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

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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
Iowa Methodist Medical Center 1200 Pleasant Street Des Moines, Iowa 50308 TELEPHONE NO.: AREA CODE (515) 283 6201	Same as 1.a.
2. PERSON TO CONTACT REGARDING THIS APPLICATION Alexander Ervanian, M.D. TELEPHONE NO.: AREA CODE (515) 283 6458	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. _____ c. ☒ RENEWAL OF LICENSE NO. 14-01908-01
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* See Supplement 4.	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.)* Charles Bischof, Ph.D.

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	3 mCi
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	2 curies of each
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	X	2 curies

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100 mCi
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	25 mCi
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50 mCi
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	100 mCi
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	500 mCi
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	1 curie

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
153 Gadolinium	Sealed source	1.5 curie	Dual Photon Radioabsorptiometry
169 Ytterbium	DTPA	1 curie	Cisternography
235 Uranium (Depleted in Uranium-235)	Cadmium-plated metal	205 kg	Shielding in Linear Accelerator

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. _____ Date: _____

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
X	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(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)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
X	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	
NA	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer	2 weeks
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer	2 weeks
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

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: Renewal

(2) LICENSE FEE ENCLOSED: $ 150.00 paid November 1983

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Glenn E. Potter

(2) TITLE
Executive Vice President and Administrator

c. DATE
5-24-85

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.

Alexander Ervanian, M.D.
John W. Green, Jr., M.D.
Russell H. Mahoney, M.D.
Edward F. Loeb, M.D.
Louis L. Maher, M.D.
Terrance J. Allen, M.D.
Gordon L. Grado, M.D.
Jeffrey H. Watters, M.D.
Thomas E. Murphy, M.D.
William L. McGinnis, M.D.

SUPPLEMENT TO ITEM 4, NRC-313M

RADIATION PROTECTION OFFICER

The Radiation Safety Officer is Charles Bischof, Ph.D. NRC-313M Supplement A for Dr. Bischof is attached. He has had extensive prior experience as a radiation physicist at the University of Iowa. He was formerly on the license of the University of Iowa.

SUPPLEMENT TO ITEM 5, NRC-313M

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Charles J. Bischof, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiological Physics	June 1981

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Johns University 9/66-6/70 Iowa State University 9/70-9/75 University of Iowa 9/75-6/77	60 240 120	480
b. RADIATION PROTECTION	University of Iowa 9/75-6/77	60	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	St. Johns University 9/66-6/70	240	
d. RADIATION BIOLOGY	University of Iowa 9/75-6/77	180	
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
P-32	15 mCi	University of Iowa	6/77-7/83	Intraperitoneal & Intravenous Therapy
Au-198	150 mCi	University of Iowa	6/77-7/83	Interstitial Implants
Cs-137	450 mCi	University of Iowa	6/77-7/83	Interstitial & Intracavitary Implants
Ra-226	150 mCi	University of Iowa	6/77-6/83	Interstitial & Intracavitary Implants
Co-60	6 kCi	University of Iowa	6/77-7/83	External Therapy
Xe-133	20 mCi	University of Iowa	6/77-7/83	Cerebral Blood Flow

MEDICAL ISOTOPES COMMITTEE

The title of the Medical Isotopes Committee at this hospital is the Radiation Safety Committee.

The members of this Committee are: Alexander Ervanian, M.D., is Board certified in Pathology and Nuclear Medicine and has been licensed by the NRC for use of radioisotopes for almost 20 years. He is the current Chairman of the Radiation Safety Committee.

William McGinnis, M.D., is Board certified in Radiation Therapy.

Stuart Lehr, M.D., is Board certified in Diagnostic Radiology.

Chad Williams, M.D., is Board certified in Internal Medicine and has subspecialty certification in Cardiology.

Thomas Ghrist, M.D., is Board certified in Internal Medicine.

Charles Bischof, Ph.D., is certified by the American Board of Radiology in Therapeutic Radiological Physics, and he is the current Radiation Safety Officer.

Lavonne Cox is an Assistant Vice President for the hospital who is the Administration member of the Radiation Safety Committee.

The responsibilities and duties of the Committee and the meeting frequency of the Committee will be identical to that in Appendix B of Regulatory Guide 10.8.

TRAINING AND EXPERIENCE

Alexander Ervanian, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current user and licensee.

John W. Green, Jr., M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current user and licensee.

Russell H. Mahoney, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current user and licensee.

Edward F. Loeb, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current user and licensee.

Thomas E. Murphy, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

Jeffrey H. Watters, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

Louis L. Maher, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

Terrance J. Allen, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

William L. McGinnis, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

Gordon L. Grado, M.D. has been previously licensed under 14-01908-01 for the Iowa Methodist Medical Center and is a current licensee.

SUPPLEMENT TO ITEM 8, SUBITEM A,
NRC-313M

RADIATION SAFETY OFFICER

The Radiation Safety Officer is Charles Bischof, Ph.D. His NRC-313M Supplement A for training and experience are attached.

SUPPLEMENT TO ITEM 8, SUBITEM B,
NRC-313M

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Charles J. Bischof, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiological Physics	June 1981

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Johns University 9/66-6/70 Iowa State University 9/70-9/75 University of Iowa 9/75-6/77	60 240 120	480
b. RADIATION PROTECTION	University of Iowa 9/75-6/77	60	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	St. Johns University 9/66-6/70	240	
d. RADIATION BIOLOGY	University of Iowa 9/75-6/77	180	
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
P-32	15 mCi	University of Iowa	6/77-7/83	Intraperitoneal & Intravenous Therapy
Au-198	150 mCi	University of Iowa	6/77-7/83	Interstitial Implants
Cs-137	450 mCi	University of Iowa	6/77-7/83	Interstitial & Intracavitary Implants
Ra-226	150 mCi	University of Iowa	6/77-6/83	Interstitial & Intracavitary Implants
Co-60	6 kCi	University of Iowa	6/77-7/83	External Therapy
Xe-133	20 mCi	University of Iowa	6/77-7/83	Cerebral Blood Flow

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: The Victoreen Instrument Company

Manufacturer's model number: 6B

Number of instruments available: 2

Minimum range: 0.1 mR/hr to 0.5 mR/hr

Maximum range: 10 mR/hr to 50 mR/hr

b. Manufacturer's name: The Victoreen Instrument Company

Manufacturer's model number: 1A

Number of instruments available: 1

Minimum range: 100 mR/hr to 500 mR/hr

Maximum range: 100,000 mR/hr to 500,000 mR/hr

2. Dose calibrator

	a.	b.
Manufacturer's name:	Capintec, Inc.	Radx Corporation
Manufacturer's model number:	CRC-30	Mark V
Number of instruments available:	1	1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
a. Scintillation Well Counter	Nuclear Chicago	1185
b. Scintillation Well Counter	Micromedic	053547
c. Scintillation Well Counter	Micromedic	28059
d. Scintillation Well Counter	Picker Nuclear	2804
e. Scintillation Probe	Picker Nuclear	600321
f. Gamma Camera	Searle	000-64306
g. Gamma Camera	Picker Nuclear	001109
h. Gamma Camera	Technicare	4105
i. Gamma Camera	Technicare	500

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Area monitor, The Victoreen Instrument Company, Model #495
Min. range - 100 cpm to 500 cpm; Max. range - 100,000 cpm to 500,000 cpm
Victoreen, Model #36-751, Xen Alert, Xenon air monitor
Atomic Products, Model #130-500, Xenon delivery system

SUPPLEMENT TO ITEM 9, NRC-313M

SUPPLEMENT TO ITEM 10, NRC-313M

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

✓ 1. Survey instruments will be calibrated at least annually and following repair.

✓ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used
or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

✓ c. By a consultant or outside firm

(1) Name Radiation Oncology, P.C.

(2) Location 1440 Pleasant Street, Suite 119, Des Moines, IA 50314

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. _____

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

✓ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
✓ the consultant's reporting form as attached.

RADIATION ONCOLOGY

PROFESSIONAL CORPORATION
1440 PLEASANT • SUITE 119
DES MOINES, IOWA 50314

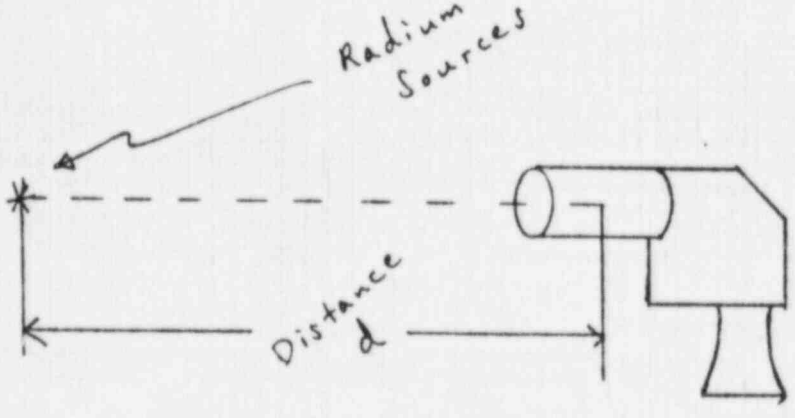
(515) 282-0680

LOUIS L. MAHER, M.D.
TERRENCE J. ALLEN, M.D.
WILLIAM L. McGINNIS, M.D.

CHARLES J. BISCHOF, Ph.D.

SURVEY METER CALIBRATION

1. Record date, manufacturer, model and serial numbers of survey meter on the calibration form.
2. Check the batteries in the survey meter. Use the "battery check" mode on the instrument or a voltmeter having an internal resistance of at least 50,000 ohms/volt.
3. Check the zero position of the survey meter and adjust if necessary.
4. Mount the rack for the calibration sources on a movable cart. Position the survey meter on another cart at the appropriate distance from the calibration rack (see the table on the following page). These carts should be set up inside one of the shielded treatment rooms.
5. Remove the necessary number of Ra-226 sources from the radium safe using tongs and place them in the lead pig. Transport the lead pig to the shielded room and place the sources in the calibration rack using tongs.
6. Check the calibration of the survey meter at two points on each scale using the appropriate distance and correct source activity. Calculate the true exposure rate on the basis of the specific gamma ray constant for radium and the inverse square law. If the instrument reading differs by more than 10%, attempt to adjust the calibration. If this is not possible, and the readings are within 20%, prepare a calibration curve and attach it to the instrument. Otherwise return the instrument to the manufacturer for repair.
7. After calibration replace the sources in the lead pig and transport them to the radium room for return to the radium safe.
8. If the survey meter has a check source use it to obtain a consistency reading and record this reading on the calibration form.



$$\dot{X} = \Gamma A / d^2$$

Γ = specific gamma ray constant

A = activity of radium sources (mCi)

d = distance from source to survey meter (cm)

Γ^* = 8.25 R-cm²/mg-hr x 0.90

Γ = 7.43 R-cm²/mg-hr

*Corrected for 1.0 mm Pt filtration in radium tubes.

Radium Source Activities:

Serial No.	Activity
38842	10.21 mgm
38843	10.14 mgm
38869	19.88 mgm
	40.23 mgm

Activity	Distance	Calculated Exposure Rate
40.23 mg	20 cm	747 mR/h
40.23 mg	30 cm	332 mR/h
40.23 mg	40 cm	187 mR/h
40.23 mg	50 cm	120 mR/h
40.23 mg	60 cm	83.0 mR/h
40.23 mg	70 cm	61.0 mR/h
40.23 mg	95 cm	33.1 mR/h
19.88 mg	95 cm	16.4 mR/h
10.14 mg	95 cm	8.3 mR/h
19.88 mg	200 cm	3.7 mR/h
10.14 mg	200 cm	1.9 mR/h
10.14 mg	500 cm	0.30 mR/h
10.14 mg	700 cm	0.15 mR/h

SURVEY METER CALIBRATION

Instrument:

Manufacturer _____

Model No. _____

Serial No. _____

Battery Check:

Zero Check:

Calibration Data:

Scale	Exposure Rate (mR/hr)	Instrument Reading (mR/hr)	Exposure Rate (mR/hr)	Instrument Reading (mR/hr)

Check Source Reading:

Comments:

Calibrations Source(s):

Nuclide	Activity	Calibration Accuracy

Calibrated by _____ Date _____

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

__X__ Other* (specify) 200 mCi is used since this is larger than any patient dose and the first elution would saturate the dose calibrator

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	_____	_____
Ba-133	0.1-0.5	0.265	+/- 5%
Cs-137	0.1-0.2	1.0	+/- 5%
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.

C. Procedures described in Section 2 of Appendix D will be followed except for the linearity test. The linearity test will be performed using the Calicheck Linearity Test Kit manufactured by:

Calcorp, Inc.
P.O. Box 25589
Cleveland, OH 44125

This kit contains seven attenuators designed to simulate the decay of Tc-99m at approximately 0, 6, 12, 20, 30, 40, and 50 hours. The actual attenuation factors have been measured using a sample of Tc-99m. These measurements were made in conjunction with a linearity test performed according to the procedure in Section 2 of Appendix D. The readings obtained are listed below.

Attenuator	Reading	Attenuation Factor
Black only	346 mCi	1.00
Black with red	200 mCi	1.73
Black with orange	110.1 mCi	3.14
Black with yellow	31.7 mCi	10.9
Black with green	10.2 mCi	33.9
Black with blue	3.10 mCi	112.
Black with purple	1.17 mCi	296.

The actual linearity test is then performed as follows:

1. Prepare a sample of Tc-99m having an activity of at least 200 mCi.

2. Place this sample in a vial inside the black holder provided with the linearity test kit. Place the black holder in the dose calibrator. Measure and record the activity.

3. Place the sample and the black holder inside the red attenuator. Place the entire assembly in the dose calibrator. Measure and record the activity.

4. Repeat step 3 for the orange, yellow, green, blue, and purple attenuators.

5. Multiply the measured activity readings by the correction factors listed below.

   Black only - 1.00
   Black with red - 1.73
   Black with orange - 3.14
   Black with yellow - 10.9
   Black with green - 33.9
   Black with blue - 112.
   Black with purple - 296.

6. Compare the corrected activity readings. All readings should be within +/- 5% of the first reading. Present to the physicist for his review.

SUPPLEMENT TO ITEM 11, NRC-313M

Key to Details of Hot Laboratory

1. Long-term waste storage space. Walls lined with 12" concrete block. Doors are metal with lead lining.

2. Area radiation monitor Victoreen Model #495, Serial #237.

3. Chromatography quantitative strip analyzer: Atomic Products Corp. Model #149-200.

4. chromatography center

5. Work station for preparing Sulfur Colloid and short-term storage of radiopharmaceutical vials. Entire area is lead brick shielded and front is shielded with heavy leaded glass shield.

6. Molybdenum generator in lead shield

7. emergency eyewash center

8. telephone & intercom

9. Lead shielded work station for preparation and withdrawal of radiopharmaceuticals. Front is shielded with heavy lead plate and heavy leaded glass.

10. Capintec dose calibrator

11. well for dose calibrator

12. lead lined refrigerator

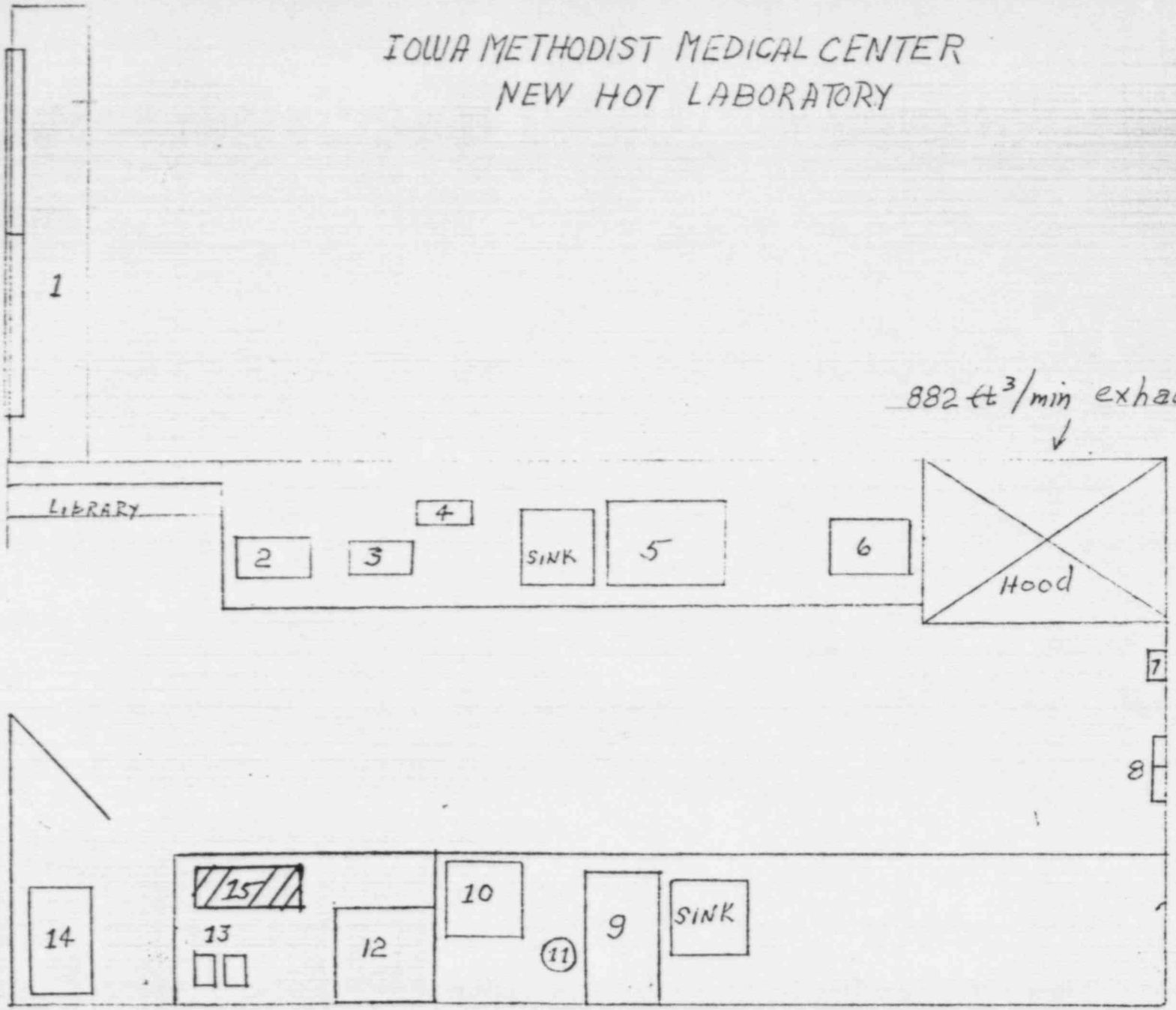
13. Two portable radiation monitors Victoreen Model #1A, Lionel Electronics Labs Model #6b.

14. lead lined box for storage of sheet sources, phantoms, etc.

