Medicine Department

On April 3, 1985, air flow measurements were taken in both camera rooms of the Nuclear Medicine Department to ensure that the release of Xe-133 to restricted and unrestricted areas does not exceed the requirements of 10 CFR Parts 20.103 and 20.106.

Table I shows the required flow rates needed to keep activity of Xe-133 below the MPC for restricted and unrestricted areas. These flow rates were calculated using conservative assumptions.

Table II shows the air flow measurements taken in both camera rooms with an alnor velometer.

Conclusion

The exhaust flow rates in the camera rooms exceeded the required flow rates neded to keep the release of Xe-133 below the requirements of 10 CFR Parts 20.103 and 20.106. In keeping with our ALARA program, these concentrations are greatly reduced by the use of a charcoal trapping system. The charcoal trap is monitored by a Xenalarm trap monitor to ensure proper trapping.

Carmine A. Pierno
Radiologic Physicist

CAPled

cc: D. Morel, M.D.
J. Kohler, R.T.

ITEM 21
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Table I

Assumptions: 1. One Xe-133 study is performed per week.

2. Fifty percent of the Xe-133 is available for release.

3. 20 mCi of Xe-133 are used per patient.

Activity per week: $\frac{1 \text{ patient}}{\text{week}} * \frac{20 \text{ mCi}}{\text{patient}} * \frac{10^3 \text{ uCi}}{\text{mCi}} * 0.5 = 1 \times 10^4 \frac{\text{uCi}}{\text{week}}$

Required ventilation rate in restricted areas

$$1 \times 10^4 \frac{\text{uCi}}{\text{week}} * \frac{1 \text{ ml}}{1 \times 10^{-5} \text{ uCi}} * \frac{1 \text{ week}}{40 \text{ hrs}} * \frac{\text{hr-ft}^3}{1.7 \times 10^6 \text{ ml-min}} = 14.7 \text{ft}^3/\text{min}$$

Required ventilation rate in unrestricted areas

Activity per year = $1 \times 10 \frac{\text{uCi}}{\text{week}} * \frac{52 \text{ weeks}}{\text{yr}} = 5.2 \times 10^5$ uCi/year

Needed ventilation rate

$$\frac{5.2 \times 10^5 \text{ uCi /year}}{3 \times 10^{-7} \text{ uCi/ml}} * \frac{\text{ft}^3/\text{min}}{1.49 \times 10^{10} \text{ ml/yr}} = 116 \text{ ft}^3/\text{min}$$