15. Area where radioactive materials are received and surface measurements performed.

B

IOWA METHODIST MEDICAL CENTER
NEW HOT LABORATORY

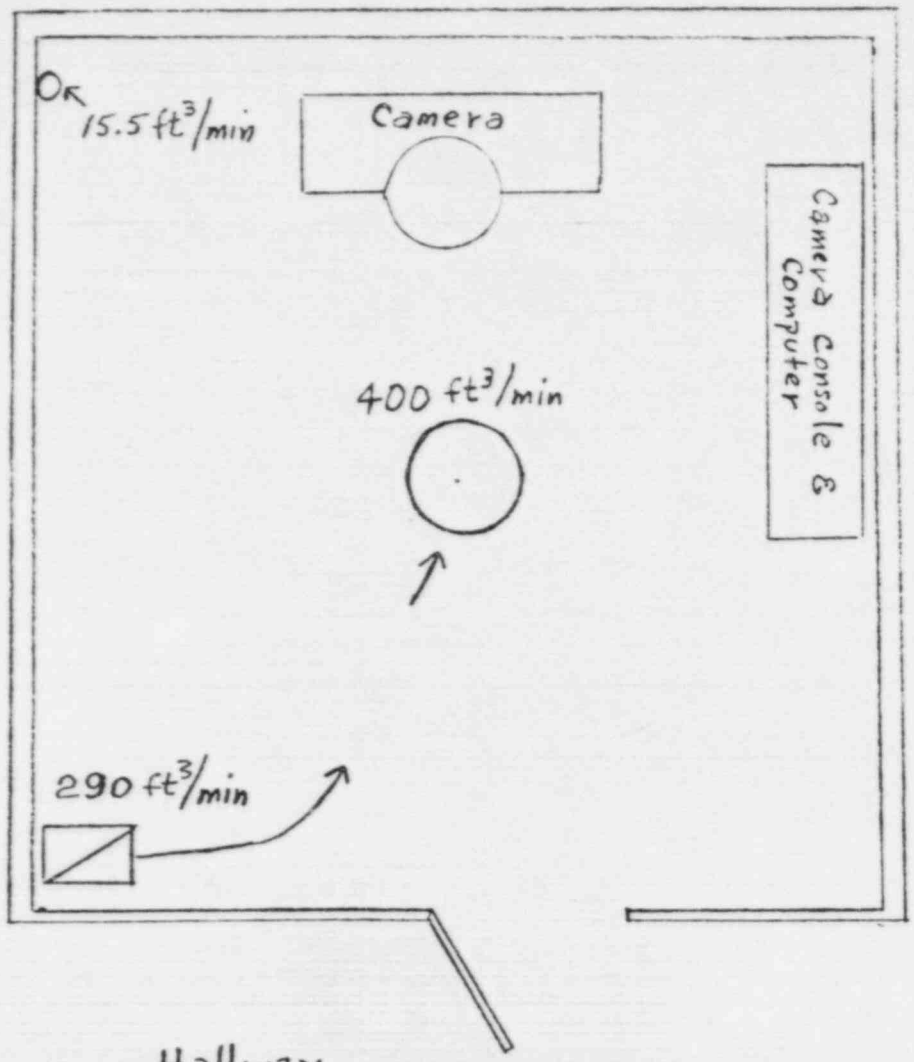


Scale: 1"=30" May 11, 1982

Key on attached page

IMMC Nuclear Medicine Dept.
Xenon Ventilation Imaging Jan, 1985

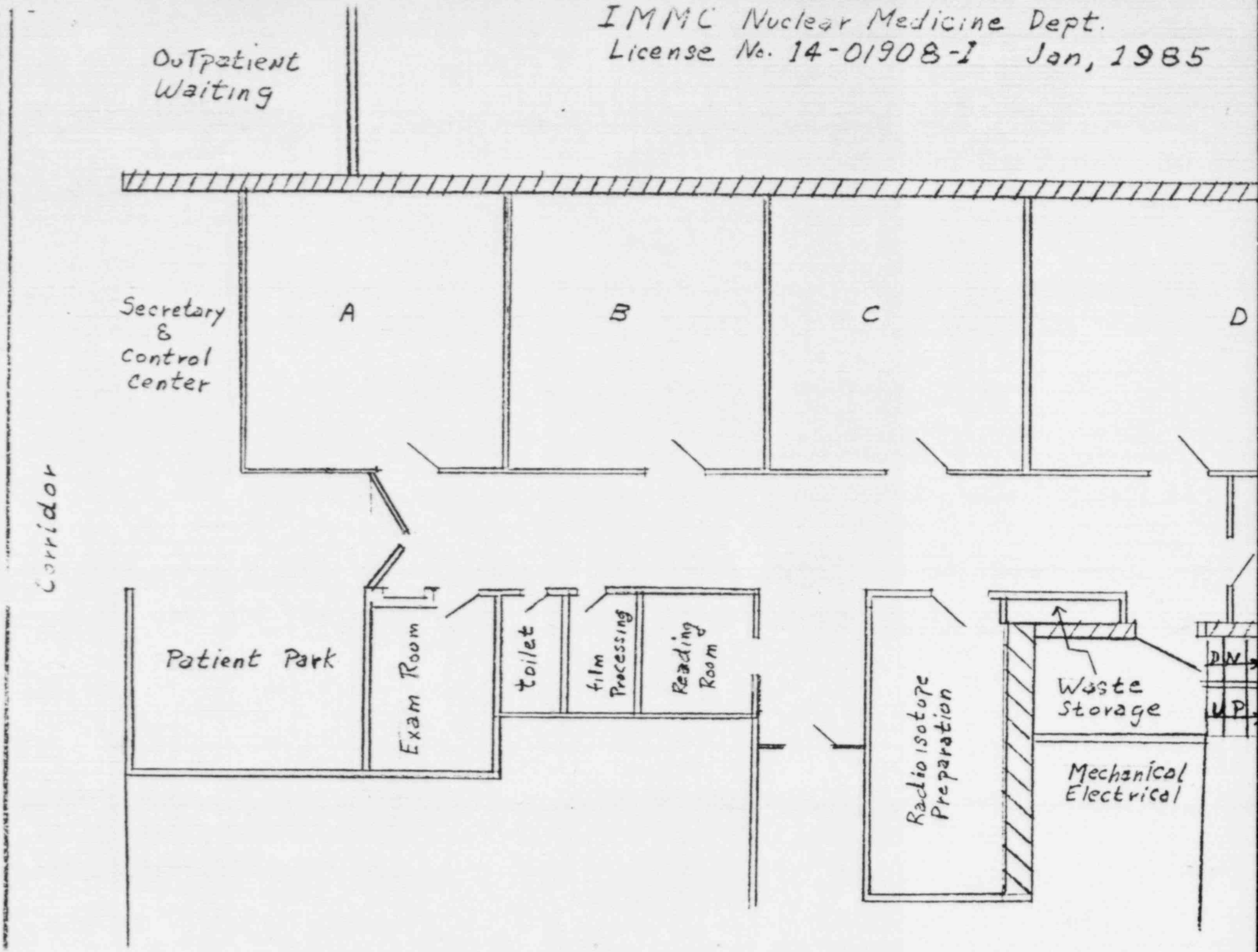
Scan Room A



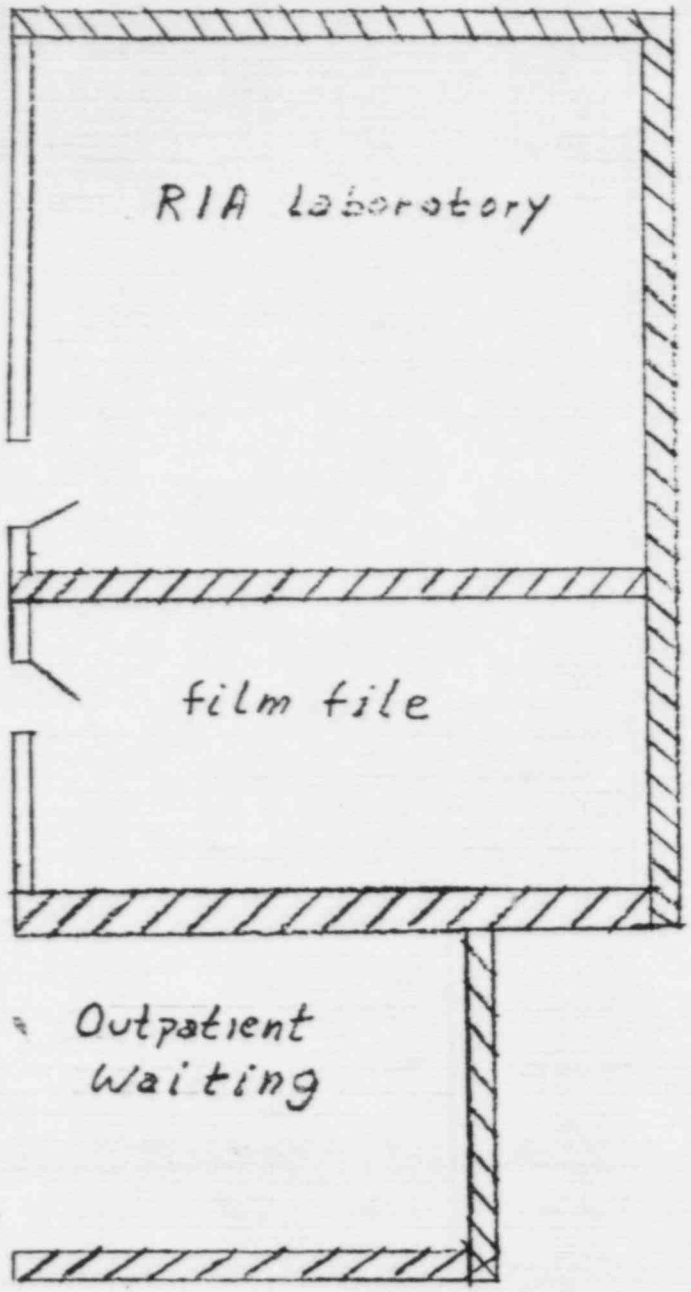
Secretarial & Control Center

Scale: 1" = 4'

IMMC Nuclear Medicine Dept.
License No. 14-01908-1 Jan, 1985



IMMC Nuclear Medicine Dept.
License No. 14-01908-1 Jan., 1985



1" = 8'

SUPPLEMENT TO AEC 313
ITEM 12

PERSONNEL TRAINING PROGRAM

All of the technologists working in the Nuclear Medicine diagnostic section have been professionally trained and during a period of indoctrination before starting their duties have been observed to be competent in radiation safety matters. I have verified that they are cognizant of and are aware of the safety features outlined in Appendix 1 of the United States Nuclear Regulatory Commission Office of Nuclear Regulatory Research Draft Guide of January 1984. However, at the current time there is no formal continuing education program in radiation safety. Beginning with this application, we will institute an annual training program for our Nuclear Medicine technologists incorporating all of the material in the outline of Appendix 1. It is anticipated that this can all be accomplished in about 5 hours of lecture in our current trained personnel. This will be conducted in five separate one-hour lectures during our regular Tuesday meetings. A record of this activity will be maintained.

Our Nuclear Medicine personnel will also be kept informed of all changes in regulations or whenever our license changes.

At the current time we do not have any clerical personnel who work in and around radiation sources. We do not have any nursing personnel that work around radiation sources. Instructions to nursing personnel taking care of therapy patients are listed in the Supplement later in this application. Housekeeping personnel are in the Nuclear Medicine area at the end of the day during cleanup. All housekeeping personnel are instructed not to touch or handle any of the containers that contain disposed materials which may be radioactive. These containers are all properly labelled, and we have verified that they do not touch any of these items. All disposal of such materials is handled by our Nuclear Medicine technologists. Housekeeping personnel are involved only in cleanliness of the floors. They are not present in the area during working hours when radioactive materials are in use. Housekeeping supervisors are familiar with these safety requirements. Furthermore, most of the housekeeping personnel are of less than average intelligence and it would be impossible for us to give instructions as indicated in Appendix 1 of the proposed regulatory guide.

Security personnel are only involved in delivery of radioactive packages to the Nuclear Medicine area as indicated in Supplement 13. They are aware of simple radiation safety requirements but have not received any instructions as suggested in Appendix 1. If the Commission insists that this be performed, we will, of course, conform to this requirement and give them instructions as suggested in Appendix 1.

All of our personnel are aware of our license and its requirements in regard to radiation safety, and all of our personnel are thoroughly familiar with the areas where radioactive materials are used and stored. By training, they are all familiar with the hazards associated with radioactive materials as indicated previously. They are all completely cognizant of standard radiological safety procedures appropriate to their duties. Our personnel are familiar with the appropriate NRC regulations, and in future refresher courses they will be kept abreast of these regulations. All radiation hazards and unsafe conditions are reported to the Radiation Safety Officer as required. Radiation emergencies are reported to the Radiation Safety Officer and to the Director of Nuclear Medicine. Our personnel are constantly

and regularly informed of their radiation exposures and bioassay results which are performed on a regular basis. The license is located in the office of the Director, and the personnel all have access to that. They have access to the complete regulations which are also kept in the Director's office, and pertinent safety regulations are posted in the patient examining room.

SUPPLEMENT TO AEC 313
ITEMS 13, 14, 15, 16, 17 and 18

IOWA METHODIST MEDICAL CENTER
NUCLEAR MEDICINE

PROCEDURE FOR MAKING RADIATION SURVEYS OF THE NUCLEAR MEDICINE WORK AREAS

A. Imaging rooms A, B, C, & D, Waste Store Room, Reception Area, Examination Room, and Hot Lab.

1. Radiation surveys to determine exposure rates of these areas in the Nuclear Medicine Department shall be done not less than once per normal working day.
2. Monitoring of these areas shall be done with the radiation survey meter that is sufficiently sensitive to detect 0.1 mR per hour.
3. The results of these surveys will be recorded in the area monitor Log Book and will include the following: location, date, exposure reading in mR per hour, and initials of the person conducting the survey.
4. Areas which show exposure rates two times background or more must be noted in the log along with a description of the corrective action taken to reduce the exposure rates to the appropriate level. No area or object can be returned to normal service until a repeat survey is below two times background.

B.

1. Radiation surveys using the Wipe Test will be done not less than once per week.
2. The wipe disc are commercially obtained and are used according to the following instructions: hold paper by the printed end close to the tape dispenser. Hold the tape with the other hand, depositing the circle to printed circle. Do not touch the circle with your fingers. To perform the Wipe Test, hold the disc by the printed end, and firmly wipe an area about six inch square. Tear along dotted line, and fold the cloth circle to the inside. Position the folded disc in a large test tube and push to the bottom of the tube with a wooden stick.
3. Count each wipe disc for five minutes on the autogamma counter. Use the 125 iodine baseline with the window at 1000 and record this count in the Log Book.
4. Take a five minute background count at the same settings and also record in the Log Book.
5. This procedure is followed for work areas as described in A above.
6. If any work area shows count values of two times background or higher, corrective action must be taken immediately and a description of this action recorded in the Log Book. No area or object can be returned to normal service until a repeat wipe test is below two times background.

10-22-84
Safe

IOWA METHODIST MEDICAL CENTER
NUCLEAR MEDICINE

ACCEPTABLE EXPOSURE RATES (mR/hr)

AREA	RATE
At top of lead wall	2.0-8.0
Radioimaging preparation	0.2-2.2
Quality assurance	0.2-1.0
Hot Lab waste container (surface)	0.3-0.5
Hot Lab waste container (½ meter)	0.1-0.25
Storage room - right door	0.2-0.5
Storage room - left door	0.2-0.5
Exam room - phlebotomy chair	0.15-0.4
Exam room - waste container (surface)	0.15-0.5
Room A	0.15-0.5
Room B	0.15-0.4
Room C	0.15-0.4
Waste container, Room C (surface)	0.15-0.5
Reception area (background)	0.05-0.15
Room D	0.15-0.5
Waste storage, Room A	0.3-0.5
Waste storage, Room D	0.3-0.5

PROCEDURE MANUAL
RADIOCHEMICAL PURITY OF 99mTc
RADIOIMAGING AGENTS USING
INSTANT THIN LAYER CHROMATOGRAPHY (ITLC)

I. INTRODUCTION

This is a convenient screening procedure to determine relative radiochemical labelling efficiency in 99mTechnetium radioimaging agents. The entire procedure may be run in about 30 minutes.

II. DESCRIPTION (Gelman commercial ITLC-SG)

Instant Thin Layer Chromatography (ITLC) is a ready-to-use medium. The ITLC sheet of glass microfiber is impregnated with silica gel by dipping the glass fiber into a freshly prepared supersaturated solution of potassium silicate in ammonium chloride. The solution gels in a short time and the ammonia is removed by a distilled water chromatographic step or by heating in an oven at 400°C. for 60 minutes. The resultant medium is slightly acidic (pH 5.0 monosilicic acid layer). The silica gel impregnated sheets are extremely sensitive and give excellent resolution of monopolar compounds. The sensitivity is a result, in part, of the small amount of adsorbent impregnated into the glass fiber.

III. PRINCIPLES OF PROCEDURE

Instant Thin Layer Chromatography with Silica Gel (ITLC-SG) is used to identify radiochemical impurities resulting from physical, chemical and radiation decomposition of radioimaging agents.

The application of as little activity as 0.001uCi (2,200dpm) to ITLC-SG and the choice of the proper solvent allows for chromotagraphic separation.

By definition a chromatographic separation is a Mobile Phase passing over a Stationary Phase thereby transporting different substances with different velocities in the direction of flow.

The Stationary Phase is the adsorbent such as silica gel. This is impregnated into a support, glass mylar or glass microfiber. The thickness of this adsorbent is 250 microns.

PRINCIPLES OF PROCEDURE (con't.)

The Mobile Phase is a developing solvent. A sample of compound is spotted onto the glass microfiber with silica gel, the spot is allowed to dry and is then placed in a chromatographic chamber containing a developing solvent. As the solvent rises through microfiber medium by adsorption and capillary action, it tends to resolve or separate the components of the sample.

Electrostatic forces of the Stationary Phase act to retard the components in the sample as the Mobile Phase rises. This and the fact that the components have different solubilities in the Mobile Phase cause the individual components to move at different rates below the Solvent Front. Substances being separated constantly move back and forth and equilibrate between the Stationary and Mobile Phases. This determines the rate of travel up the sheet.

After the ITLC is developed, the distance the compounds migrated is measured. The migration of individual compounds in a sample may be determined by photographing the developed ITLC-SG sheet with a scintillation camera. The sheets should be allowed to dry after developing has ended. Place the sheets between two unexposed, developed pieces of radiographic film (8" x 10"). Place this arrangement on or near the surface of a low energy collimator attached to the scintillation camera. Record 20-50K counts at a predetermined CRT intensity from camera chart or past experience. Develope this image which will show the distribution or movement of the radioimaging agent components during the chromatographic procedure.

IV. GENERAL METHOD

A. Sample Application

1. Spot a small volume, usually 2-20ul, with a lcc tuberculin syringe with a 25g needle onto a strip of glass microfiber (ITLC-SG sheet) that has been cut into two pieces lengthwise. ITLC-SG is highly purified. Even fingerprints may interfere with separation. Handle only above the top punched hole. Always apply sample at bottom part of strip.
2. Use fine tip marking pen on edge of strip to mark spot level.
3. Let spot dry 5-10 minutes.

GENERAL METHOD (con't.)

B. Migration
   1. Pour approximately 100 ml. of Acetone into chamber base. Equilibrate 3 minutes.
   2. After spots are dry introduce strip to the chamber using magnetic clip to hold the strip upright. The level of the spot should be well above the solvent (Acetone) surface. (Do not place the spotted area directly into the solvent.)
   3. When in position do not move the chamber.
   4. Allow migration to continue 5-10 minutes, then remove the strip. Let ITLC-SG dry thoroughly (5-8 minutes at room temperature).

C. Assay Methods
   1. The spots produced by the chromatographed material may be located immediately by placing the dried strips between two sheets of unexposed, developed radiographic film. This allows the strips to be imaged by a scintillation camera by taping the film directly to a low energy collimator. Besides acting as a holding device, the "film sandwich" also prevents contamination of the collimator. The camera should be peaked for 99mTc using the 140keV photon with 20% window and follow camera chart for other settings. Develop the exposure, identify and staple in log book.

D. Interpretation
   The migration of individual compounds in a sample may be determined by Rf values. The Rf is the relative position an individual compound moves in relation to the distance the Solvent Front (Sf) moves. These distances are calculated by measuring the distance from the origin to the center of the particular spot and dividing this by the distance from the origin to the Solvent Front.

$$Rf = \frac{\text{Distance from origin to spot center}}{\text{Distance from origin to Solvent Front}} \times 100$$

   With this system pertechnetate (99mTc) moves with an Rf of 1.0. Colloids, chelates and reduced 99mTc remain at the origin. The system does not differentiate between these components but does allow recognition of inconsistencies from day to day in the proportion of 99mTc O_4 to these components. The imaging system

GENERAL METHOD (con't.)

is capable of resolving two spots at a minimum separation of about 1.5 cm and can detect as little as 2% of total activity on a chromatographed strip. Visual estimations of spot radioactivity can be made to within 10%. Any radioactive contaminants in sulfur colloid, macroaggregates, human serum albumin and chelating agents are immediately evident.

REFERENCES

1. Procedure Manual Technical Bulletin 32 (February, 1975)
2. Gelman Instrument Company

NUCLEAR MEDICINE PATIENT DOSE POLICIES
(From Hot Lab to Injection Area)

1. Calculate radioactivity and volume needed for patient dose. Withdraw from vial with properly shielded syringe. For children use posted chart (dose based on weight).

2. Re-check radioactive dose with calibrator.

3. Log dose in Inventory Book if necessary. Patient, date, quantity (μCi or mCi), volume used (ml), and volume remaining in vial.

4. Return vial to proper storage (refrigerator or color coded boxes). If storage box please close lid.

5. Label syringe with contents and amount of radioactivity.

6. After use remove or destroy needle and dispose of with syringe, in proper radioactive garbage storage container. Return syringe shield to Hot Lab area.

7. Log all patient doses in In-Vivo (Imaging) NRC Record Book. This includes identification number, date, patient name, type of image or study, amount of radioactivity administered, radionuclide, and chemical form. The technologist that injects the radioagent is responsible for entry of this data.

8. Use proper lead shielding when transporting doses from the hot lab. A syringe shield is a minimum amount when delivering doses. Utilize a container which shields 360 degrees.

10-30-84

SAK

Iowa Methodist Medical Center

Nuclear Medicine

EMERGENCY PROCEDURES

IMMEDIATE PROCEDURES

1. REMOVE ANY INJURED PERSON(S) FROM ROOM AND PLACE IN AN UNCONTAMINATED AREA CLOSE BY.

2. LOCALIZE AND CONTAIN CONTAMINATION. CHECK FOR CONTAMINATION WITH HAND-FOOT MONITOR. IF CONTAMINATED, STAY IN ONE AREA UNTIL HELP ARRIVES.

3. IMMEDIATELY NOTIFY THE PROPER AUTHORITIES:

   A. DR. A. ERVANIAN, HEAD OF NUCLEAR MEDICINE.
   PHONE: IMMC 6853
   HOME 223-6764

   OR

   STEPHEN A. KUHN, SUPERVISOR NUCLEAR MEDICINE.
   PHONE: IMMC 6458
   HOME 961-6417

   OR

   Charles Bischof, Ph.D.
   Radiation Safety Officer
   Phone: IMMC 5864
   Home 223-9068

IOWA METHODIST MEDICAL CENTER

NUCLEAR MEDICINE

Nuclear Medicine Policies and Procedures
Incoming Radionuclide Shipments

A. All shipments and packages that contain radioactive materials will be delivered to the Nuclear Medicine Laboratory immediately after receipt at IMMC. During weekdays (Monday-Friday) between 8:00 a.m. and 4:30 p.m. the receiving dock will sign for delivery and notify or bring shipments to Nuclear Medicine. After 4:30 p.m. and all day Saturday and Sunday shipments should be delivered and signed for only by the switchboard (information desk) operator(s) on N-1. All companies making deliveries of radioactive materials have been requested to follow this procedure.

After receiving a package the switchboard operator will notify a Security Officer. The Security Officer will deliver the package to Room A-37 and relock the door.

B. In the event that a radioactive shipment or package is observed to be damaged and/or possibly leaking its contents, notify one of the following:

Stephen A. Kuhn, Nuclear Medicine Supervisor, 6458 or 961-6417
Dr. Ervanian, 6853 or 223-6764
Dr. Charles Bischof, 6860 or 223-9068
or
Page Nuclear Medicine Technologist on call, 245-1829

If leakage is confirmed notify the carrier and the regional NRC office immediately. The NRC regional office address and phone number are on the Notice To Employees Chart found in the Exam Room (A-46).

C. All radioactive shipments will be monitored externally and opened in the Hot Lab. Monitoring is carried out to detect leakage of radioactivity outside of lead shielding. The survey data (MR/hr) will be recorded and if the value is unusually high the shipment will be opened with special caution including disposable gloves. A list of expected exposure rates can be found on the next page.

D. After shipments have been opened check all containers for proper contents, amount of radioactivity, volume and expiration date.

E. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not, obliterate radiation labels before discarding in regular trash.

F. Complete inventory sheet and affix copy of product data label. Put this sheet in inventory disposition book located in Hot Lab.

G. Date all containers with date received and store properly in lead-lined refrigerator or at room temperature behind lead brick wall.

H. Complete the inventory record for that order.

I. Complete and file a "Radioactive Shipment Receipt Report" form.

J. Complete and file a "Receipt of Goods" form.

10-22-01 CoK

Expected G-M Readings for Radionuclide Shipments

Packages Monitored at all Surfaces Prior to Opening

Radionuclide	Amount	Company	Average mR/hr.	ISD Range mR/hr.
51 Chromium	250 uCi	Mallinckrodt	3.0	----
67 Gallium	9 mCi	NEN	2.77	1.5-5.9
67 Gallium	18 mCi	Mallinckrodt	13.9	6.9-27.9
131-I Capsules	250 uCi	Mallinckrodt	3.1	0.9-4.9
99Mo-99mTc.	500 mCi	Mallinckrodt	22.7	11.9-33.4
75 Selenium	1 mCi	Mallinckrodt	2.5	2.0-6.6
133 Xenon Gas	100 mCi	NEN	0.4	0.2-0.88
201 Thallium	1.6-3.3 mCi	NEN	0.65	0.2-2.3
169 Ytterbium	2 mCi	3-M	0.90	0.40-1.7
99Mo - 99mTc	4140 mCi	Union Carbide	19	14-24
67 Gallium	24 mCi	NEN	11	4.6-17.6
67 Gallium	30 mCi	NEN	13	9-17
131-I Capsule	5 mCi	Mallinckrodt	20	17-23

10-22-87 Sak

8-30-87 Sak

7-8-82 Sak

8-17-81 Sak

Reviewed 5-8-80 Sak

IOWA METHODIST MEDICAL CENTER
NUCLEAR MEDICINE LABORATORY

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. #_____ SURVEY DATE_____ TIME_____

2. SURVEYOR: _____

3. CONDITION OF PACKAGE:

_____O.K._____PUNCTURED_____STAINS_____WET

_____CRUSHED_____OTHER_____

4. RADIATION UNITS OF LABEL _____UNITS (mR/hr)

5. MEASURED RADIATION LEVELS: a. Package surface_____mR/hr
Radionuclide
b. 3' from surface_____mR/hr.

6. DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. Radionuclide_____yes _____ no difference_____

b. Amount _____yes _____ no difference _____

c. Chem. Form_____yes _____ no difference_____

7. WIPE RESULTS FROM: a. Outer_____CPM = _____DPM
eff = ( )

b. Final source container_____ CPM = _____DPM
eff = ( )

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS_____mR/hr, CPM
above Bkg.

9. IF PACKAGE WAS SHIPPED WITH DRY ICE, WAS DRY ICE PRESENT IN PACKAGE AT TIME OF RECEPIT?_____YES_____NO _____N/A

10. DISPOSITION OF PACKAGE AFTER INSPECTION: _____

11. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, PERSONS NOTIFIED.

Iowa Methodist Medical Center

Nuclear Medicine

Ordering and Purchasing Policies for Nuclear Medicine Materials and Supplies:

REVIEWED BY:

DATE:

NOTATION OF ALTERATIONS:

Iowa Methodist Medical Center

Nuclear Medicine

Ordering and Purchasing Policies for Nuclear Medicine Materials and Supplies:

1. To order and purchase materials and supplies a Request To Purchase form must be completed. NOTE: Materials and supplies that are on "standing" orders will be received periodically according to instructions to supplier regarding time interval etc. (See section 5). The following data is required to properly complete a Request To Purchase form: Date, Date wanted, Catalogue number, Quantity, Complete specification (description) of article, Department Heads estimated cost per item, Budget account number to be charged, Company or supplier, Nuclear Regulatory Commission license number if item is a radionuclide product, signature of person requesting purchase and signature of Department Head. Dr. A. Ervanian, Dr. J. Green or Mr. L. Claycomb may initial Request as "Department Head". In the event that all of these people are absent the Request must be initialed by someone in Administration; usually Mr. Donald Courtright.

2. Film and film processing chemicals (developer and fixer replenisher) are on a "Demand standing order". To request delivery telephone Litton Medical (288-3656), state item wanted, quantity, and date wanted.

3. All Request To Purchase must be documented in Nuclear Medicine ordering and purchasing log book. Information needed includes: date, company or supplier, item ordered, date wanted, number of request to purchase form, and amount ordered. Subsequently, when supplies are received the receiving date is entered to complete the log.

4. All completed Request To Purchase forms should be hand delivered to our purchasing agent, Mr. Robert Neriem or placed on his desk in a conspicuous area.

5. Use the following guide to determine delivery information:

COMPANY OR SUPPLIER	DELIVERY
Mallinckrodt Nuclear	Most orders placed by phone before 11:00A.M. will be received the next day in the A.M.
E. R. Squibb & Sons	Most orders placed by phone before 11:00 A.M. will be delivered in 48 hours.
Diagnostic Isotopes Inc.	Most orders placed by phone before 11:00 A.M. will be received at some time during the following day, usually in the P.M. Orders placed after 11:00 A.M. on Friday usually cannot be received until the following Tuesday.

Iowa Methodist Medical Center

Nuclear Medicine

COMPANY OR SUPPLIER	DELIVERY
Medi-Physics, Inc.	Rush orders placed by phone before 11:00 A.M. will arrive the following day. Casual orders take about 48 hours.
3-M Company	Most orders placed by phone before 11:00 A.M. will arrive within 48 hours.
Scientific Products	Most orders arrive within 72 hours.
New England Nuclear	Most orders arrive within 2 - 4 days.
Amersham-Searle	Most orders arrive 48 - 72 hours.
H. B. Leiserowitz Co.	Most orders arrive in 24 hours.
Litton Medical	Most orders arrive in 24 hours.
Millipore Corporation	Most orders arrive in 48 hours.
Curtis Nuclear	Most orders arrive in 3 - 4 days.
Clinical Assays	Most orders arrive in 3 days.
Roche	Most orders arrive in 3 - 5 days.
Pharmacia	Most orders arrive 2 - 4 days.
Nuclear Medical Systems	Most orders arrive 1 - 2 days.

6. The following is a list of "STANDING ORDERS":

COMPANY	PRODUCT	SHIPPING INTERVAL
Curtis Nuclear	Digoxin	1 Kit/10 days
Clinical Assays, Inc.	RIA-T4	500 tubes/3 weeks
Beckman Inst.	RIA-TSH	4 kits/4 weeks
Roche	CEA Kits	1 kit/2 weeks
Mallinckrodt Nuclear	99 Mo - 99 MTC Gen. 131 I Capsules	1 each week 10 (50 uCi) every other week - on Monday.
(Litton Medical Demand	Film, Film Chemicals	Phone as needed.

7. If an expected shipment is overdue double check all laboratory storage areas and the receiving dock. If the shipment is still not found ask Mr. Robert Neriem, of the Purchasing Department, to inquire. He will usually call the supplier and report back in a short time.

8. All shipments of radioactivity (except in-vitro test kits) must be taken to the Hot Lab. immediately after receipt. They will then be monitored with 6-M survey instrument. All surfaces of the container are surveyed before opening. The range of exposure rate (MR/hr) is then documented in Radionuclide Receiving Log Book. If the range is usual for that product, amount and company the container may be opened. If survey data indicates leakage caution should be used during opening including the use of disposable gloves and absorbant pads.

9. Most deliveries of supplies include a packaging list and or invoice. These papers are used by the Accounting Department and by the Clinical Laboratory office Supervisor in confirming receipt of ordered materials. Therefore, all packaging lists and invoices should be processed promptly. Processing includes: signature or initial of Nuclear Medicine Supervisor, date received and any special notation that may be indicated regarding condition of product when opened.

10. If product and all contents of shipment conform to ordering specifications, the packaging list and/or invoice should be hand delivered to the Clinical Laboratory Office supervisor so payment of charges will be initiated. Many Companies and suppliers charge a "Carrying Fee" or give a percentage discount based on the length of time from delivery to payment of charges, so the cost per item ordered can be affected by proper and prompt handling of these forms.

11. If information is needed about past orders check Nuclear Medicine Purchasing Log or Purchase Order file in Clinical Laboratory Office.

12. Rush orders cost more for transportation. Try to avoid Rush Orders.

IOWA METHODIST MEDICAL CENTER

EMPLOYEE JOB DESCRIPTION

Karen Stuyvesant
Title: Nuclear Medicine Technologist Department: Nuclear Medicine Lab.

Approved by: Department Head Administration:

Date Effective: 12-19-77 Date Revised:

Primary Function and Relation to Total Organization:
To operate radiation detection equipment such as scintillation cameras, well type counters, and scintillation probes. To prepare and administer radioactive imaging agents to patients. To produce scintiphotos and radioisotope assays which measure concentrations of drugs, hormones, and body products. To obtain information for use by physicians in diagnosing patient illness.

Reports To:
Nuclear Medicine Supervisor and/or Chief of Nuclear Medicine.

Supervises:
None

Duties and Responsibilities:
(1) To operate scintillation detection equipment. (2) To prepare and administer radiomaging agents to patients. (3) To observe strict precautions in handling radioactive substances to safeguard against any unnecessary radiation exposure. This means using shielding, time and distance. (4) Explain nature of tests to patient to relieve anxieties and to obtain cooperation during testing. The performance of in vivo imaging procedures includes recording all necessary information in the Nuclear Regulatory Commission Log Book and the use of proper anatomical markings on all films. (5) Assist patient in assuming the required anatomical position for studies. (6) To perform in vivo non-imaging tests such as blood volumes, red cell survivals, and Schillings test. To perform in vitro radioimmunoassays. Performance of these tests include the calculation of the test result, using electronic calculator or nomogram, following specified statistical procedures; posting results to appropriate forms; posting results to physicians for interpretations; and assaying and recording reference standards tested with patient specimens. (7) To assist in performing test under investigation by the Nuclear Medicine Laboratory. (8) This includes the use of matched specimens and reference control material. Also, the calculation of matched specimens and reference control material. Also, the calculation of statistics to indicate performance and to make reports about the investigation. (8) To

keep records of tests, test results, use and deposition of radionuclides and quality assurance procedures. (9) To be responsible for the general good housekeeping of the Nuclear Medicine Laboratory. (10) To clean and maintain Kodak film processor according to scheduled services. (11) To perform all duties and responsibilities in such a manner as to insure the most efficient and accurate in vivo and in vitro Nuclear Medicine service possible to the clinicians and patients of Iowa Methodist Medical Center.

Personal Specifications:
Experience: One year employment in Department of Radiology as Staff Technologist in charge of Nuclear Medicine service and radiation therapy. Two and a half years employment in department of Nuclear Medicine as Staff Technologist.

Education: High School graduation. Graduate of School of Radiologic Technology. Graduate of Nuclear Medicine Technology Training Program. Registration by American Registry of Radiologic Technologists (ARRT) in the field of X-Ray Technology and Nuclear Medicine Technology.

Mental Demands: Must be able to react well to constant verbal stimuli. Must be able to psychologically cope with doctors, patients, nurses, students and co-workers.

Physical Demands: The work is light except for occasional patient anatomical positioning for studies. There is considerable standing and frequent reaching. Near visual acuity and depth perception are required for handling and administering radioactive agents. Much talking and hearing are required to instruct patients and to explain procedures to be performed. Radiation dosemeters are worn on body and hands to measure accumulative radiological exposure. The use of gloves, tongs, and lead shielding are required when preparing radionuclide doses.

Working Conditions: The Nuclear Medicine Laboratory is located in a modern building designed for Nuclear Medicine studies. It has excellent ventilation and adequate lighting.

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NUCLEAR MEDICINE LABORATORY PROCEDURE FOR RADIATION MONITORING

1. Nuclear Regulatory Commission licensure of the Nuclear Medicine Laboratory stipulates that the facility will be routinely monitored (surveyed) for radiation contamination. A Nuclear Medicine Area Monitoring log book is kept to document these surveys.

2. "Monitor" comes from a Latin verb that means "to warn". In health physics to monitor means "to test for intensity of radiations" in order to warn people of contamination and possible undesirable levels of radiation exposure.

3. The Nuclear Medicine Laboratory has a Geiger-Mueller monitor instrument which is usually used for area monitors. If an area needs monitoring and the G-M instrument is not operable use the portable ion chamber (cutie pie) that is kept in Radiology. This cutie pie instrument is jointly owned by Nuclear Medicine and Radiology.

4. Follow these general suggestions to do a proper monitoring inspection:

   a. Turn the G-M on and allow about 5 seconds to come to full power.
   b. Inspect the G-M for mechanical defects such as broken tube, loose knob or frayed cable.
   c. Before starting your survey check the level of radiation in the background.
   d. With the instrument turned to the Xl, or most sensitive scale, the needle will fluctuate visible due to background radiation. You need to know your G-M reaponse to background radiation so that you will be able to interpret your later survey readings. Observe the dial long enough to find the maximum fluctuation and the apparent average reading because the intensity of background varies. Background should not exceed 300 cpm. If it does exceed 300 cpm you should check for the presence of a radiation source nearby and/or contamination on the probe.
   e. Make sure that the G-M responds properly to a known source of radiation. As the probe is brought near a test source, the dial reading should increase. From this check procedure you can also observe that the G-M has a time log in its response. The Maximum reading is not given instantaneously. It will take a few seconds for the needle to reach its greatest deflection. If the probe is moved too fast over the surface that is surveyed, it could miss some spots of contamination. Also note the length of time necessary for the needle to return to its normal background position after the source is removed.
   f. Hold the probe as close as possible to all surfaces to be monitored without actually touching it. The correct distance is about one inch. When the needle reaches its maximum reading, you can read the cpm directly off the dial and multiply by the scale you are operating on (xl, xl0 or xl00).

NUCLEAR MEDICINE LABORATORY PROCEDURE FOR RADIATION MONITORING

g. If you take a positive reading, allow time for the needle to return to the normal background position before continuing the survey.
h. Record findings in area monitor log that is stored in the hot lab. If you find no positive reading above background in an area, report as indicated by the log book.

NOTE: 1. The life of the G-M tube is limited to about 1×10^7 counts. The instrument should not be left on needlessly because it has a limited use time and because the batteries will be rapidly depleted.

2. If you use a G-M in the presence of a strong electrostatic or electromagnetic field, you may get a false reading.

"HOT" LAB PROCEDURE MANUAL

I. Quality Assurance

A. Always discard outdated agents.

B. Check dose calibrator with 137Cs reference vial daily and log. Once every six months do wipe test on 137 Cs standard. Use the 133 Ba standard to check the medium energy range of the calibrator. This is done at the start of each work day using the 133 Ba module.

Use the 137Cs standard with all the other modules to check precision. Do not use any module which is outside two standard deviations from the most recently calculated mean for that module. Record all results.