Table II

Exhaust measurements made by Engineering Department

438 Camera room with Whole Body Camera

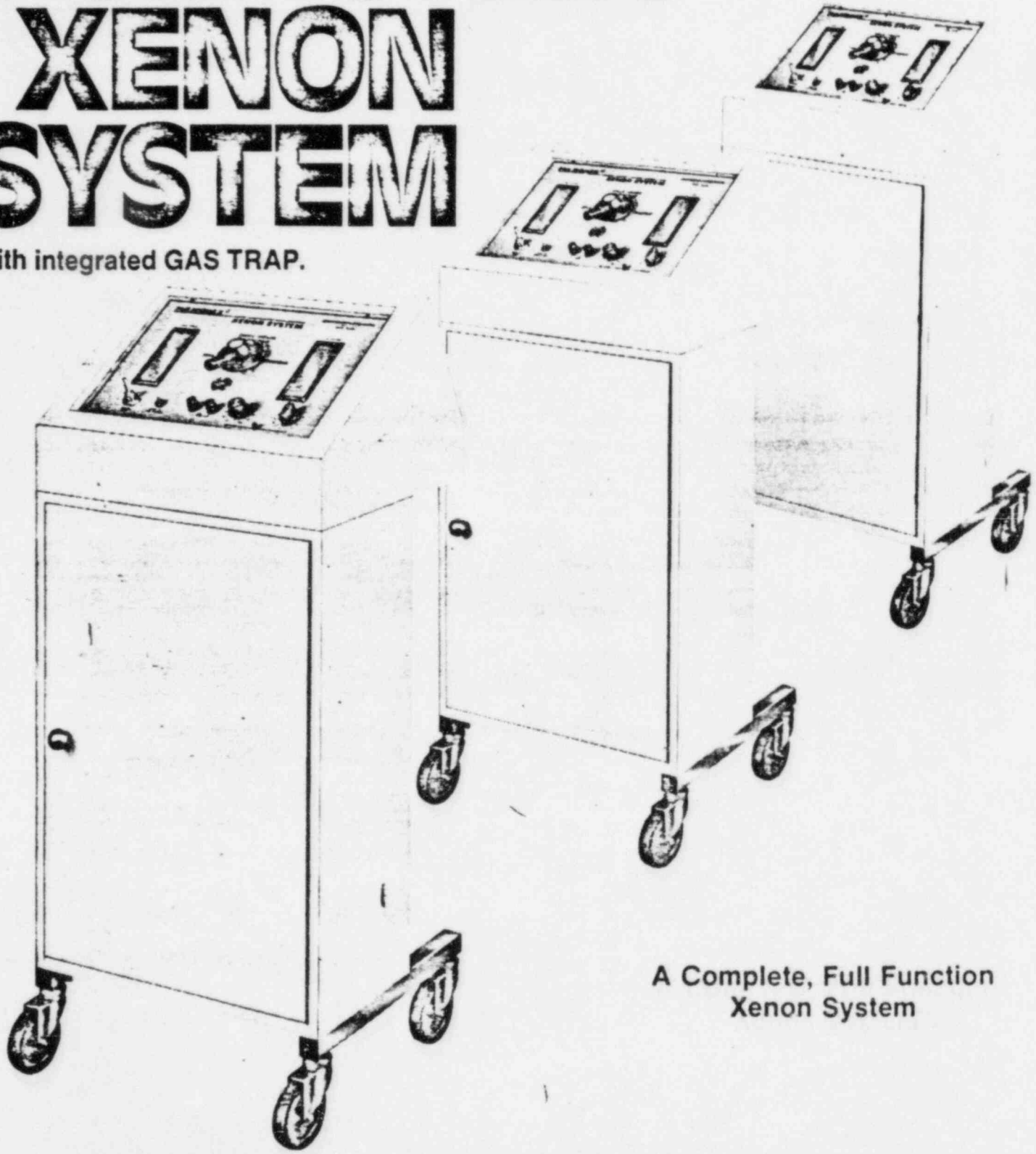
Supply of Air = 580 cfm
Exhaust = 820 cfm
Negative Pressure = 240 cfm

438 Camera Room

Supply of Air = 530 cfm
Exhaust = 700 cfm
Negative Pressure = 170 cfm

PULMONEX XENON SYSTEM

with integrated GAS TRAP.



A Complete, Full Function
Xenon System

Atomic Products Corporation

Center Moriches, New York 11934, U.S.A.
(516) 878-1074

PULMONEX XENON SYSTEM

One technician can perform an entire study by simply moving a single handle.

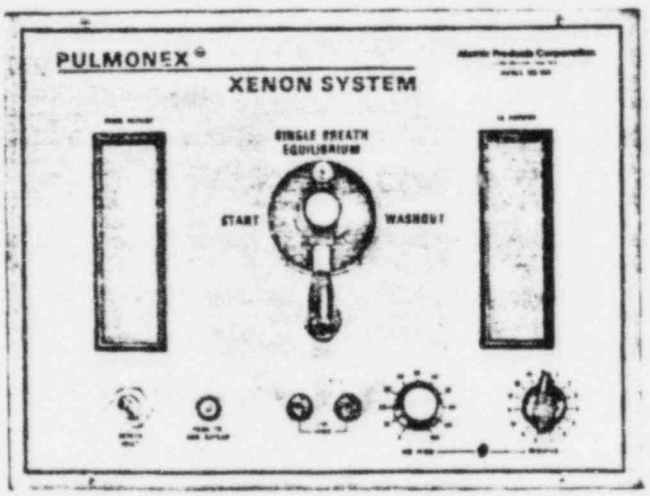
Single handle, 3-position control directs all functions for regional ventilation studies.

The Pulmonex Xenon System is a simple to use, reliable and complete system for the performance of all regional ventilation studies. A built-in xenon gas trap with disposable charcoal cartridge removes xenon effluent after each study and eliminates the need for expensive venting systems. Motor-controlled air flow assures resistance-free breathing regardless of your patient's pulmonary condition. Practical cabinet design and total mobility permit easy patient positioning in the seated or supine positions.