C. Check for 99Mo contamination in the 99mTc. O_4 after each generator elution and log results. A patient dose of 99mTc. X may not contain more than 5 microcures of 99Mo. Discard any 99mTc. preparation which exceeds this limit.

D. Enter the amount (mCi) and volume (ml) of 99mTc. O_4 eluate and the time and date of the elution.

E. Check level of Aluminum ion (Al^{+3}) in 99mTc. O_4 and enter in Radioagent Q.C. log book.

F. Use I.T.L.C. quality control (Q.C.) kit to evaluate bound and unbound 99mTc. in all 99mTc. X preparations.

G. When not in use all radioagents shall be kept in proper lead container and stored in proper colored box with lid closed.

II. Preventative Maintanence

A. Clean exterior instrument surfaces.

B. Replace absorbant bench covers as needed.

C. Transfer waste materials to storage room and label with date and relative half life (short=less than five days).

D. All work areas shall be kept neat and orderly.

III. Radioagent preparation

A. 99m Technetium pertechnetate (99mTc. O_4)
(From Mallinckrodt 99Mo-99mTc. Generator)

1. Remove the protective cap from the bottom of dispenser plunger and attach Luer-Lock needle and return needle guard to position.

2. Place collecting vial in the elution shield (white) so that the ml. graduations can be viewed through the lead glass window. Remove aluminum cap and clean rubber closure of collecting vial with antiseptic swab.

3. Slide elution shield into the dispensing station as far as it will go. The dispensing station automatically centers the collecting vial under the needle.

4. Depress dispenser plunger completely and rotate one-half times clockwise to lock in position. The dispenser needle at this time will have pierced the rubber closure of the collecting vial and the elution procedure is in progress. If the plunger is left in this position the elution will continue to completion. The lead glass window allows visual determination of the eluate volume, and the elution process may be stopped at any volume desired by releasing the plunger.
5. Rotate the plunger counter clockwise to release it and withdraw needle from vial. Remove elution shield from dispensing station.
6. Replace dispenser needle with sterile Luer-lock needle with plastic needle cover in place. Do not remove this cover until next elution.
7. Use dose calibrator and special 99mTc. shield to assay eluant for 99Mo contamination. Log amount of 99Mo. If 99Mo exceeds 5 microcuries per dose, discard that eluant.
8. Use dose calibrator to assay eluant for 99mTc. Log amount and volume.
9. Test eluant for aluminum ion (Al^{+3}) with Al^{+3} test kit. Do not use preparation if Al^{+3} exceeds 10 mcg/ml.
10. Apply proper data to vial and shield. This includes time, date, concentration, total volume, total radioactivity and chemical form.

B. 99mTc. Sulfur Colloid (S.C.)
(Mallinckrodt #090)

1. Attach string tag to reaction vial and aseptically inject 99mTc. O_4^- (0.1 - 5.0 ml.) into reaction vial. To release pressure withdraw air equal to volume injected. Do not exceed 400 mCi.
2. Aseptically inject contents of syringe I. Relieve pressure by withdrawing up to 5 ml of air from the vial.
3. Shake gently and boil in water bath for 8 minutes.
4. Remove and aseptically inject contents of syringe II. Return vial to water bath for 2 minutes.
5. Shake gently and assay and record proper data on string tag. This includes time, date, volume, concentration, total radioactivity, and chemical form. Preparation should be clear to slightly hazy in appearance.
6. No precipitate should be present. If precipitate is visible, the preparation should not be used. Do not use after six hours from time of preparation.
7. Calculate % bound or unbound with Q.C. kit and log. Do not use preparation if unbound exceeds 10%.
8. Adult liver dose is 2.0-4.0 mCi.

C. 99mTc. Pyrophosphate (99mTc. PYP)
(From Mallinckrodt #094)

1. Remove PYP reaction vial from refrigerator and allow to come to room temperature (5 minutes).
2. Attach string tag and aseptically inject 1-10 ml. 99mTc. O_4^-. Do not exceed 100 mCi.
3. Shake gently for at least one minute. Allow to stand for 5 minutes or put in ultrasonic bath for 5 minutes.

4. Assay and record data on tag. This includes time, date, volume, concentration, total radioactivity and chemical form.
5. Do Q.C. and log. Do not use if unbound 99mTc. exceeds 15%.
6. Adult dose for bone is 20.0 mCi, cardiac (M.I.) dose is 10.0-15.0 mCi.

D. ^{99m}Tc. Disofenin (DSF)

1. Attach string tag to reaction vial and aseptically inject 2-4 ml of $^{99m}TcO_4^-$ into the vial. The TcO_4^- may be diluted with additive-free NaCl. Release pressure by withdrawing an equal volume of air. Do not exceed 100 mCi.
2. Agitate the vial by repeated inversions for 60-90 seconds.
3. Assay the amount of radioactivity and prepare a label with the necessary information; affix it to the tag.
4. DSF should be allowed to set 1-2 minutes before using or performing the ITLC procedure. This allows maximum labelling. Examine vial for particles.
5. After waiting 1-2 minutes, spot a small drop of ^{99m}Tc. DSF on a strip of Whatman #1 filter paper (5 X 20 cm). Also, spot a small drop on a strip of silica gel paper (5 x 20 cm. ITLC paper).
6. Allow these drops to air dry before developing. This requires about 5 minutes.
7. Develop the ITLC silica gel paper in a mixture of Acetonitrile and water 3:1. This checks for hydrolyzed DSF.
8. Develop the Whatman filter paper in Acetone. This checks for free $^{99m}TcO_4^-$.
9. Read the filter and chromatography strips and interpret according to the established procedure for such.
10. Do not use any DSF preparation that has a labelling efficiency under 90%.
11. Document this Q.C. procedure.
12. Adult dose in 3-5 mCi of ^{99m}Tc. DSF.

NOTE: Acetronitrile is poison. Keep stored, capped and under negative pressure hood.

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ROUTINE RADIATION SAFETY REGULATIONS

1. Only designated, trained Nuclear Medicine employees are allowed to handle or in any way manipulate radionuclide sources.

2. Pregnant personnel are not allowed in room A-37, the "Hot Lab", may not check in any shipment which exceeds one millicurie, and may not empty radioactive waste containers in the imaging areas.

   The HCG (RIA) test will be considered the standard test to determine pregnancy.

3. Personnel monitoring devices are to be worn while in the laboratory (eg. film badges, pocket ionization chambers, etc.).

4. Only work involving the preparation or dispensing of radiopharmaceuticals is to be carried out in the laboratory.

5. Laboratory coats and rubber gloves are required to be worn when working in the laboratory. The Lab coats shall be buttoned. Personnel must dispose of the rubber gloves before leaving the laboratory or monitor either for contamination. The gloves should be properly removed so as not to contaminate the hands and then disposed of as contaminated waste.

6. Eating, drinking, smoking and the application of cosmetics are prohibited in the laboratory. The storage of food in the laboratory is prohibited.

7. Pipetting or any similar operation by mouth suction is prohibited.

8. Radioactive waste and contaminated materials are to be disposed of in a specially designated receptacle in the laboratory.

9. "Good Housekeeping" shall be maintained at all times. Spillage should be prevented, but in the event of such an accident, the following procedure shall be used:

   a. The liquid shall be blotted up with absorbent paper. (Wear rubber gloves!)
   b. All disposable materials contaminated by the spill and cleaning materials shall be placed in the radioactive trash can.
   c. Mark the area of the spill, designate the type of radioactivity, name of the isotope, date and your name. Report the occurrence to the Nuclear Medicine Supervisor.

10. Hood exhaust fans are to be kept running when hood areas are in use.

11. All handling of Radionuclides should be done over surfaces lined with absorbent material. In general, a series of covered stainless steel, aluminum, or plastic trays is better than simply covered table tops.

12. In no instance should preparative radiopharmaceutical procedures be conducted outside of Room A-37, "HOT LAB".

13. Radioactive material shall not be removed from the "HOT" laboratory unless:

    a. Totally enclosed in a non-contaminated, shatter-proof container.
    b. Properly labeled.

14. Equipment, articles or objects shall not be carried out of the "HOT" laboratory unless they have been found to be free of surface contamination.

15. At the end of each procedure the person responsible should clean up his work space, disposing of any contaminated material in a suitable fashion. If a spill occurs it should be dealt with immediately. Frequent monitoring of work areas is required during radiochemical procedures and at their completion.

16. A special kit containing equipment for decontamination procedures shall be kept in the "HOT LABORATORY" ready for emergency use.

17. All contaminated wounds, spills and other emergencies should be reported to the Nuclear Medicine Supervisor or Physician.

18. It is required that anyone leaving the "HOT" laboratory monitor their hands, for radioactive contamination before entering any other area of the Nuclear Medicine Section.

19. Whenever a new radionuclide procedure is initiated, dummy runs must be made and precautions taken to prevent contamination.

20. Syringes shields shall be used for the preparation and administration of patient doses. Shields should be 3-4 mm (Pb) thick, this will attenuate 99mTc. emmissions by a factor of about 1000.

21. Whenever possible remote handling devices (tongs) shall be used.

22. After decontamination the area or equipment must be at background before putting back into operation.

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EMERGENCY PROCEDURES

Auxiliary Emergency Procedures

The following emergency procedures should be observed when the surface or air-borne contamination level is suddenly raised to an unsafe level as a result of a spill, release, or by any other means. It should be remembered that in the case of any accident, the individual's first responsibility is for himself and others. Loss or damage of materials and equipment, under emergency conditions, is of secondary importance.

1. Procedure for individual contamination:

   a. Warn other occupants of the room; leave the room. If you have time, right containers, drop absorbent pads on liquids, or other primary measures to prevent the spread of contamination.

   b. Close the laboratory door or effectively isolate the area and ask someone to prevent entrance by personnel until the area is posted.

   c. Wash and flush any radioactive material from your skin.

   d. As soon as possible, report or ask someone to report the accident to the proper authorities. This should not be done at the expense of delaying personal decontamination when the hazard has been isolated from others and the immediate danger is to yourself.

   e. Remove contaminated clothing and rewash with tepid (not hot) water and a mild soap or detergent.

   f. Check your body for cuts and abrasions. If there are any, whether they were caused by the accident or not, notify a physician in Nuclear Medicine and Health Service.

   g. If no immediate medical attention is required, wait for the Nuclear Medicine personnel. A detailed account of the incident will aid in the decontamination of the area for re-occupancy.

   h. In areas where the air is not exhausted through absolute filters, turn off the exhaust fans. This will prevent the spread of contamination throughout the building by way of the ventilation system.

2. Procedures for personnel not directly involved in the radiation contamination incident.

   a. Notify the Supervisor and a physician in Nuclear Medicine (in case of injury).

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b. Care of persons involved in the incident:

1. Apply necessary first aid.

2. Measure clothing for contamination.

3. Remove significantly contaminated clothing, and, if necessary, clothe in an uncontaminated laboratory coat.

4. Stay with persons involved in incident until emergency help arrives. Advise the emergency help on the extent of the personnel contamination.

c. Contamination control procedures while waiting for help:

1. For a localized non-volatile liquid spill:

a) Rope off or guard spill area against re-entry.

b) Assemble potentially contaminated persons in one location of laboratory and monitor them for contamination.

c) Remain in the area until released by Nuclear Medicine personnel.

2. For a release of powdered volatile-liquid, or gaseous activity:

a) Evacuate personnel immediately, turning off any laboratory apparatus that needs contant attention.

b) Assemble personnel immediately outside the room and instruct them to stay in one location, to prevent the spread of contamination.

c) Close and lock the room doors to prevent re-entry. If the fans are off, try to seal accessible openings into the laboratory to prevent further escape of airborne activity to the corridors.

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Safe

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Operational Procedures for Radionuclides

1. Operational Safety

A. Generally standard precautions observed in routine chemical procedures are not sufficient for radioactive work.

B. Work with radioactive material should be confined to as small an area as possible. This aids in limiting the affected area in cases of accidental contamination.

C. Transfer of radionuclides from one area or vessel to another should be minimized and kept as simple as possible.

D. Limiting the duration of personnel exposure, lead shielding (ie. rubberized apron or solid forms) and distance should be used as ways to control exposure.

E. Liquids and or solids containing gamma emitting radionuclides which emit in excess of 2mR/hr. at the surface of the container must be stored in a lead container or provided with lead shielding.

F. Glassware, tongs and other similar tools used in a radiation area should not be used in a non-radioactive area. Equipment of this sort used in a restricted area must be suitably marked.

G. Gloves must be worn during any manipulation with radioactive material which may possibly result in contamination. When using gloves care should be taken not to contaminate switches, door handles and similar objects. Always discard gloves in radioactive waste container.

H. Laboratory coats or aprons must cover normal attire.

I. Absorbent paper with a non-absorbing backing is required for work surface coverage.

J. Smoking, eating and the application of cosmetics is prohibited in rooms where radionuclides are stored or used.

K. Food or drink must not be stored in the same refrigerator or other area or container with radioactive materials.

L. Mouth pipetting of radioactive material is prohibited.

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2. Supervision of Procedures

A. All procedures and operations involving actual or potential radiation exposure shall be under the direct supervision of competent personnel who are qualified by training and experience to deal effectively with technical and safety problems which may arise.

3. Hazards to consider when working with Radioactive material

A. Internal hazards occur as a result of deposition of radioactive materials within the human body, as a result of inhalation, ingestion, immersion or entry through cuts or wounds. Relatively small amounts of radioactive materials may give exposures equivalent to maximum permissible external exposures.

B. External exposures can be controlled by adequate shielding. Normally all operations shall be shielded so exposure levels cannot exceed 2½ mR/hour.

C. Exposure to hands can be kept to safe levels by use of proper techniques. Every operation of this type must be checked with ring or wrist-badges. Remote use tongs, local shields and limiting of time all must be utilized in safe procedures.

4. Posting and labeling

A. Federal law requires that containers, rooms, areas and glassware requiring warning labels shall use the conventional radiation caution colors of Magenta (purple) on yellow background. The symbol described by this regulation is the conventional three-bladed design. In addition the proper wording is also essential. "RADIOACTIVE MATERIAL", this sign will be posted at the entrance to all rooms or areas in which the quantity of radionuclide present exceeds amounts in Appendix I.

"RADIATION AREA" - This sign will be posted in every area in which there is a radiation level of 5mR/hour.

"HIGH RADIATION AREA" - This sign will be posted in every area in which the radiation level is 100mR/hour or more.

"AIR-BORNE RADIOACTIVITY" - This sign will be posted in any room in which air-borne radioactive materials exist.

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5. "Unrestricted Area" is defined as any area where access is not controlled by Iowa Methodist Medical Center Nuclear Medicine personnel for purposes of protection of individuals from exposure to radiation. Unrestricted areas have radiation levels less than 0.5 mR/hour.

6. "Restricted Area" is defined as any area where access is controlled by Iowa Methodist Medical Center Nuclear Medicine personnel for purposes of protection of individuals from exposure to radiation levels in excess of 2 mR/hour or 100 mR in seven consecutive days. Access shall be controlled either by locked doors, guards or visually. Visitors may be shown through the area but must wear suitable dosimeters and/or film badges if they are likely to receive an exposure in excess of 10 millirem.

   All janitors entering radiation areas or high radiation areas must be on the dosimetry program if they are likely to receive a radiation dose in excess of 2mR. It is the responsibility of the Nuclear Medicine personnel to instruct the custodian not to handle radioactive containers.

7. All radioactive materials in non-restricted areas must be secured against unauthorized removal from place of storage or use. When in use the material shall be under supervision of one or more individuals in order to prevent unauthorized removal. When the material is not in use it will be under lock and key.

8. Contamination is defined as deposition of radioactive material in any place except where it is specifically supposed to be. The two objectives of decontamination procedures are to minimize human exposure and to prevent invalidation of present and future procedures by spreading radioactivity.

   When an accident occurs isolate the area by such means as a locked door roping off or guarding to prevent spread. If human contamination occurs, surface contamination should be treated by washing with pure soap and copious amounts of warm water. When skin is lacerated the wounded area must be washed immediately under a stream of cold water. After first aid measures have been taken report to Health Services or Emergency Service Department. If the accident occurs after working hours, the person in charge shall call the Nuclear Medicine Physician or Nuclear Medicine Supervisor.

The following items should be readily available-plastic waste bags, paper towels, plastic gloves, reagents for decontamination (Radiac Wash), soft brush, absorbent tissue, hand soap, tape.

9. Decontamination Techniques

   A. Concentrate and confine to avoid spread.

   B. Large amounts of liquid in clean-up should be avoided as excess liquid merely flushes the contamination into porous surfaces.

   C. Excess liquid contaminants are often easiest removed by blotting.

   D. With short-lived materials decay is an acceptable technique, provided that during decay provision is made for preventing spread and exposure of personnel.

   E. Dry powder contaminants can be picked up with tape.

   F. Decontaminated areas and items must be at background with a G-M meter before being put back into operation.

10. "Radioactive Waste" includes all radionuclide material which is due for disposal. Such items as paper, glassware, needles and syringes that have been used for radionuclide work are included.

   A. Liquid waste shall be stored in a suitable container.

   B. All waste will be stored until radioactivity has decayed to background.

   C. All waste shall be marked with relative half-life, short (5 days) and long (over 6 days) and date put in storage.

   D. Radionuclide inventory book should be updated with date and method of disposal.

11. Emergency Procedures for Radionuclides

   A. In the event of a spill of a radionuclide solution notify all persons in the room and vacate the room immediately but remain in the vicinity in order to avoid widespread dispersal of the spilled material.

   B. Contact the Nuclear Medicine Physician and Supervisor, also determine the extent of hazard.

C. If no radiation hazard to personnel exists, confine the spill and decontaminate, following the procedures outlined in Section numbers 8 and 9.

D. If a radiation hazard to personnel does exist, notify the Medical Center Physicist immediately.

E. Restrict personnel involved to an adjacent area till they can be monitored.

F. Minor spills (those involving little or no radiation hazard to personnel) may be decontaminated by Nuclear Medicine personnel under supervision of the Nuclear Medicine Physician and/or Supervisor.

12. Leak Testing Requirements

A. All by-product sources (atomic number 1-83 inclusive) with a half-life in excess of 30 days, if the total quantity of the source is equal to or greater than that listed in SCHEDULE OF QUANTITIES REQUIRING LEAK TESTING.

SCHEDULE OF QUANTITIES REQUIRING LEAK TESTING

By-product Material	Amount (microcuries)
Antimony (Sb 124)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	10
Barium 140-Lanthanium 140 (BaLa 140)	10
Beryllium (Be 7)	50
Cadmium 109 - Silver 109 (CdAg 109)	10
Calcium 45 (Ca 45)	10
Carbon 14 (C 14)	50
Cerium 144 - Praseodymium (CePr 144)	10
Cesium - Barium 137 (CsBa 137)	10
Chlorine 36 (Cl 36)	10
Chromium 51 (Cr 51)	50
Cobalt 60 (Co 60)	10
Copper 64 (Cu 64)	50
Europium 154 (Eu 154)	10
Fluorine 18 (F 18)	50
Gallium 72 (Ga 72)	10

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SCHEDULE OF QUANTITIES REQUIRING LEAK TESTING

By-product Material	Amount (microcuries)
Germanium 71 (Ge 71)	50
Gold 198 (Au 198)	10
Gold 199 (Au 199)	10
Hydrogen 3 (Tritium H 3)	250
Indium 144 (In 144)	10
Iodine 131 (I 131)	10
Iridium 192 (Ir 192)	10
Iron 55 (Fe 55)	50
Iron 59 (Fe 59)	10
Lanthanum 140 (La 140)	10
Manganese 52 (Mn 52)	10
Manganese 56 (Mn 56)	50
Molybdenum 99 (Mo 99)	10
Nickel 59 (Ni 59)	10
Nickel 63 (Ni 63)	10
Niobium 95 (Nb 95)	10
Palladium 109 (Pd 109)	10
Palladium 103 - Rhodium 103 (PdRh 103)	50
Phosphorus 32 (P 32)	10
Polonium 210 (Po 210)	1
Potassium 42 (K 42)	10
Praseodymium 143 (Pr 143)	10
Promethium 147 (Pm 147)	10
Rhenium 186 (Re 186)	10
Rhodium 105 (Rh 105)	10
Rubidium 86 (Rb 86)	10
Ruthenium 106 - Rhodium 106 (RuRh 106)	10
Samarium 153 (Sm 153)	10
Scandium 46 (Sc 46)	10
Silver 105 (Ag 105)	10
Silver 111 (Ag 111)	10
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 89 (Sr 89)	10
Strontium 90 - Yttrium 90 (SrY)	1
Sulfur 35 (S 35)	50
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 99 (Tc 99)	10
Tellurium 127 (Te 127)	10
Tellurium 129 (Te 129)	10
Thallium 204 (Tl 204)	50
Tin 113 (Sn 113)	10
Tungsten 185 (W 185)	10
Vanadium 48 (V 48)	10
Yttrium 90 (Y90)	10
Yttrium 91 (Y91)	10
Zinc 65 (Zn 65)	10

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APPENDIX I

POSTING REQUIREMENTS

Material	Room or Area (microcuries)	Container (microcuries)
Ag 105	10	1
Ag 111	100	10
As 76, As 77	100	10
Au 198	100	10
Au 199	100	10
Ba 140 + La 140	10	1
Be 7	500	50
C 14	500	50
Ca 45	100	10
Cd 109 + Ag 109	100	10
Ce 144 + Pr 144	10	1
Cl 36	10	1
Co 60	10	1
Cr 51	500	50
Cs 137 + Ba 137	10	1
Cu 64	500	50
Eu 154	10	1
F 18	500	50
Fe 55	500	50
Fe 59	10	1
Ga 72	100	10
Ge 71	500	50
H 3 (HTO or H^3_2O)	2500	250
I 131	100	10
In 114	10	1
Ir 192	100	10
K 42	100	10
La 140	100	10
Mn 52	10	1
Mn 56	500	50
Mo 99	100	10
Na 22	100	10
Na 24	100	10
Nb 95	100	10
Ni 59	10	1
Ni 63	10	1
P 32	100	10
Pd 103 + Rh 103	500	50
Pd 109	100	10

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APPENDIX I (con't)

Material	Room or Area (microcuries)	Container (microcuries)
Pm 147	100	10
Po 210	1	0.1
Pr 143	100	10
Pu 239	10	1
Ra 226	1	0.1
Rb 86	100	10
Re 186	100	10
Rh 105	100	10
Ru 106 + Rh 106	10	1
S 35	500	50
Sb 124	10	1
Sc 46	10	1
Sm 153	100	10
Sn 113	10	1
Sr 89	10	
Sr 90 + Y 90	1	10.1
Ta 182	100	1
Tc 96	10	1
Tc 99	10	10
Te 127	100	1
Te 129	10	50
Th (natural)	500	50
Tl 204	500	250
Tritium--See H3	2500	50
U (natural)	500	1
U 233	10	50
U 234 - U 235	500	1
V 48	10	10
W 185	100	1
Y 90	10	1
Y 91	10	10
Zn 65	100	
Unidentified radioactive materials or any of the above in unknown mixtures	1	0.1

B. All other radioactive materials with half-life in excess of 30 days, if the quantity of the source is one microcurie or more.

13. Instrument Calibration

A. All instruments used in evaluating radiation exposure or absorbed dose should be routinely calibrated at least once every twelve (12) months. Battery checks should be made on the instrument at routine intervals.

B. Any instrument which fails to operate properly must be re-calibrated after repairs have been made.

14. Radiation Monitoring

A. All rooms in which radioactive materials are used or stored are monitored once each weekday. Monitoring is performed at a specified, constant distance from containers.

B. Monitoring data in mR/hour and date of survey and location are entered in the "Area Monitoring Log".

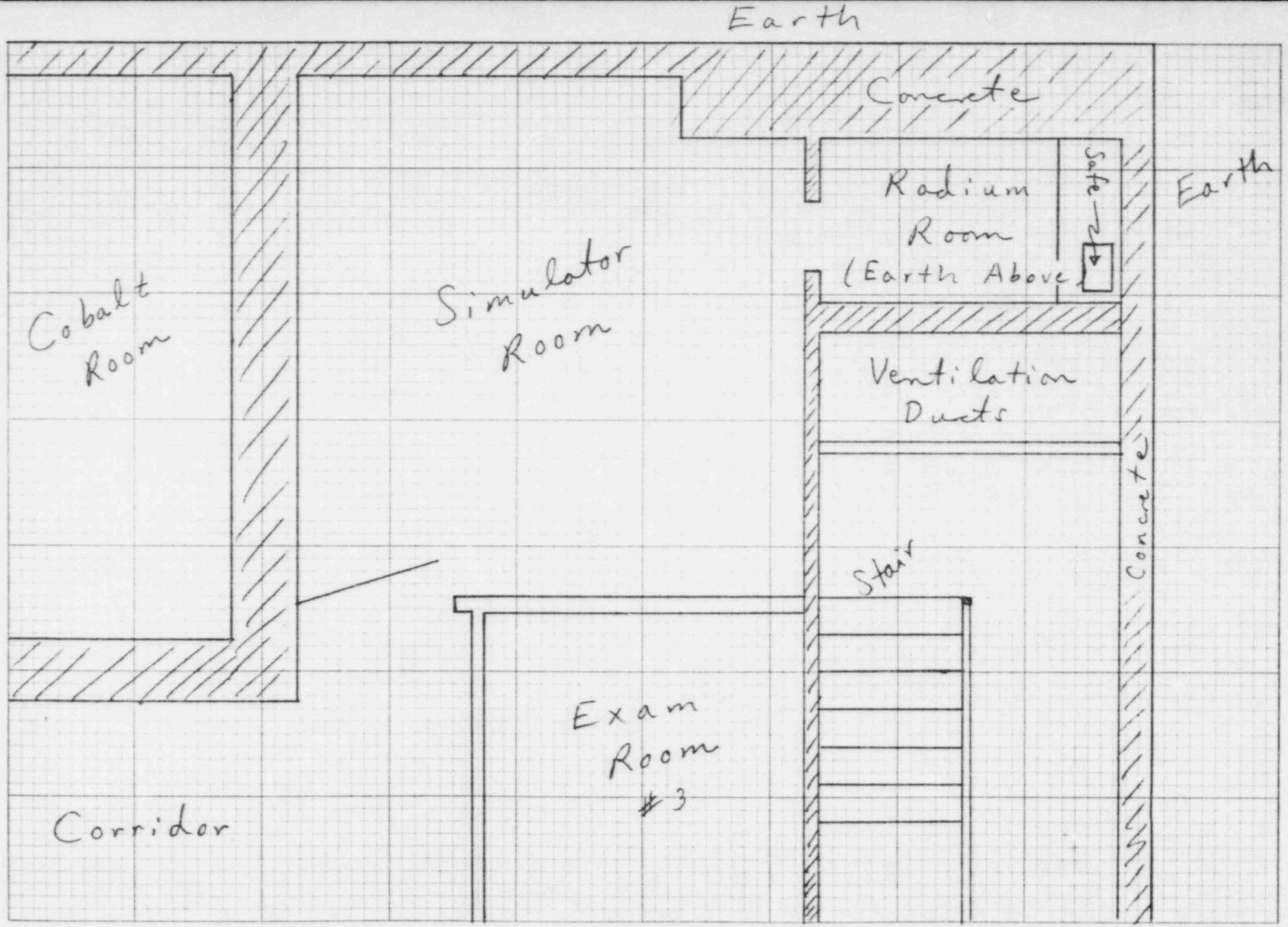
SUPPLEMENT TO AEC 313
ITEMS 19 and 20

11. Facilities and Equipment

Facility Diagram (copy attached)
Two-drawer storage safe Radium Chemical Cat. No. 470-3-H
Lead-glass L-block Radium Chemical Cat. No. 462
Long-handled tongs
Lead pig with handle
Description: Lead pig with 1 inch thick side walls. The bottom of the pig also has a thickness of 1 inch. The lid of the pig is a steel lock with a thickness of 1 inch. The handle for the pig is 6 inches long.

The Cs-137 sources are to be stored in the lead safe shown in the attached diagram of the facility. The sources will be loaded into the applicators behind the lead-glass L-block using long-handled tongs. These applicators will be placed in the lead pig for transport to the simulator room where they will be loaded into the patient. The patient will then be transferred to a private room in the hospital. At the time the sources are removed, they will again be placed in the lead pig for return to the lead safe in the radium room.

The P-32, I-131, Ir-192, and I-125 sources are stored in their shielded shipping containers in the radium room. The P-32 and Ir-192 sources are transported in their shielded containers to the adjoining simulator room for administration to or implantion in the patient. The waste from the P-32 administration is stored in the radium room until decayed. The unused Ir-192 sources are stored in the radium room until the implanted seeds are removed from the patient. At that time, all the Ir-192 sources are returned to the manufacturer. The I-131 sources are transported in their shielded containers to the nearest exam room for administration to the patient. The radioactive waste from the I-131 administration is held in the radium room until decayed. The I-125 sources are transported in a shielded container to the OR for implantion in the patient. The unused I-125 sources are returned to the radium room to be held for a later implant or until decayed.


Earth
Concrete
Radium
Room
(Earth Above)
Safe
Earth
Cobalt
Room
Simulator
Room
Ventilation
Ducts
Concrete
Stair
Exam
Room
#3
Corridor

11. 2/28/85

13. Procedures for Ordering and Receiving Radioactive Materials

(See procedures on following pages for various radionuclides used in Radiation Therapy)

Procedure for Ordering and Receiving Cs-137 Tubes and Needles

1. The Physicist should place all orders for Cs-137 tubes and needles. It will be his responsibility to ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded (1 curie total of radioactive materials in group VI).

2. The physicist will complete the radioactive cesium order form and contact the appropriate supplier.

3. When the shipment is received, the loading dock personnel will immediately transfer the shipping container to the Radiation Therapy Department.

4. The physicist or his representative will monitor the package as outlined below:

   a) Visually inspect the package for any sign of damage. Record the date and time the package was received, the condition of the package, and the transport index on the Radioactive Shipment Receipt Form.

   b) Measure the exposure rate at 3 feet (or 1 m) from the package surface and on the surface. Record these readings on the Radioactive Shipment Receipt Form. The readings should be less than the limits listed below.

Label	Surface	3 Feet
"Radioactive - White I"	0.5 mR/hr	0 mR/hr
"Radioactive - Yellow II"	50.0 mR/hr	1.0 mR/hr
"Radioactive - Yellow III"*	200. mR/hr	10. mR/hr

   *Require vehicle placarding

   c) Wipe the surface of the shipping container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100 sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

   d) Open the outer package (while wearing gloves and following manufacturer's directions, if supplied) and remove packing slip.

   e) Open the inner package and verify that contents agree with those on packing slip and the physician's original order. Record the results of the this comparison on the Radioactive Shipment Receipt Form.

   f) Wipe the external surface of the final source container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100 sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

   g) Monitor the packing material and packages for contamination. If contaminated, treat as radioactive waste. If not contaminated, either retain for return shipment

or obliterate radiation labels and discard in regular trash. Indicate on the Radioactive Shipment Receipt Form, the survey results and the disposition of the packing materials.

5. Place the Cs-137 tubes and needles in the storage safe in the radium room.

6. Update the Cs-137 inventory sheet to indicate the addition of these sources.

IOWA METHODIST MEDICAL CENTER

1200 PLEASANT STREET, DES MOINES, IOWA 50308 TELEPHONE 515-283-6212

RADIATION THERAPY
515-283-6860

LOUIS L. MAHER, M.D.
TERRENCE J. ALLEN, M.D.
WILLIAM L. McGINNIS, M.D.

RADIOLOGICAL PHYSICS
515-283-6860

CHARLES J. BISCHOF, Ph.D.

Cesium Order Form

Part I - Cesium Tubes

Vendor _____

Number of Sources _____

Radium-Equivalence _____

Date of Request _____

Physicist Placing Order _____

Part II - Cesium Needles

Vendor _____

Number of Sources _____

Radium-Equivalence _____

Date of Request _____

Physicist Placing Order _____

Signed _____

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515-283-6860

LOUIS L. MAHER, M.D.
TERRENCE J. ALLEN, M.D.
WILLIAM L. McGINNIS, M.D.

RADIOLOGICAL PHYSICS
515-283-6860

CHARLES J. BISCHOF, Ph.D.

Radioactive Shipment Receipt Form

Date _____ Time _____

Condition of Package:

_____ O.K. _____ Punctured _____ Crushed

Transport Index: _____

Measured Radiation Levels:

Package surface _____ mR/hr

3 feet (1 m) from surface _____ mR/hr

Do Packing Slip and Vial Contents Agree?

Radionuclide _____ yes _____ no, difference _____

Amount _____ yes _____ no, difference _____

Does Shipment Agree with Physician's Order?

Radionuclide _____ yes _____ no, difference _____

Amount _____ yes _____ no, difference _____

Wipe Test Results:

Outer Container _____ μCi

Final Source Container _____ μCi

Survey Results of Packing Material and Container _____ mR/hr

Disposition of Package After Inspection _____

If NRC/Carrier Notification Required, Give Time, Date, and Persons Notified.

Signed _____

Procedure for Ordering and Receiving Radioactive I-131 and P-32

1. I-131 and P-32 are ordered to be shipped directly to the Radiation Therapy Department with specific attention to one of the radiotherapists. The radiotherapist should enter his name, the patient's name, the radionuclide, the desired activity, the patient's name, the vendor's name and the planned date of administration on the Radionuclide Order Form.

2. The shipment will either be delivered directly to the Radiation Therapy Department (if ordered from NPI) or will be transferred immediately to the Radiation Therapy Department by the loading dock personnel (if ordered from another vendor).

3. The physicist or his representative will monitor the package as outlined below:

   a) Visually inspect the package for any sign of damage. Record the date and time the package was received, the condition of the package, and the transport index (not needed if delivered by NPI) on the Radioactive Shipment Receipt Form.

   b) Measure the exposure rate at 3 feet (or 1 m) from the package surface and on the surface. Record these readings on the Radioactive Shipment Receipt Form. The readings should be less than the limits listed below.

Label	Surface	3 feet
"Radioactive - White I"	0.5 mR/hr	0 mR/hr
"Radioactive - Yellow II"	50.0 mR/hr	1.0 mR/hr
"Radioactive - Yellow III"*	200. mR/hr	10. mR/hr

*Require vehicle placarding

   c) Wipe the surface of the shipping container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100 sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

   d) Open the outer package (while wearing gloves and following the manufacturer's directions, if supplied) and remove the packing slip.

   e) Open the inner package and verify that the contents agree with those on the packing slip and the physician's original order. Record the results of this comparison on the Radioactive Shipment Receipt Form.

   f) Wipe the external surface of the final source container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100 sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

   g) Monitor the packing material and packages for contamination. If contaminated, treat as radioactive waste.

If not contaminated, either retain for return shipment or obliterate radiation labels and discard in regular trash. Indicate on the Radioactive Shipment Receipt Form, the survey results and the disposition of the packing materials.

4. Place the I-131 or P-32 in their shielded shipping containers in the radium room until time for administration to the patient.

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515-283-6860

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TERRENCE J. ALLEN, M.D.
WILLIAM L. McGINNIS, M.D.

RADIOLOGICAL PHYSICS
515-283-6860

CHARLES J. BISCHOF, Ph.D.

Radionuclide

Order Form

Part I

Patient's Name: _____

Radionuclide: _____

Activity: _____

Vendor: _____

Date of Administration: _____

Physician's Name: _____

Date of Request: _____

Procedure for Ordering and Receiving Radioactive I-125 and Ir-192 Seeds

1. The physicist should place all orders for radioactive seeds. It will be his responsibility to ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded (1 curie total of radioactive materials in group VI).

2. When accepting an order for radioactive seeds from the physician, the physicist will need the following information:

   a) Patient's name
   b) Radionuclide
   c) Activity per seed
   d) Number of seeds
   e) Date of implant

3. The physicist will record this information on the order form along with the physician's name and the date the request was received.

4. The physicist will then contact the appropriate supplier and record the vendor's quoted activity per seed and the cost of the radioactive seeds (including shipping).

5. On the day the shipment is to be received, the vendor will contact the physicist regarding the approximate time of delivery. When the shipment is received, the loading dock personnel will immediately transfer the shipping container to the Radiation Therapy Department.

6. The physicist or his representative will monitor the package as outlined below:

   a) Visually inspect the package for any sign of damage. Record the date and time the package was received, the condition of the package, and the transport index (not needed if delivered by NPI) on the Radioactive Shipment Receipt Form.
   b) Measure the exposure rate at 3 feet (or 1 m) from the package surface and on the surface. Record these readings on the Radioactive Shipment Receipt Form. The readings should be less than the limits listed below.

Label	Surface	3 feet
"Radioactive - White I"	0.5 mR/hr	0 mR/hr
"Radioactive - Yellow II"	50.0 mR/hr	1.0 mR/hr
"Radioactive - Yellow III"*	200. mR/hr	10. mR/hr

*Require vehicle placarding

   c) Wipe the surface of the shipping container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100

sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

d) Open the outer package (while wearing gloves and following the manufacturer's directions, if supplied) and remove the packing slip.

e) Open the inner package and verify that the contents agree with those on the packing slip and the physician's original order. Record the results of this comparison on the Radioactive Shipment Receipt Form.

f) Wipe the external surface of the final source container and monitor the wipes using the multichannel analyser. (The removable contamination should not exceed 0.01 uCi/100 sq. cm.) Record the results of this wipe test on the Radioactive Shipment Receipt Form.

g) Monitor the packing material and packages for contamination. If contaminated, treat as radioactive waste. If not contaminated, either retain for return shipment or obliterate radiation labels and discard in regular trash. Indicate on the Radioactive Shipment Receipt Form, the survey results and the disposition of the packing materials.

7. Place the radioactive seeds in their shielded shipping container in the radium room until they are needed for implanting.

8. After the seeds are implanted in the patient, the physician should record the number of seeds actually used in the implant on the original order form.

9. The disposition of the unused seeds (permanent implant) or all the seeds (temporary implant) should be indicated on the original order form. If the seeds are to be returned to the manufacturer, the seeds should be placed in their original shipping container, the waste disposal forms should be completed, and the shipping container should be carried to the loading dock for pickup the same day. If the seeds are to be held for decay, they should be placed in a shielded container in the radium room.

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LOUIS L. MAHER, M.D.
TERRENCE J. ALLEN, M.D.
WILLIAM L. McGINNIS, M.D.

RADIOLOGICAL PHYSICS
515-283-6860

CHARLES J. BISCHOF, Ph.D.

Radioactive Seed

Order Form

Part I

Patient's Name: _____

Radionuclide: _____

Desired Activity/Seed: _____

Number of Seeds: _____

Date of Implant: _____

Physician's Name: _____

Date of Request: _____

Physicist Placing Order: _____

Available Activity/Seed: _____

Cost (including shipping): _____

Part II

Number of Seeds Implanted: _____

Type of Implant:

_____ Permanent

Disposition of Seeds:

_____ Returned to manufacturer

_____ Held for radioactive decay

Signed _____

14. Procedures for Safely Opening Packages Containing Radioactive Materials.

(See the procedures outlined in item 13 for details regarding the opening of packages containing radioactive materials used in Radiation Therapy.)