PULMONEX. .the complete, self-contained xenon system

Pulmonex provides a completely integrated system (delivery unit, and built-in gas trap) for performing xenon studies. A sensitive, responsive master valve, controlled by a single handle on the front panel, and silent synchronized motors permit full-system control of xenon gas flow from initial application to ultimate disposition of the xenon effluent into the gas trap.

All controls are conveniently located on an "up-front" control panel. With the patient on-line, either seated or supine, the user can control the system and observe the patient and gamma camera from one position. The control panel is clearly marked and each mode in the study procedure is distinctively apparent. The two internal patient breathing bags (Air-in and Air-out) are easily observed through individual viewing windows on the front panel. An adjustable manual 15-minute timer initially activates all functions and automatically shuts down the system to complete the study after patient and system washout.

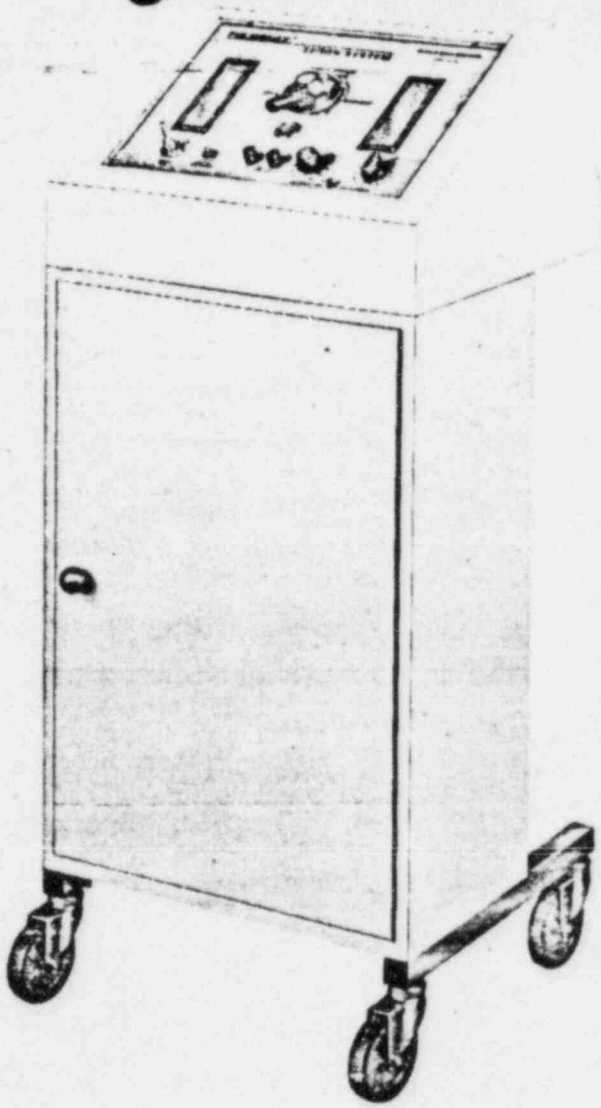


The PULMONEX SYSTEM

The Pulmonex Xenon System effectively integrates manual and electronic controls into a simple, sensitive system that provides maximum, reliable test results using minimum effort. System complexities have been eliminated. All internal circuitry, valves and tubing have been designed to afford ease of operation and patient comfort.

A master valve, controlled by one handle on the front panel, directs the flow of gases throughout the system. Oxygen may be added to the system any time during a study by fingertip button control. A push button operates a circulator blower motor

- Complete easy-to-use system.
- "Air-in"/"Air-out" breathing tubes and motor-driven circulator assures resistance-free breathing.
- Two lead glass windows permit observation of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- Accepts any commercial form of xenon.
- Rolls easily on large casters for positioning of supine or seated patients.
- Fully shielded.
- Carbon dioxide and moisture traps included.



to provide gentle positive system pressure. This, combined with a specially-designed master valve and wide diameter, short circuit airways, provides resistance-free patient breathing. There is no dead air space. An injected bolus of xenon reaches your patient exactly when desired. An in-line CO_2 absorber prevents hyperventilation. The system has automatic timer and pressure control dials to accommodate your patient's breathing pattern and to assure complete system washout into the gas trap.

All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter may be used at the mouthpiece to prevent system contamination.

INTEGRATED XENON GAS TRAP

The Pulmonex system has its own built-in gas trap. Exhaled xenon is gently pulled through activated charcoal contained within a "U" shaped cartridge made of 1/8" lead by an induction vacuum pump. The control panel timer and airflow pressure dial regulation of the trap pump assures complete patient and system purging. Only clean air leaves the trap exit port. Under normal usage the charcoal cartridge will last about a year. The gas trap cartridge is easily replaced when expended.