19. Therapeutic Use of Radiopharmaceuticals

a. The radiation safety procedures outlined below will be followed.

Radiation Safety Procedures for
Therapeutic Use of Radiopharmaceuticals

1. All patients treated with I-131 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination expected.

2. The patient's room will be properly posted or attended in accordance with 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, 3 feet from the patient, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a visitor may remain at a distance of 3 feet from the patient. The measured exposure rates and visiting time will then be recorded, along with other pertinent data, on the Nursing Precautions for Patients Containing Radioactive Materials Form. A copy will be posted on the patient's chart.

4. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20 (i.e. 2 mrem in any one hour, or 100 mrem in any seven consecutive days).

5. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

6. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. These materials will then be disposed of as normal or radioactive waste, as appropriate.

7. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

8. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with

a low-level survey meter. They will then be released to the sanitary sewer system.

9. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

10. Nursing Instructions

a) Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses shoud read these instructions before administering to the patients. Call the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear monitoring devices as advised by the Radiation Safety Officer.

b) Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

c) Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

d) Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Radiation Therapy Department.

e) No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

f) Attending personnel should wear rubber or disposable gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g) Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h) All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i) All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j) Surgical dressings should be changed only as directed by the physician. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k) For I-131 patients:

(1) The patient should be encouraged to use the toilet himself, and to triple flush the toilet after each use.

(2) Disposable plates, cups, and eating utensils will be used by patients who are treated with I-131.

(3) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. 6860. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(4) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see item 11 below).

l) If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m) If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Radiation Therapy Department immediately.

n) When the patient is discharged, call the Radiation Safety Officer or his designee or the Radiation Therapy Department and request that the room be surveyed for contamination before remaking the room.

11. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

b.

P-32 is being used in liquid form for administration to therapy patients. Since P-32 is nonvolatile, precautions with this radionuclide do not involve the use of a fume hood. The P-32 (in its shielded container) is placed on an absorbent pad on a portable cart. This portable cart is used to transfer the P-32 from the radium room to the adjoining simulator room for administration to the patient. The physician handling the P-32 wears disposable gloves. After the physician has instilled (colloidal P-32) or injected (soluble P-32) the P-32 into the patient, a radiation survey of the simulator room and the materials used in the administration is performed. Any contaminated materials are placed in a disposable plastic bag and stored in the radium room until decayed. If the simulator or the room is contaminated, the radiation safety officer or his designee is contacted to institute decontamination procedures.

I-131 is ordered in liquid form and received in a glass vial which is sealed with a rubber stopper. At the time of administration to the patient, the I-131 (in its shielded container) is placed on an absorbent pad on a portable cart. This cart is used to transfer the I-131 from the radium room to exam room #3 for administration to the patient. The physician handling the I-131 wears disposable gloves. A needle-tipped straw is inserted through the rubber stopper into the I-131 solution. The patient uses this straw to suck up the I-131 solution. A second "breather" needle is also inserted through the rubber stopper to avoid the creation of a vacuum inside the stoppered bottle. After the I-131 solution has been administered to the patient, the needle-tipped straw is removed from the vial and placed in a zip-loc plastic bag. This plastic bag and the empty glass vial are placed in the original shielded shipping container for return to the manufacturer. The "breather" needle and the absorbent pad are surveyed and, if contaminated, are stored in a plastic bag in the radium room until decayed. Since the stoppered bottle is never opened, it is not felt to be necessary to perform the procedure under a fume hood or to perform bioassays of the physicians handling the I-131. However, emergency bioassays would be deemed necessary if the stoppered vial were accidently opened. The procedure to be followed is outlined below.

1) A bioassay should be performed as soon as possible after any incident that might cause thyroid uptakes to exceed 0.04 uCi of I-131.

2) If the thyroid burden at the time of measurement exceeds 0.14 uCi of I-131, therapeutic procedures to accelerate removal of radioactive iodine from the body should be considered. This should be done within 2-3 hours after exposure so that any prescribed thyroid blocking agent would be effective.

3) If the thyroid burden at the time of measurement exceeds 0.04 uCi of I-131, a repeat bioassay should be taken within 2 weeks in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.

4) Carry out repeated bioassay measurements at approximately 1-week intervals at least until the thyroid burden is less than 0.04 uCi of I-131.

20. Therapeutic Use of Sealed Sources

Cesium-137

a. The Cs-137 sealed sources will be placed in the lead-lined safe (Radium Chemical Corporation, Cat. No. 470-3-H) at the location shown in the facility diagram of item 11 of this application. The nearest unrestricted area is the public staircase to the South of the storage room. The approximate distance to this unrestricted area is 7 feet.

The long-term exposure rate is determined by the shielding provided by the lead-lined safe and the concrete wall. The walls of the lead safe are at least 4 inches thick in all directions. The concrete wall is 12 inches thick. Therefore, the calculated exposure rate in the staircase would be

$$XR = [(375\ mCi)(3.28\ R\text{-}cm^2/mCi\text{-}hr)/(213\ cm)^2] \times \exp(-ux)$$
$$= 27.1\ mR/hr \times 1.91 \times 10^{-8}$$
$$= 5.2 \times 10^{-7}\ mR/hr$$

and the dose equivalent would be much less than 100 mrem in any 7 consecutive days.

The short-term exposure rate is determined by the presence of Cs-137 sources outside of the lead safe during the loading of the applicators. During this time, there would be a maximum of 175 mCi of Cs-137 outside of the safe for a period of time not exceeding 5 minutes. The distance to the unrestricted area in this case is approximately 7 feet. Based on these assumptions, the exposure rate would be

$$XR = [(175\ mCi)(3.28\ R\text{-}cm^2/mCi\text{-}hr)/(213\ cm)^2] \exp(-ux)$$

The shielding in the wall consists of 12 inches of concrete. Thus

$$XR = 12.7\ mR/hr \times 0.0024$$

and

$$XR = 0.030\ mR/hr$$

The dose equivalent received during a one hour period when the sources are out of the safe for 5 minutes would be

$$DE = (0.030\ mrem/hr)(5\ min/60\ min)$$
$$= 0.0025\ mrem/hr$$

b. The sealed sources will be loaded into the applicators using long-handled tongs while working behind a lead-glass L-block (Radium Chemical Corportation, Cat. No. 462). When loading the applicators into the patient the work will also be performed using long-handled tongs.

c. Ring badges will be worn by all personnel handling sealed sources.

d. The sealed sources will be transported in the lead pig described in item 11 of this application. The exposure rate at the end of the handle used to carry the lead pig would be

$$XR = [(175\ mCi)(3.28\ R\text{-}cm^2)/(25.4\ cm)^2] \times \exp(-ux)$$
$$= 890\ mR/hr \times \exp(-ux)$$

Correcting for the shielding provided by the steel lid

$$\exp(-ux) = 0.131$$

Hence,

$$XR = 117\ mR/hr$$

e. Attached is the signout sheet that will be used to record the removal of the sealed sources from the lead safe. This same sheet will be used to record the return of the sealed sources and verify that a radiation survey was performed. Semi-annual inventories will be made of the sealed sources.

f. A radiation survey will be performed as soon as possible after the patient is returned to her room. Exposure rates will be measured at the patient's bedside, at 3 feet from the patient, and at the entrance to the room. These exposure rates will be recorded on the attached Nursing Precautions Form a copy of which will be placed in the patient's chart. Upon completion of treatment, the sources will be removed and counted. After the sources are removed and placed in the shielded cart, a survey will made of the patient and the room to ensure that no sources have been misplaced.

g. A copy of the Radiation Safety Procedures for Therapeutic Use of Sealed Sources is attached.

I-125

a. The I-125 seeds (3M Corporation, Cat. No. 6701) will be shipped from the manufacturer for arrival the day before the proposed implant. The seeds are shipped in a glass vial inside a lead container (wall thickness approximately 5 mm) and will be stored in the radium room of the Radiation Therapy Department. The nearest unrestricted area is approximately 7 feet from the storage site. The dose rate in this area, assuming 100 mCi activity, would be

$$DR = (100\ mCi)(1.32\ rad\text{-}cm^2/mCi\text{-}hr)/(213\ cm)^2 \times \exp(-ux)$$
$$= 2.9\ mrad/hr \times \exp(-ux)$$

For long term storage, the seeds will be inside their shipping container. In that case, $\exp(-ux)$ is nearly zero

and the radiation levels in the unrestricted area will be less than 100 mrem in any 7 consecutive days.

For short periods of time, the seeds will be outside of their shipping container (e.g. during transfer to the implant gun magazine or inventory). In that case, the walls of the radium room provide attenuation given by

$$\exp(-ux) = \exp[-(0.693)(30.5\ cm)/(0.85\ cm)]$$
$$= 1.59 \times 10^{-11}$$

where it has been assumed that the wall is composed of 12 inches of concrete and that the HVL for concrete is equal to that for tissue after correcting for density. Hence, the dose rate in the unrestricted area would be

$$DR = 2.9\ mrad/hr \times 1.59 \times 10^{-11}$$
$$= 4.6 \times 10^{-11}\ mrad/hr$$

and the radiation levels in the unrestricted area should not exceed 2 mrem in any one hour.

b. The following equipment is available for handling the I-125 seeds and descriptions of this equipment are attached.

Manufacturer	Description	Cat. No.
Mick Radio-Nuclear Instruments	V-Block	7509
Radium Chemical Corporation	Lead-Glass L-Block	462
Mick Radio-Nuclear Instruments	I-125 Gun	7203-1
Mick Radio-Nuclear Instruments	Gun Magazines	7203-2
Mick Radio-Nuclear Instruments	Magazine Holder	7203-5
Mick Radio-Nuclear Instruments	Stainless Steel Tray	7203-6
Mick Radio-Nuclear Instruments	Tweezers	7613

The seeds are handled following the procedure described in the attached instruction sheet from Mick Radio-Nuclear Instruments, Inc.

c. Ring badges will be used to monitor the radiation doses to the extremities of personnel handling the I-125 seeds.

d. The I-125 seeds will transported either in their original shipping container or in the gun magazines/magazine holder described in item b) above.

e. The sources will be counted when the shipment is received to verify that their number agrees with the quantity ordered. They will be counted again as they are loaded into the gun magazines. Folowing implantation, a count will be made of the unused seeds. Films of the patient will also be taken after implantation. The number of seeds observed on these films will be added to the number of unused seeds and this total will be compared to the original shipment quantity. The unused seeds will then be returned to the radium room in

Radiation Therapy where they will be held for decay.

f. After the patient is returned to his room, a radiation survey will be made. Exposure rates will be measured at the patient's bedside, 3 feet from the patient, and at the entrance to the room. The patient and the room will also be surveyed before the patient is discharged from the hospital.

g. A copy of the Radiation Safety Procedures for Therapeutic Use of Sealed Sources is attached.

Ir-192

a. The Ir-192 seeds (Best Industries, Inc.) will be shipped from the manufacturer for arrival the day before the proposed implant. The seeds are shipped in nylon ribbons inside a lead container (wall thickness approximately 3.2 cm) and will be stored in the radium room of the Radiation Therapy Department. The nearest unrestricted area is approximately 7 feet from the storage site. The dose rate in this area, assuming 100 mCi activity, would be

$$DR = (100\ mCi)(4.72\ rad\text{-}cm^2/mCi\text{-}hr)/(213\ cm)^2 \times \exp(-ux)$$
$$= 10.4\ mrad/hr \times \exp(-ux)$$

For long term storage, the seeds will be inside their shipping container. In that case, $\exp(-ux)$ is 7.35×10^{-5} and the dose rate would be

$$DR = 7.64 \times 10^{-4}\ mrad/hr$$

and the radiation levels in the unrestricted area will be less than 100 mrem in any 7 consecutive days.

For short periods of time, the seeds will be outside of their shipping container. In that case, the walls of the radium room provide attenuation given by

$$\exp(-ux) = \exp[-(0.693)(30.5\ cm)/(6.3\ cm)]$$
$$= 3.49 \times 10^{-2}$$

where it has been assumed that the wall is composed of 12 inches of concrete and that the HVL for concrete is equal to that for tissue after correcting for density. Hence, the dose rate in the unrestricted area would be

$$DR = 10.4\ mrad/hr \times 3.49 \times 10^{-2}$$
$$= 3.6 \times 10^{-1}\ mrad/hr$$

and the radiation levels in the unrestricted area should not exceed 2 mrem in any one hour.

b. The Ir-192 seeds are used with an afterloading system that is implanted in the patient in the operating room. After the patient has recovered from surgery, he is brought to the

simulator room in Radiation Therapy. Nylon ribbons containing dummy sources are placed in the afterloading system. Films are then taken to determine the appropriate number of seeds to be implanted. The Ir-192 seeds are transported in their shielded container from the adjoining radium room. Long-handled tongs are used to thread the nylon ribbons containing the Ir-192 seeds into the afterloading system. Stainless steel buttons are crimped on the nylon ribbons to hold them in place. The patient is then transported to a private room in the hospital.

When the implant is to be removed, the shielded shipping container is carried to the patient's room. The nylon ribbons are clipped and the sources are removed using long-handled tongs. The sources are counted as they are placed in the shipping container. The shielded container is then carried back to the radium room and held for return shipment to the manufacturer.

c. Ring badges will be used to monitor the radiation doses to the extremities of personnel handling the Ir-192 seeds.

d. The Ir-192 seeds are transported in their original shipping container. Assuming a total activity of 100 mCi, the dose rate 20 cm from the container would be

$$DR = (100\ mCi)(4.72\ rad\text{-}cm^2/mCi\text{-}hr)/(20\ cm)^2 \times \exp(-ux)$$
$$= 1.18\ rad/hr \times 2.1 \times 10^{-3}$$
$$= 2.5\ mrad/hr$$

e. The sources will be counted when the shipment is received to verify that their number agrees with the quantity ordered. Following implantation, a count will be made of the unused seeds. Films of the patient will also be taken after implantation. The number of seeds observed on these films will be added to the number of unused seeds and this total will be compared to the original shipment quantity. The unused seeds will be stored in the radium room in Radiation Therapy. When the implanted seeds are removed, the used and unused seeds will be returned to the manufacturer.

f. After the patient is returned to his room, a radiation survey will be made. Exposure rates will be measured at the patient's bedside, 3 feet from the patient, and at the entrance to the room. The patient and the room will also be surveyed before the patient is discharged from the hospital.

g. A copy of the Radiation Safety Procedures for Therapeutic Use of Sealed Sources is attached.

NURSING PRECAUTIONS FOR PATIENTS CONTAINING RADIOACTIVE MATERIALS

Iowa Methodist Medical Center
Des Moines, Iowa

PATIENT _____ DATE _____

Room No. _____ Physicians _____

Radioisotope and Dose _____ Administration Date/Time _____

Source Removal Time/Date _____

Exposure Rates in mR/hr

DATE/TIME	BEDSIDE	3 FEET	DOOR WAY

Comply with checked items

_____ 1. Visiting time at 3 feet. _____

_____ 2. Patient may not leave room.

_____ 3. No pregnant visitors or visitors under 18 years of age permitted.

_____ 4. Film badges must be worn.

_____ 5. Disposable gloves must be worn while attending patient.

_____ 6. Patient must use disposable utensils.

_____ 7. Linens and disposable utensils are to be collected.

_____ 8. Smoking not permitted.

_____ 9. Room is not to be released to Admitting Office until approved by Radiation Therapy Department or Radiation Safety Office.

_____ 10. Special Instructions _____

_____

_____

_____

In case of emergency call _____

_____

LOADING ACCESSORIES

V-BLOCK

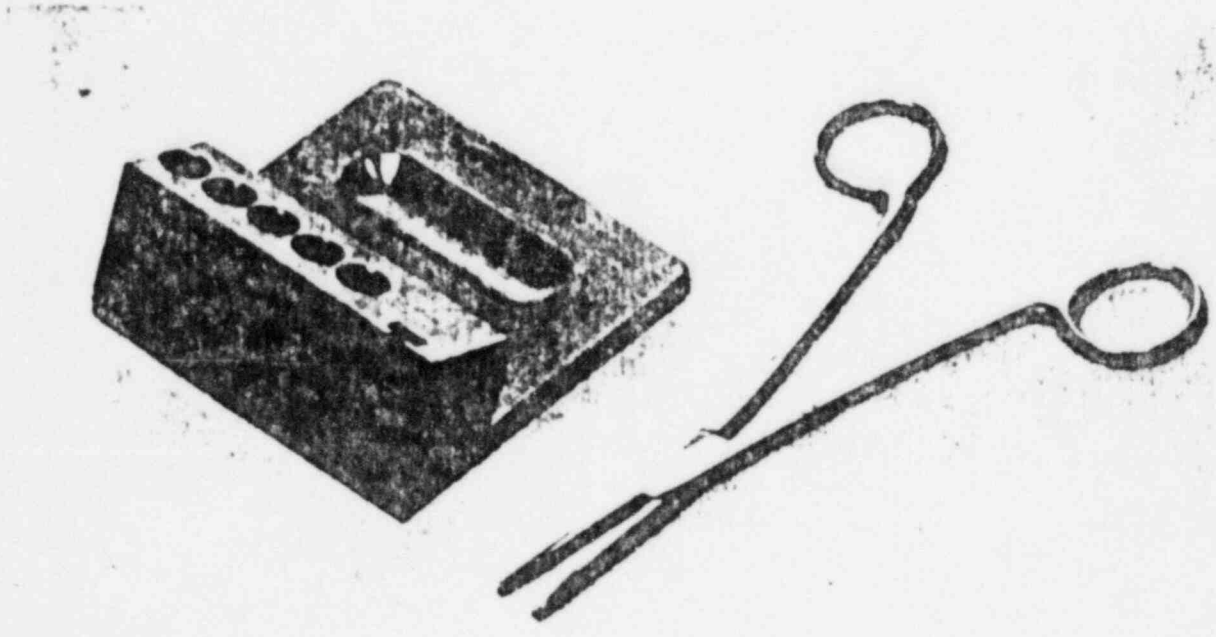
This tool is available to facilitate the loading of I-125 seeds into the magazines of the **Mick Applicator** and **I-125 Gun.**

It consists of two parts: A base plate with a well for seed pick up, and a permanently attached stabilizer block. The stabilizer block, positioned at an angle, has in the right hand corner a rectangular cartridge receiver opening which fits the cartridge. To the left of the cartridge receiver are five threaded holes which serve as storage compartments for the loaded magazines. With five loaded magazines in the storage compartments, the **V-Block** offers sufficient protection against radiation exposure.

Both components of the **V-Block** are made of brass. The surface is finished with decorative electroless nickel.

For loading seeds into the cartridge, separate the magazine head from the cartridge. This is achieved by turning the magazine head counterclockwise. Insert the cartridge into the cartridge receiver of the stabilizer block and push it as far down as possible, the cartridge slot matching the opening. From the I-125 seed shipping container, drop 10 seeds into the well. Carefully recount the number of seeds. With our special forceps, pick up one seed, holding the seed in the center; automatically the seed will be perpenticular to the forceps; and, without squeezing, feed it down slowly into the cartridge slot until it reaches the bottom. Do not drop the seed into the cartridge; guide it down. Pick up the next seed in the same manner, feed it down into the slot until the seed rests parallel on top of the previous one. Continue procedure until the well of the **V-Block** is empty which means the cartridge is full to capacity (10 seeds).

Check once more the number of seeds in the cartridge. If only nine seeds are accounted for, it may be that one has fallen upright behind the already stacked seeds. In this case, empty the cartridge into the well again and repeat the loading procedure. With 10 seeds visible in the cartridge, insert magazine head plunger into cartridge slot and turn clockwise, with down pressure, until it stops. Remove magazine from cartridge receiver and, before storing, look shielded by lead glass for irregularities in the stacked seeds.



#7509

Tips

The seed manufacturer guarantees quality control of each seed by passing them through our cartridge before shipment. To avoid difficulties it is advisable not to use seeds that are too long, seeds that are extremely short, or seeds that have large welds at the end.

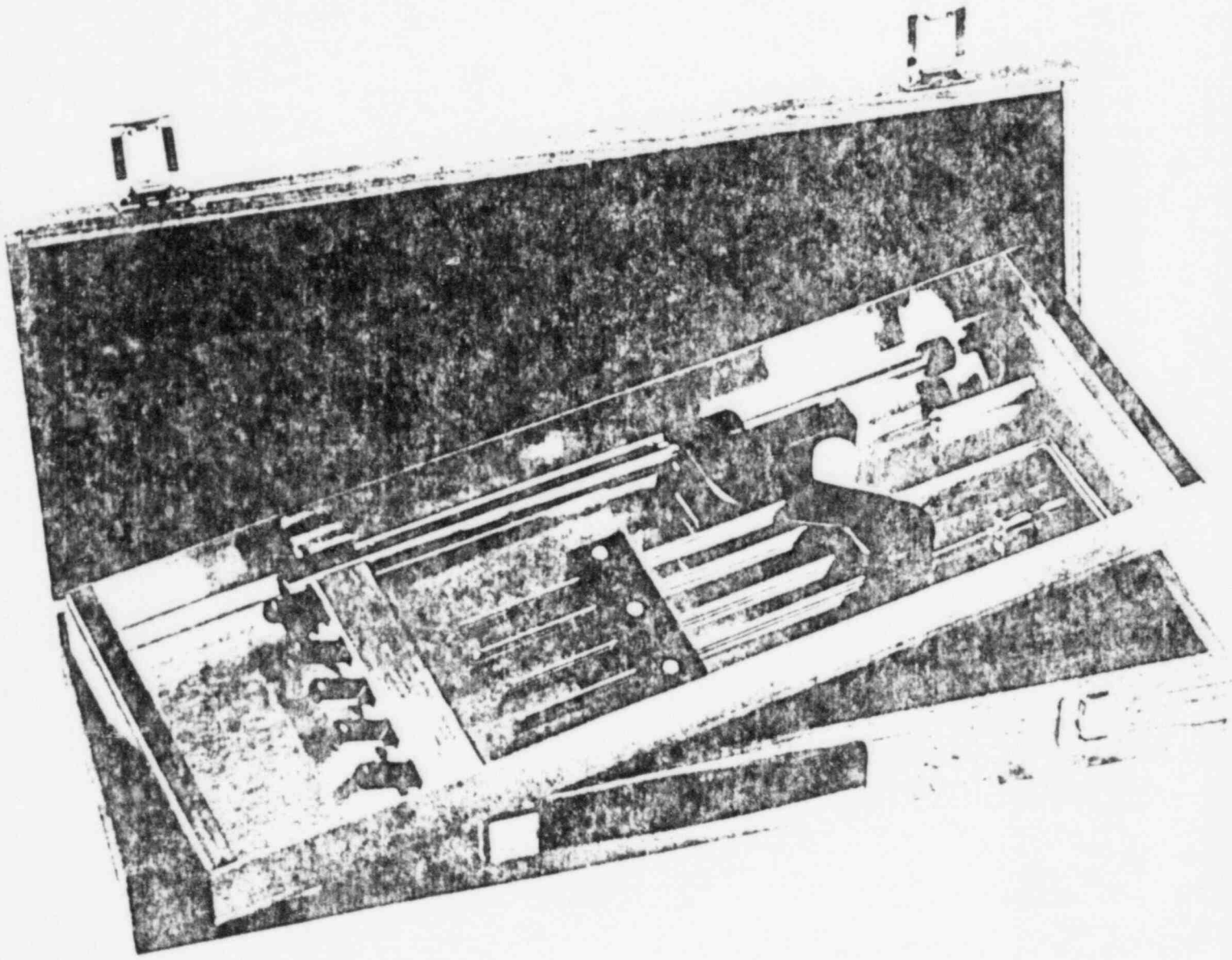
Over or undersized seeds can be used for superficial implants where, with the help of a 17 gauge needle and our needle funnel attachment, the seed is dropped into the funnel and transferred into the tumor by means of a stylet.

The **V-Block** and the forceps should be part of the sterilized instrument tray in the operating room.

With the help of the **V-Block**, the loading of I-125 seeds is a simple procedure which requires only a few minutes of practice.

I-125 GUN

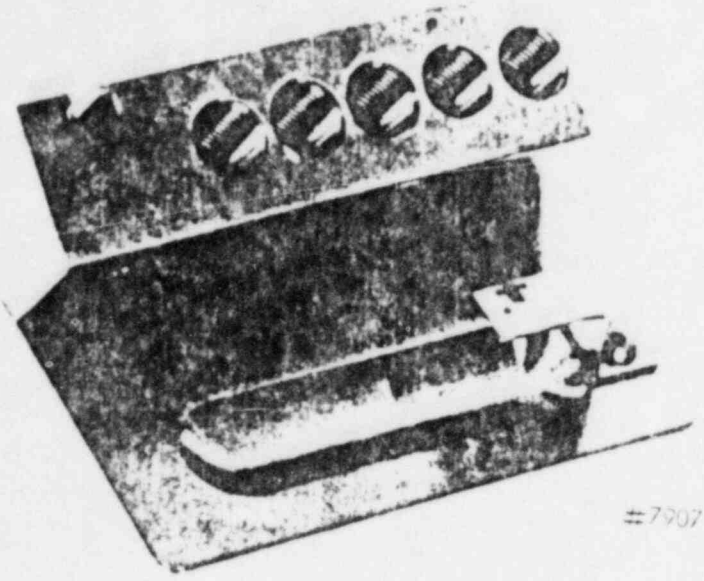
FOR IMPLANTATION OF I-125 SEEDS AND AU-198 GRAINS



Mick Radio-Nuclear Instruments, Inc.

1470 Outlook Avenue, Bronx, N.Y. 10465
(212) 597-3999

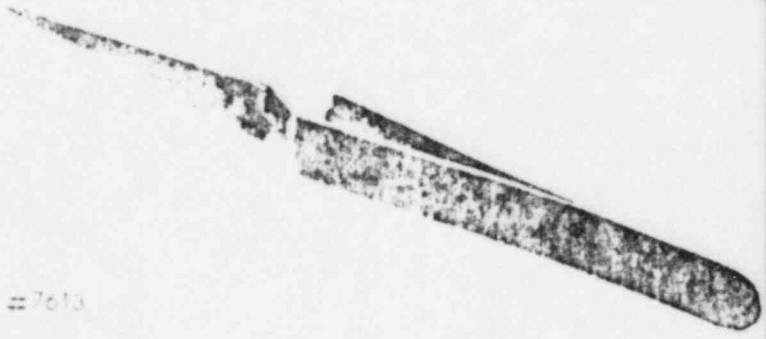
SEED GAUGE



#7907

This is a helpful tool if need arises, to determine if a I 125 seed will pass through the instrument without getting stuck. The top of the seed gauge is provided with a hole and a slot. If a seed passes through both, it will pass freely through the instrument. The seed gauge can be attached to the V Block (cat. #7509) as shown.

REVERSED ACTION TWEEZERS



#7613

The reversed action tweezers avoids crushing the seed because of its own clamping capability. The front is provided with a 45° tip and the upper blade contains a groove to accommodate the seed for secure grasp.

FLANGED NEEDLE

#7502F

The flange is attached at the upper end of the 15 cm needle and serves as a visual reference point. It indicates if the needle is properly inserted into the chuck of the Mick Applicator. When inserted correctly, the flange is flush with the tip of the chuck. The remaining part of the needle behind the flange is sandblasted, providing more gripping power.

Needles are available individually or as part of a set of 24 with 24 obturators and 2 loop wires, catalogue #7905.

Mick Radio-Nuclear Instruments, Inc.

INSTRUCTIONS

Modified by P. Veerling

INTRODUCTION

The preparation of the I-125 Gun prior to surgery is most important. Many difficulties and inconveniences will be avoided by carefully following certain steps. As with any other new equipment, it is vital to get acquainted with its features and functions before using in surgery. Particular attention should be given to the details of attaching the guide needles to the applicator to insure proper seating and fit, and to the vertical spacing procedures during implantation of the seeds.

The I-125 Gun is basically a very simple instrument and its construction is rugged enough so that damage during normal use is practically impossible. Naturally, good care must be taken after each use. All parts should be cleaned and stored in their designated locations. The needles should be placed in the needle holder, which contains four slots for eight needles each. The magazine holder is provided with five holes to store five magazines. The instrument can be cleaned by soaking in hydrogen peroxide immediately after use followed by gentle scrubbing with a soft brush and spraying with jets of water. The sterilization tray can be cleaned with a regular stainless steel cleaning spray. After all parts are correctly stored, it is immediately visible if the set is complete.

PREPARATION FOR USE

The stainless steel tray containing the applicator and accessories should be examined for completeness. All parts should be visually examined and any moving parts should be quickly tested for smoothness of motion. The guide needles should be straight, not crimped, and the points should be sharp.

The first step in preparing the instrument for implantation of I-125 seeds is loading of the magazines. The magazines are stored in the magazine holder of the stainless steel tray and may be removed by unscrewing counter-clockwise (clockwise for storage). The magazine consists of two components: magazine head and cartridge. The magazine head is a hexagonal body containing a plunger under spring tension. The cartridge has a rectangular shape and contains a slot to hold the I-125 seeds. The front of the cartridge is open for loading. The cartridge is best loaded using our V-block (see our leaflet for loading accessories). Pick up the seeds with our special forceps and feed into the slot from top to bottom. It is important that the seed is not dropped into the cavity, but placed carefully at the bottom of the cartridge. The next seed is picked up in the same manner and fed into the slot until it rests parallel on top of the previous one. This procedure is repeated until the cartridge is filled to capacity of ten (10) seeds. The seeds should slide smoothly and fit across the opening in the front of the cartridge. Seeds which are under or oversized should not be used since they could cause jamming of the magazine or applicator. When the cartridge is loaded to capacity, insert the magazine head plunger into the cartridge slot and turn clockwise with slight downward pressure until it stops. The magazine is now ready for implantation and can be put back into the stainless steel tray.

The entire stainless steel tray and its contents may be sterilized by autoclaving just prior to use. The wooden case is used for transportation and shelf storage only.

Magazines for Au-198 grains are available and work with the same principle except that the receiving slot is smaller to accommodate the size of the grains. Au-198 magazines are easily identified because of their golden color.

AFTERLOADING TECHNIQUE

The implantation of the I-125 seeds is done by means of an after-loading technique. This technique consists of five basic steps: 1) plan distribution of seeds, 2) insert guide needles, 3) attach applicator to needles, 4) insert magazine containing radioactive seeds and, 5) implant seeds through guide needles.

Using the tumor volume and shape, seed strength, and desired therapeutic dose, the spacing between guide needles and between seeds should be planned so as to achieve the desired therapeutic effect with a minimum of complications. The dosimetry of I-125 seed implants is discussed in *Handbook of Interstitial Brachytherapy*, edited by Basil S. Hilaris, M.D. of Memorial Sloan Kettering Cancer Center (published by Publishing Sciences Group, Inc., Acton, Mass. 1975).

Insertion of guide needles may be accomplished as follows. Insert hollow 17 gauge stainless steel needles, 15 cm long, and ground to a 45 degree point, around the periphery of the tumor mass. (For implants through the intact skin, needles with sharp points are preferrable, but for intrathoracic and intra-abdominal implants, it is better to use less sharp needles that do not penetrate and change their position so easily). For a spherical shaped tumor, 0.55 millicurie nominal seed strength, and an aim of 16000 rads delivered through total therapy, needles are usually spaced 1 cm apart for tumors up to 4 cm in diameter, 1.5 cm apart for tumors from 4 cm to 8 cm, and 2 cm apart for larger tumors. All needles should be inserted parallel to each other. The direction of the needles must be considered carefully before starting, so that their position may be palpated and the maximum number of seeds inserted through the needle. Each guide needle is 15 cm long which means that the length of guide needle implanted within a tumor bed may be calculated once the length of protruding needle is known. This will give a guide as to the number of seeds to be inserted in each needle, once the vertical spacing is also determined.

Attachment of the I-125 Gun to the guide needles may be accomplished as follows. After all needles have been inserted into the tumor to the required depth, remove I-125 Gun from the stainless steel tray and place horizontally in hand. While holding the instrument with index finger press down trigger lock and with the other hand pull stylet out to its extreme end. Remove protective needle from needle clamping chuck by turning it clockwise. In order to avoid deeper penetration of the guide needle, a hemostat may be clamped to the needle at the tissue surface prior to attaching the applicator to the needle. Next, lower the Gun over the protruding part of the needle and when it has reached a definite stop, turn the needle chuck cap clockwise as far as possible.

With the needle firmly attached to the instrument, a pin located in the needle chuck cap will appear in the middle of the tissue ring cut-out. Check if needle is firmly attached to the instrument by slightly lifting the instrument upward while grasping the needle firmly. Care must be taken at this point not to displace the correctly inserted needle by pulling it out of the tissue. To establish the depth of the inserted needle, set the tissue ring to the tumor surface. With index finger of one hand depress trigger lock and with the other hand hold inner barrel steady (behind the instrument handle) and lower Gun to the tumor surface. Release trigger lock and remove hemostat. The rectangular opening (cartridge receiver) appearing through the outer barrel slot indicates the depth of needle on the adjacent scale, where the first seed should be placed.

Insertion of the seed magazine is as follows: the loaded magazine is taken out of storage position and inserted all the way into the rectangular cartridge receiver of the inner barrel with the cartridge slot aiming away from the scale. Note that the stylet must be completely retracted out of position in order to allow the cartridge to be inserted. The magazine is firmly in place once a click is heard indicating that the small ball is caught in the indentation of the magazine.

Implantation of the seeds is accomplished as follows. The first of the ten seeds in the cartridge is deposited into the needle by pushing the stylet all the way down. In order to penetrate hard tissue it may be necessary to apply extra pressure to push the wire rod handle as it reaches its end. If the stylet is not completely depressed, the seed will remain in the needle, thus by inserting the next seed, two seeds will be placed on top of each other. Palpation of the under side of the tumor mass during this process can generally give assurance that the seed has in fact been deposited at the bottom of the needle.

To insert the next seed, usually spaced 1 cm, pull trigger twice (two clicks = 1 cm), three clicks for 1.5 cm. Pull stylet out to its extreme end and observe

To attach the Gun to the following needle, with index finger of one hand depress the trigger lock and with other hand push the inner barrel completely forward. Pull stylet out to its extreme end, turn needle clamping chuck clockwise one half turn, remove needle and lower Gun as far as it will go over protruding part of next needle. (To move the inner barrel the trigger lock must be depressed.)

During the implant procedure, it is recommended that the instrument be rinsed frequently in normal saline or heparin solution in order to remove tissue or blood which will interfere with smooth movement of the moving parts of the applicator. A small syringe or aspirator is helpful in forcing the solution through the chuck and magazine receiving areas.

In addition to radiation exposure precautions, an accurate accountability of all sources must be maintained. For this reason, records of sources implanted and remaining sources must coincide with the number of seeds available. All instruments and surgical accessories including sponges and suction devices should be surveyed immediately after the implant procedure. Follow-up of patients may be necessary in order to retrieve sources which are sloughed off post-operatively.

Another danger in use of the applicator for I-125 seeds is the rupture of the outer metal encapsulation. This could occur through excessive use of force in the event of a stacking seed or seed in a cartridge. The tiny ceramic beads containing radioactive I-125 are barely visible once the capsule is ruptured. This can be avoided by proper use of the instrument and sizing of the seeds before use.

An individual familiar with radiation safety procedures and pertinent regulations should be consulted prior to undertaking an implant program in order to assure proper radiation safety of personnel, patient, patient's family, and the general public. A number of guidelines are available through the National Council on Radiation Protection and Measurements, 4201 Connecticut Avenue, NW, Washington, D.C. 20008 and the source suppliers.

CLEANING

Immediately after the implant procedure and before start of the cleaning operations, all guide needles should be checked for possible remaining seeds. This can be accomplished by inserting the loop wire through each needle and observing for any seeds which are ejected from the bottom.

For best results remove tissue and blood from instrument immediately after use. Soaking in hydrogen peroxide or heparin solution should loosen all biological materials. The applicator and accessories should be gently scrubbed with a soft brush and loose materials washed away with a jet of water. A loop wire is included for removing stubborn debris from guide needles. Keeping the instruments clean and in good operating condition insures a precise and efficient implant procedure.

RADIATION SAFETY

Using the I-125 Gun and accessories entails handling solid radioactive sources, namely I-125 seeds, Au-198 grains and similar sources. As with any other sources, the principles of time, distance, and shielding should be utilized. Personnel monitoring devices, such as low energy pocket chambers, film badges and thermoluminescence dosimeter devices should be utilized. Portable shielding devices for bodies and eyes are available as accessories through this company. Lead rubber gloves are available for surgical manipulation and handling during the implant procedure. These are especially effective for I-125 seed implants because of the low energy of the radionuclide.

Radiation Safety Procedures for
Therapeutic Use of Sealed Sources

1. All patients treated with brachytherapy sources will be placed in a private room that has a toilet.

2. The patient's room will be properly posted or attended in accordance with 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, at 3 feet (or 1 m) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a visitor may remain at a distance of 3 feet (or 1 m) from the patient.

4. Immediately after sources are implanted, the form "Nursing Precautions for Patients Containing Radioactive Materials" will be completed and attached to the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient.

7. At the conclusion of treatment, a survey will be performed in accordance with paragraph 35.14(b)(5)(vii) of 10 CFR Part 35 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in any other area occupied by the patient. At the same time, all radiation signs will be removed. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient meets conditions for release from the hospital.

8. Instructions to Nurses

   a) Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. The Radiation Safety Officer should be contacted to answer any questions about the care of these patients in regard to radiation safety precautions.

   b) Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film badge as instructed by the Radiation Safety Officer.

c) When a nurse is assigned to a therapy patient, a film badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged among nurses.

d) Pregnant nurses should not be assigned to the personal care of these patients.

e) Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy or the Radiation Safety Officer at once.

f) Bed bath given by the nurse should be omitted while the sources are in place.

g) Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

h) Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee. Special orders will be written for oral hygiene for patients with oral implants.

i) No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.

j) All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

k) These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

l) Visitors will be limited to those 18 years of age or over unless other instruction are noted on the precaution sheet on the patient's chart.

m) Visitors should sit at least 3 feet (or 1 m) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.

n) No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o) Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call

Radiation Therapy	283-6860
Radiation Uncology, P.C.	282-0680

p) At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room, (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient, and (3) record a summary of the final survey results on the patient's chart. If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.

SUPPLEMENT TO ITEM 21, APPENDIX M

1. a. Five studies per week.
   Average 20 mCi 133 Xenon per patient.
   b. Possession limit: 1 curie.

2. a. See attached diagram.
   Room is one-foot thick concrete blocks. No unrestricted areas in proximity.
   b. See attached diagram.
   133 Xenon vials are kept in a lead cylinder shield in the fume hood in the "hot" lab.
   Fume hood has exhaust vent rate of 833 ft^3/min. Exhaust is to isolated lines with no access to hospital air supply.
   c. See attached diagram.
   The stated air flow rates and exhaust rates are checked by hospital engineering two times a year. Last check was in April 1985.