Specifications:

Motor UL approved. 115 VAC, 50/60 Hz.

Size: 18" x 19" x 46"

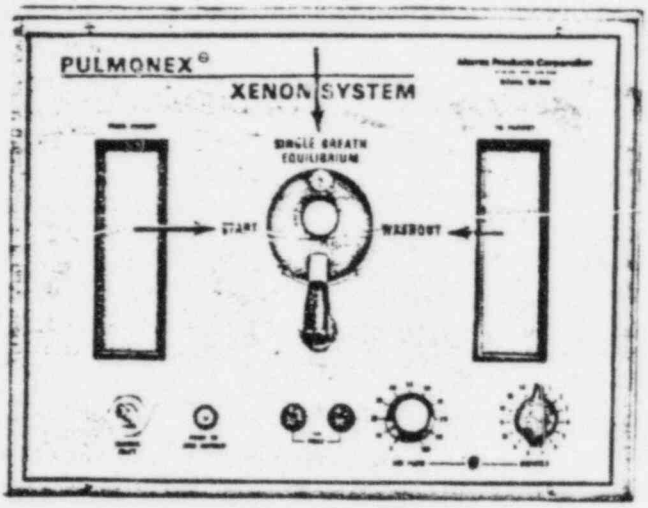
Weight: 150 lbs.

Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

130-500	Pulmonex Xenon System, Complete	$2595.00
127-318	Disposable Charcoal Cartridge	$ 295.00
130-550	Disposable Mouthpiece	$ 1.10 ea
130-700	Disposable Bacteria Filter	$ 2.95 ea
139-101	Moisture Absorber (Drierite)	$ 4.50 lb.
130-019	Soda Lime, CO^2 Absorber	$ 2.25 lb.

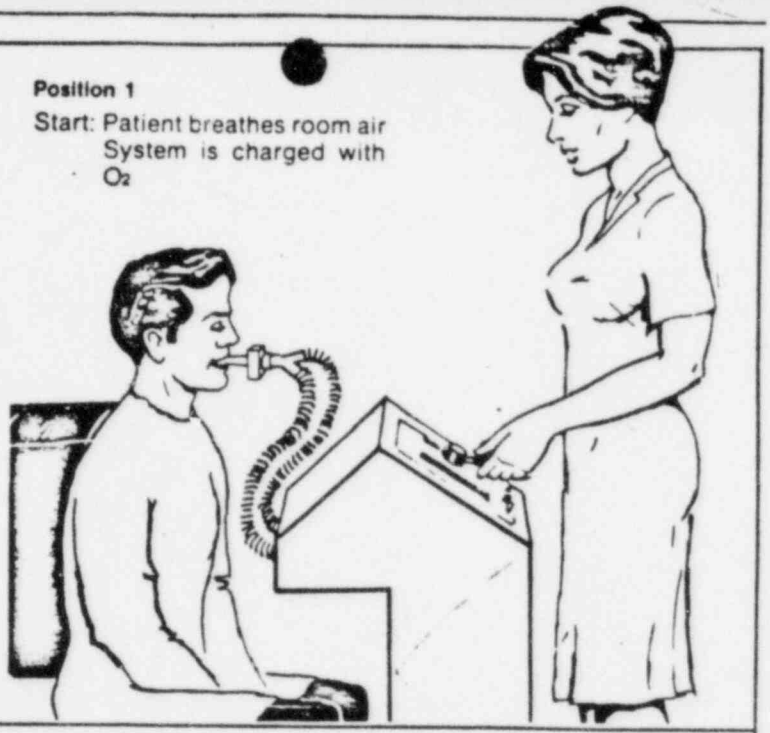
SIMPLE, SAFE OPERATION

There are only three valve positions.



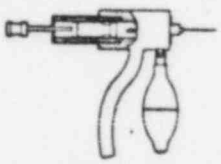
Position 1

Start: Patient breathes room air
System is charged with O_2



Position 2

Single breath and equilibrium imaging.

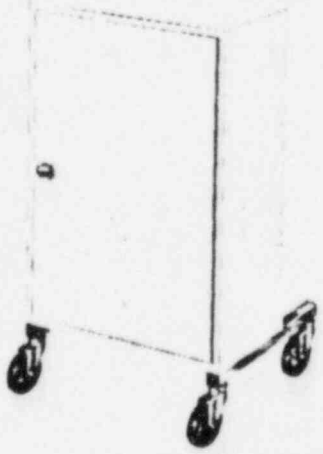


- This is when you add Xe, either a bolus or a homogeneous mixture.
- An in-line CO_2 filter prevents hyperventilation.
- When the patient equilibrates, switch the handle . . .

Position 3

Washout

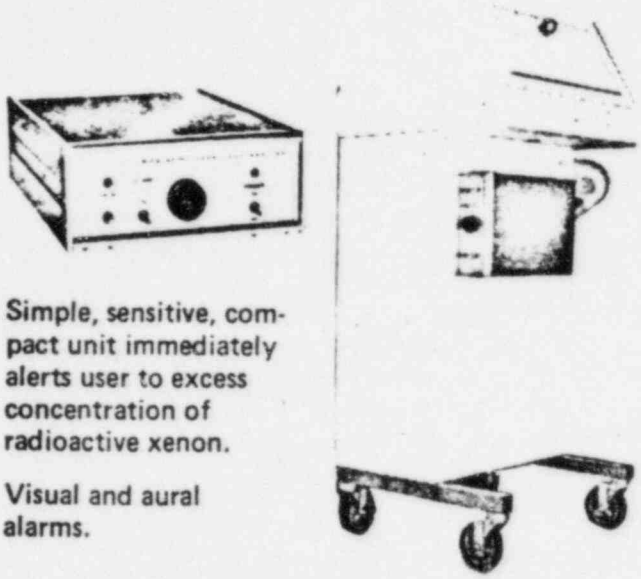
- The patient is now breathing room air from a one-way valve through the delivery system and into the built in Gas Trap. During washout, the Gas Trap is activated. A pump draws the patient's expired breath through a purifying bed of activated charcoal. The Xenon is stripped away and only clean air leaves the Trap exit port.



Atomic Products Corporation

Center Moriches, New York 11934, U.S.A.
(516) 878-1074

XENALARM XENON TRAP MONITOR



- **Simple, sensitive, compact unit immediately alerts user to excess concentration of radioactive xenon.**
- **Visual and aural alarms.**

Placed at the exhaust port of any xenon gas trap, the Xenalarm monitors the xenon exhaust level and automatically trips a visual and aural alarm when concentrations of radioactive xenon exceed 1×10^{-2} uCi/ml. NRC and State agencies require that the xenon concentration in controlled areas does not exceed 1×10^{-5} uCi/ml averaged over one year based on a 40 hour work week. Xenalarm allows an exhaust rate in excess of the limit as the exhaust is diluted in the room and still further diluted by virtue of the required room ventilation.

The detector is a sensitive end window G-M tube inserted directly in the exhaust stream. The system measures both beta and gamma emissions of xenon.

A "beeper" audio alarm and a flashing red light warn of excessive radioactive xenon. The audio alarm may be turned off at any time by a simple "off-on" switch. Should the alarm activate during or after a study, the charcoal cartridge in the trap should be changed immediately after the completion of the study.

The "Test" button permits manual activation of the alarm system to ascertain its operation. A method to calibrate the unit with a know ^{137}Cs source is provided.

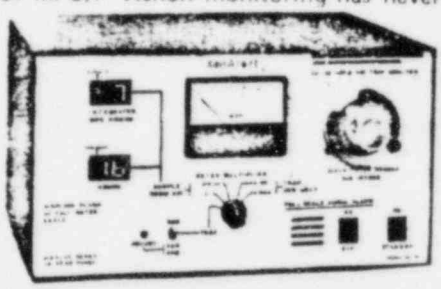
The complete unit measures 8-1/2" W x 3-11/16" H x 13-3/16" D.

136-250 Xenalarm Xenon Trap Monitor **$ 795.00**

"XenAlert" ™

XENON-133 ROOM AIR/TRAP MONITOR

Now, concentrations of xenon-133 in room air and gas trap effluent can be quantitatively monitored continuously and accurately with the unique "XenAlert" Monitor. Unlike present, non-integrating devices, the "XenAlert" eliminates tedious and complex calculations by automatically computing total exposure (in MPC-Hours units) and exposure rate (in fractions of MPC). Xenon monitoring has never been easier!



ROOM AIR MONITORING

To continuously monitor and integrate room air concentration, the "XenAlert" is positioned near the xenon administration system and the imaging equipment. Room air is drawn into the counting chamber. Air samples are counted while the air is exchanged more than 3 times per minute. An analog meter continuously displays MPC units while two digital registers display integrated MPC-Hours and total hours (running time) respectively. When the ^{133}Xe room air concentration exceeds full scale, the digital registers flash on and off as a warning to personnel. In addition, an audible alarm can be activated.

At the end of each work day, the "XenAlert" is switched to "Stand-By." Data acquisition is suspended, but accumulated data is retained in memory. In the morning, or whenever a xenon study is to be performed, the "XenAlert" is re-activated and data accumulation resumes. At the start of each work week, the "XenAlert" is reset to zero and the process repeated.

The "XenAlert's" unique features allow personnel to assess their xenon exposure quantitatively. An accidental release of xenon, such as from a broken vial or an uncooperative patient, may temporarily raise the ^{133}Xe room air concentration well above 1 MPC. The degree to which the NRC limits have been reached, however, depends on the amount of activity released and the time required for the room's exhaust system to exchange the restricted area's air. The "XenAlert" takes these factors into account with the display of MPC-Hours. Personnel are immediately aware of both the MPC concentration to which they were exposed and the total integrated MPC-Hours, in terms of NRC regulated exposure limits.

GAS TRAP MONITORING

The "XenAlert" greatly simplifies the monitoring of effluent air from any xenon trap. Setting the analog meter multiplier to X100 or X1000 displays 10^{-3} uCi/ml or 10^{-2} uCi/ml full scale. Concentrations approaching the latter level at the trap's exhaust port can result in a xenon room air concentration approaching 1 MPC. Therefore, the monitor may be used periodically to verify trap performance.

136-751 "XenAlert" ^{133}Xe Room Air/Trap Monitor . . . . . **$ 1975.00**

136-753 Particulate-Matter Replacement Filter. Package of 25 filters **25.00**

136-754 Hose for gas trap monitoring, 6-ft. **20.00**

XENON SYSTEM ACCESSORIES

139-101 Drierite, Indicating Moisture Absorber $ 7.00 lb.
1 lb. container has air-tight seal. Wide mouth permits problem-free access to contents.

130-550 Mouthpiece without Hose, Disposable $ 1.75 each
Soft flange, fits snugly between lips and teeth forming a tight seal.

139-305 Oxygen Tank Mount $ 40.00 each
Attaches firmly to system wherever convenient. Oxygen tank snaps in and holds tight even if system is moved.

139-036 (Small) Disposable
139-037 (Medium) Face Mask
139-038 (Large) $ 2.60 each
Rubber, backed with soft, face-molding sponge makes tight, comfortable seal when used with retainer.

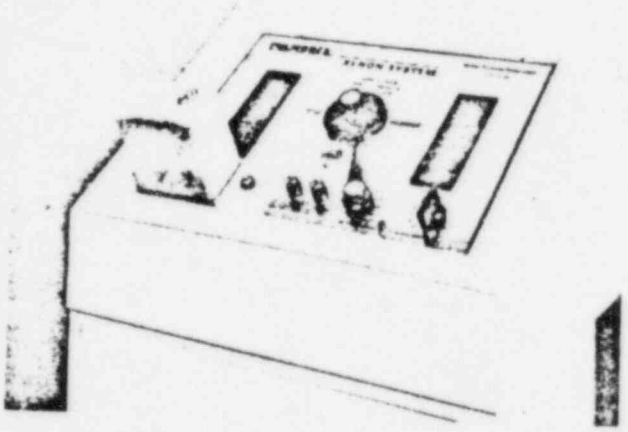
130-700 Bacteria Filter, Disposable $ 2.95 each
Attaches in-line at mouthpiece. Eliminates possibility of cross-contamination.

139-676 (Adult) Face Mask
139-690 (Pediatric) Retainer $ 13.50 each
Soft rubber-retainer is adjustable to any size head. Comfortable. Goes on in seconds.

130-939 Nose Clamps $ 9.50 each
Spring Steel with screw-lock for positioning and adjusting. Soft sponge noseguard for patient comfort.
139-945 Replacement Sponges $ 7.00 doz.

130-019 Soda Lime, CO_2 Absorber $ 3.50 each
Convenient 1 lb. containers are air-tight. Wide mouth permits easy access to contents.

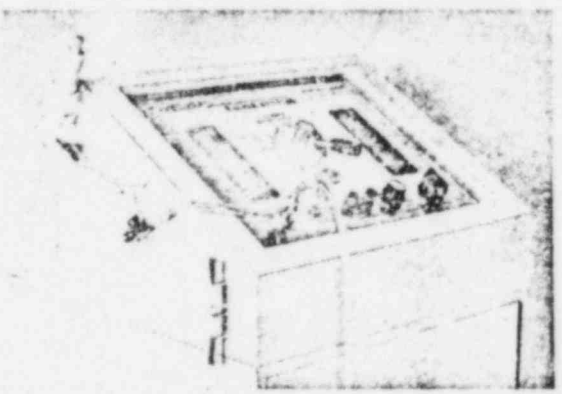
150-310 AUTOMATIC XENON DISPENSER
$ 225.00 each



Assures quick, accurate and easy delivery of xenon directly to the patient.

Attaches to the front of the Pulmonex system without tools. Using the handle from an NEN Calidose gun, load the Automatic Xenon Dispenser. At the precise moment you want the delivery of xenon, simply press the dispenser button. Xenon is automatically delivered to the patient.

150-300 XENON GUN MOUNT $ 98.50 each



Adapts the NEN Calidose gun to both the Pulmonex and Economy Systems. Attaches to the side of the unit and draws oxygen from that system. Delivers xenon to the patient on command by simple depression of a pust button.

Installation takes only minutes. Does not effect the xenon system. Comes complete, with all hardware, ready for installation. (Does not include Calidose gun).

Atomic Products Corporation
Center Moriches, New York 11934, U.S.A.
(516) 878-1074

ITEM 24

CALIBRATION OF POCKET DOSIMETERS

A. All pocket dosimeters are calibrated annually using a Nuclear Associates Dosimeter calibrator model number 06-200.

B. The half scale response of the pocket dosimeter is compared to the exposure rate from the Cs-137 source contained in the dosimeter calibrator.

C. All dosimeters which fall outside of ± 10% of the known exposure value are assigned correction factors.

D. All dosimeters which fall outside of ± 20% of the known exposure value are taken out of service.

Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

Allentown and Sacred Heart Hospital Center

I. Management Commitment

a. We, the management of this hospital, are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

Table I

		Investigational Levels - (mrems per month)	
		LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	40	125
2.	Hands and forearms; feet and ankles	625	1875

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table I:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter in when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

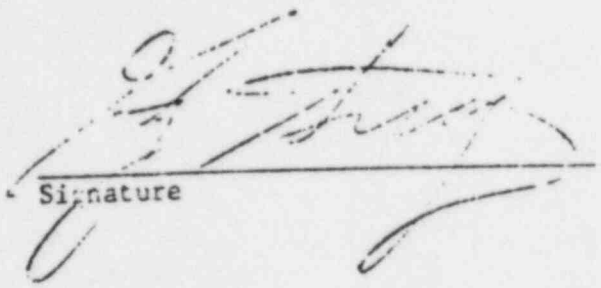
d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VIII. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.



Signature

Gary Steinberg

Name

Associate Administrator

Title

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Lehigh Valley Hospital Center

Application Dated: 4/12/85

Control No.: 03697

License No.: 37-16238-01

2. FEE ATTACHED

Amount: $ 580.00

Check No.: 153895

3. COMMENTS

Signed Brenda Platchek

Date 4/19/85

02/20

B. LICENSE FEE MANAGEMENT BRANCH 4/85

1. Fee Category and Amount: 7C $580

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal ✓

License _____

Signed Frances Brown

Date 4/26/85

bg 4/29/85

REGION I FORM 213
(MARCH 1983)

"SECTION COPY"

No. 153895

Lehigh Valley Hospital Center
A Subsidiary of HealthEast, Inc.
P.O. Box 689 • 1200 South Cedar Crest Boulevard, Allentown, PA. 18105
OPERATING ACCOUNT

CHECK DATE	CHECK NO
03/27/85	153895

PAY EXACTLY
******580.00

PAY TO THE ORDER OF

U.S. REGULATORY COMMISSION
631 PARK AVE
KING OF PRUSSIA, PA 19406

AUTHORIZED SIGNATURE

REFUND FOR

⑈00153895⑈ ⑆031301286⑆ ⑈00180137⑈