3. a. Xenon vial in lead shield is carried from fume hood to imaging room A where it is used according to the attached instruction manual. Only patient and technologist are in the room at the time. The dose of Xenon is measured in the Capintec dose calibrator before administration. Children, pregnant women and nursing mothers will not be examined unless the information to be gained outweighs the potential hazard.
   b. 133 Xenon is administered with Pulmonex Xenon System of Atomic Products Corporation, Model #130-500. Brochure of manufacturer attached.

4. In the event of an accidental release of Xenon in the imaging room, the room will be evacuated and the door closed. Air exchange in this room is complete in about 5.8 minutes, and there are 10.4 exchanges per hour. At the end of the hour, the room will be checked with one of our portable monitors. The room will be entered and used only if and when the check indicates radiation has returned to normal background levels.

   The same procedure will be followed in the radiopharmacy lab except the fume hood will also be monitored prior to use.

5. Air concentrations of 133 Xenon in restricted areas.
   We average five patient ventilation studies per week and use about 20 mCi of 133 Xenon per patient. Therefore:

$$A = \frac{20\ \text{mCi}}{\text{patient}} \times \frac{5\ \text{patients}}{\text{week}} = 1 \times 10^5\ \frac{\mu\text{Ci}}{\text{week}}$$

   Assume loss rate of 20% (f)

$$V = \frac{A \times f}{1 \times 10^{-5}\ \mu\text{Ci/ml}} = \frac{1 \times 10^5\ \mu\text{Ci/week} \times 0.20}{1 \times 10^{-5}\ \mu\text{Ci/ml}} = 2.0 \times 10^9\ \text{ml/week}$$

   Required ventilation rate is:

$$\frac{2.0 \times 10^9\ \text{ml/week}}{40\ \text{hours/week}} \div \frac{1.7 \times 10^6\ \text{ml/hour}}{ft^3/\text{min.}} = 30\ ft^3/\text{min.}$$

   Our engineering studies show (see attached diagram) 290 ft^3/min. fresh air intake and 400 ft^3/min. exhaust in imaging room A. This is far in excess of the minimum 30 ft^3/min. required.

6. Air concentration of 133 Xenon when disposal is through exhaust system. The major exhaust system for 133 Xenon disposal is through a special isolated vacuum exhaust line in imaging rooms A and B. Engineering studies indicate this is 15.5 CFM (see attached diagram) through flexible tubing extending from the ventilation module that goes directly to this exhaust vent. Exhaled Xenon passes into this vent. There is minimal Xenon exhausted through the fume hood in the radiopharmacy lab. Exhaust rate in this fume hood (see diagram of radiopharmacy lab) is 802 CFM. All of this is exhausted as part of the laboratory exhaust system which has a total capacity of 8950 CFM, so the total dilution is much greater than just the air exhausted from the rooms. The discharge of the fan is through the stack of the highest roof in this building and at a velocity of 2200 FPM which provides for even greater diffusion of 133 Xenon into the atmosphere.

   The top of the stack is 100 feet above ground level, and the plume rise is 6 feet for an effective stack height of 106 feet. This is well above the level of any adjacent hospital buildings. There are no nearby air intakes or open windows. The roof is a restricted area with no reasonable access to the roof or stack. The closest nearby building not on the hospital campus is the telephone building which is 300 meters away. This building has no open windows.

   The calculations for concentration of 133 Xenon at the stack, ground level and nearest building follow and are derived from Eisenbud:Environmental Radioactivity, Academic Press, New York, 1973, Chapter 4, pages 87-117.

$$X_{max} = \frac{2Q}{e\pi\bar{U}h^2}\frac{\sigma_z}{\sigma_y}$$

where:

Q = Source strength in Ci/sec/ml

$\bar{U}$ = mean wind speed at stack in m/sec.

e = natural log base

h = effective stack height

σ_z = vertical dispersion coefficient

Downwind distance from stack to X max equivalent to 15-30 stack heights

$\bar{U}$ = 10 miles/hr. = 4.46 m/sec

e = 2.72

h = 106 feet = 32.2 m

σ_z = for 30 stack heights (966 m) = 70
= for 15 stack heights (483 m) = 40
= for nearest building (300m) = 24

σ_y = for 30 stack heights (966 m) = 105
= for 15 stack heights (483m) = 60
= for nearest building (300 m) = 40

Q = 20 m Ci 133 Xe/patient − 5/week
= 100 m Ci/wk × 52 wks = 5.2 Ci/yr.
1 year = 3.154×10^7 sec
5.2 Ci/yr × 3.154×10^7/sec =
= 2.165 Ci/10^{-7} sec per year

Concentration of 133-Xenon at Stack Exhaust

stack exhaust = 8950 ft^3/min

1 cfM = 1.484×10^{10} ml/yr

$8950 \times 1.484 \times 10^{10} = 1.33 \times 10^{14}$ ml/yr.

133 Xenon C at stack = $\frac{2.165 \text{ Ci}/10^{-7}\text{sec/yr}}{1.33 \times 10^{14} \text{ ml/yr.}}$

$C = 1.62 \times 10^{-21}$ Ci/sec/yr.

For Ground level at 30 stack heights distance

$$X_{max} = \frac{2Q}{e\pi \bar{U} h^2} \frac{\sigma_z}{\sigma_y}$$

$$= \frac{2 \times 1.62 \times 10^{-21}}{2.72 \times 3.14 \times 4.46 \times (32.2)^2} \times \frac{70}{105}$$

$$= 0.544 \times 10^{-25} \text{ Ci/ml./yr.}$$

$$= 5.44 \times 10^{-18} \mu\text{Ci/ml./yr.}$$

For Ground level at 15 stack heights distance

$$X_{max} = \frac{2 \times 1.62 \times 10^{-21}}{2.72 \times 3.14 \times 4.46 \times (32.2)^2} \times \frac{40}{60}$$

$$= 0.544 \times 10^{-25} \text{ Ci/ml./yr}$$

$$= 5.44 \times 10^{-18} \mu\text{Ci/ml./yr.}$$

For Nearest Building – 300 m

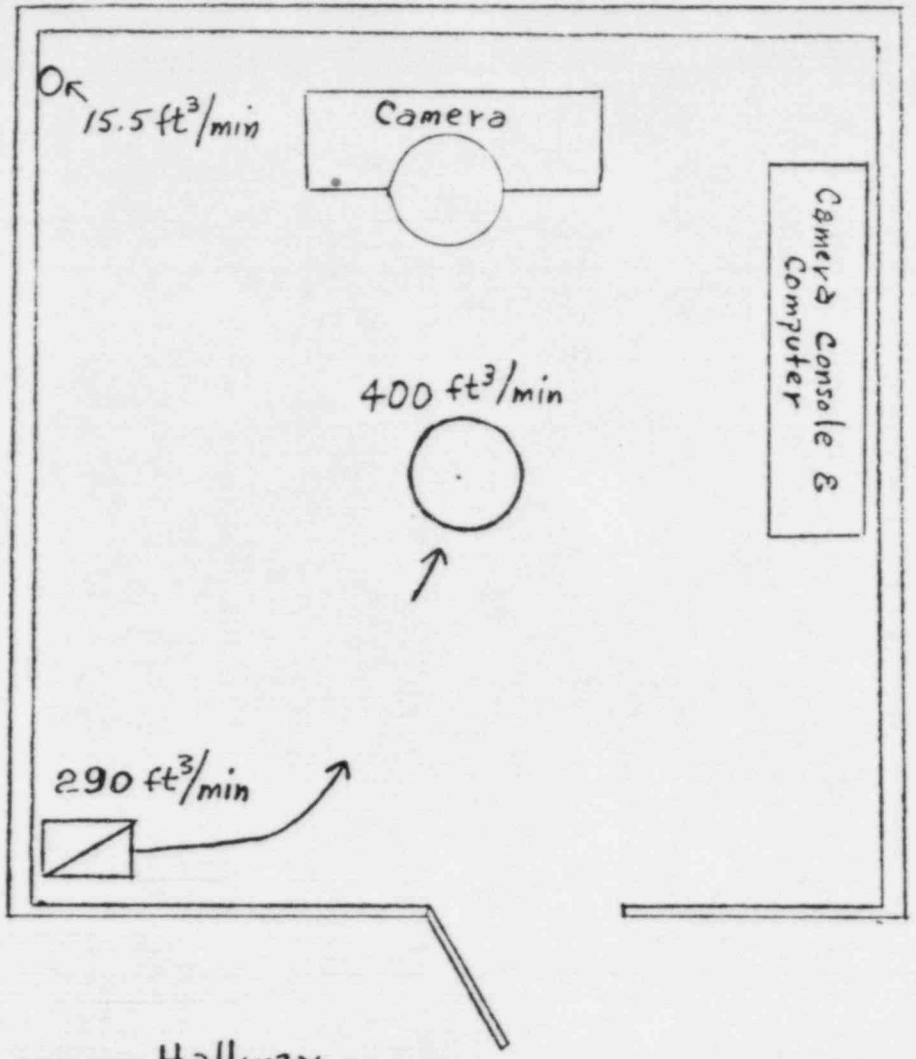
$$\chi_{max} = \frac{2 \times 1.62 \times 10^{-21}}{2.72 \times 3.14 \times 4.46 \times (32.2)^2} \times \frac{24}{40}$$

$$= 5.44 \times 10^{-18} \mu Ci/ml./yr.$$

The above data indicates that at all pertinent points the 133-Xenon concentration, averaged over 1yr., falls well below the minimum allowed concentration of 3×10^{-7} $\mu Ci/ml.$

IMMC Nuclear Medicine Dept.
Xenon Ventilation Imaging Jan, 1985

Scan Room A



Secretarial & Control Center

Scale: 1" = 4'

10-15-80
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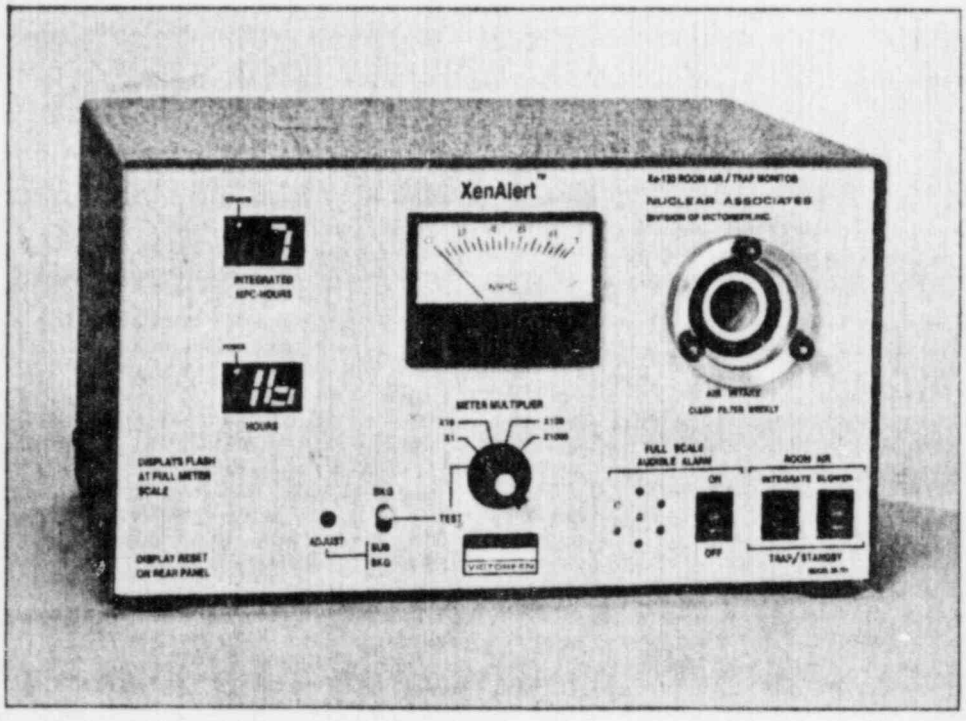
Instruction Manual

XenAlert™ *

Xenon Room Air and Trap Monitor

Model 36-751



*Patent Pending

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NUCLEAR ASSOCIATES
Division of VICTOREEN, INC.
100 Voice Road • Carle Place, N.Y. 11514
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Contents

I. INTRODUCTION

The XenAlert Monitor is designed to measure and integrate the concentration of xenon-133 in room air. Its wide range also permits measurement of the xenon-133 concentration in the exhaust air of xenon gas traps. This serves as an indicator of the condition of the trap's filter cartridges.

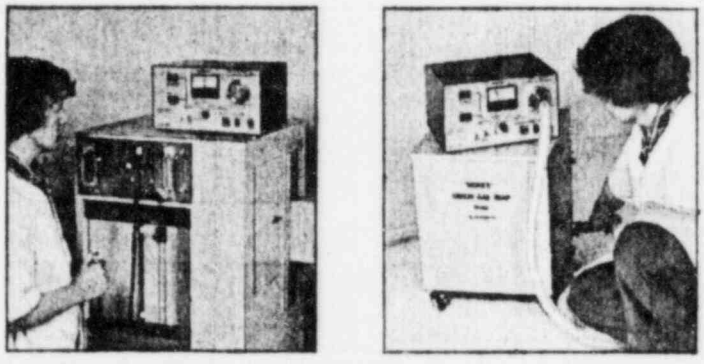
Room Air Monitoring

The Code of Federal Regulations (10 CFR 20.103) limits the quantity of xenon-133 that an individual may inhale, in any calendar quarter, to that which would result from inhaling a uniform concentration of 10^{-5} µCi/ml for 40 hours per week for 13 weeks. This quantity is called the Maximum Permissible Concentration (MPC). If the concentration is expressed in units of MPC, then the integrated concentration is in units of MPC-Hours. The average value of this concentration should not exceed 40 MPC-Hours per week.

The XenAlert indicates the xenon-133 concentration in MPC units (1 MPC = 10^{-5} µCi/ml) on an analog meter. At the same time, it integrates the concentration and displays it as MPC-Hours. Also displayed are the total number of hours over which the integration has taken place.

To comply with the Code, your XenAlert MPC-Hours must be less than 520 for any consecutive 13-week period. MPC-Hours should be recorded and examined on a weekly basis (see Appendix A). An MPC-Hours reading of less than 40 per week indicates that your accumulation rate (if it remains constant) is below that which would result in a total of 520 MPC-Hours for the 13-week period (40 x 13 = 520). While a reading greater than 40 during any week does not mean that you have exceeded the limit, it does indicate that you should investigate the source and exercise stricter adherence to safety procedures in the department.

The XenAlert provides a means of checking the concentration of xenon-133 according to the Code of Federal Regulations. Whenever there is the possibility of exposure to xenon-133, a XenAlert should be operating close by. If more than one person normally works with xenon-133, an individual log of the XenAlert MPC-Hours information may be kept (see Appendix A).



Left: "XenAlert" monitors room air during ventilation study. **Right:** Gas trap output is displayed in MPC units.

Gas Trap Monitoring

The performance of charcoal filter cartridges used in all xenon gas traps may degrade with use. Therefore, it is desirable to measure the xenon-133 concentration in the effluent air directly at the trap's exhaust port. This measurement allows the user to determine trap performance and assess its effect on the xenon-133 concentration in the total room air volume. The XenAlert can be used to determine the activity in the trap effluent; see page 7 and Appendix B.

II. DESCRIPTION

The XenAlert's detector is a large-area, thin-window GM tube, mounted in a chamber through which air is constantly circulated by a blower. The monitor is calibrated to display the count rate in MPC units and the total accumulated counts in MPC-Hours. The counting chamber is shielded by 3/8" of lead to minimize the effect of background radiation on the count rate. In addition, a background-subtract circuit is provided to subtract the background count rate for both the MPC meter and the integrated MPC-Hours readings.

A visual alarm (both digital registers flash once per second) is activated when the meter reaches full scale on any range or when the MPC-HOURS reach 80. An audible alarm (intermittent tone), selected by a front-panel switch, goes on when a full-scale meter reading is reached on any range. A constant tone is produced when the MPC-HOURS register reaches 80. When the instrument is not in use, a standby circuit retains the MPC-HOURS reading in memory and suspends further integration until both the INTEGRATE and BLOWER switches are returned to ON or ROOM AIR. A reset button returns both the MPC-HOURS and HOURS readouts to zero.

The AIR INTAKE has a particulate-matter filter and a fitting for attaching a hose when checking a gas trap. The trap's exhaust is monitored (without adding to the integrated MPC-HOURS reading) by placing both the INTEGRATE and BLOWER switches in the TRAP/STANDBY position.

III. OPERATING CONTROLS AND INDICATORS

INTEGRATE. This switch controls the integration of MPC-HOURS. It is ON when monitoring room air and OFF during gas trap monitoring or standby.

BLOWER. This switch turns the blower on. The blower must be ON when monitoring room air in order to move air past the detector. It is interlocked to the INTEGRATE switch and must be on for integration of MPC-HOURS to take place. It is placed in the OFF position when doing gas trap monitoring or during standby. It should be turned on for 5 minutes after gas trap monitoring, but before turning the integrator on, in order to blow the xenon out of the instrument.

FULL-SCALE AUDIBLE ALARM ON/OFF. A front-panel switch gives the user the choice of whether or not the alarm will sound when the analog meter reaches full scale on any range.

METER MULTIPLIER. Determines the meter scale factors and allows the user to select the appropriate range. Generally, the lower ranges (X1 and X10) are used for room air monitoring while the higher ranges (X100 and X1000) are used for gas trap monitoring.

TEST: Allows the user to observe and adjust the background reading. When the associated toggle switch is placed in the BKG position, the meter displays the background count rate. In the SUB BKG position, a screw-driver adjustment is used to enter the background count rate. In normal operation, only the net count rate from xenon-133 is displayed on the analog meter or integrated in MPC-Hours.

AIR INTAKE: A 1" I.D. hose (model #36-754) may be attached for gas trap monitoring. Three thumbscrews permit access to a coarse, reusable filter which should be cleaned or replaced weekly. Air leaves the instrument through a rear exit port.

Reset Function: Rear-panel pushbutton resets MPC-HOURS and HOURS to zero.

Standby Function: Switch suspends data integration when xenon studies are not in progress. Accumulated data remains in memory.

Power: 115V, 60 Hz, 25W (230V, 50 Hz on special order).

Accessories Supplied: Screwdriver. Instruction Manual.

Chart Recorder Output: 1 mA, 100-ohm load miniature phone jack, accepts Switchcraft 750 plug.

V. SET-UP AND OPERATION

ROOM AIR MONITORING

1. To protect the plastic air inlet tube from shipping damage, the XenAlert comes with this short tube packed separately. Remove the 3 black thumbscrews from the air inlet, and place the porous air filter in the air inlet recess. Install the plastic flange so that its flat side is against the porous filter and the air inlet tube faces out.

2. Plug unit into 115V AC line. Turn INTEGRATE and BLOWER switches on, that is, to the "Room Air" position.

3. Place METER MULTIPLIER switch on TEST. To adjust background, place toggle switch in BKG position. Wait 4 minutes, and record the background reading as it appears on the meter. Place the toggle switch in SUB BKG position. Using the supplied screwdriver, turn the ADJUST screw until the meter reads the same as it did in the BKG position.

   Note: Background radiation may affect your xenon-133 measurements and may change from time to time due to the presence of other isotopes in the room or in the patient being imaged. Check the background-subtract circuit periodically and adjust it as necessary. The background should never exceed 0.5 MPC.

4. Place the METER MULTIPLIER switch in the X1 position. The meter should read between zero and 0.1 MPC. The background has been subtracted from both the meter and digital readouts.

5. Place a radioactive source, such as Model 62-103 Cs-137 Check Source, on top of the instrument, directly over the label which reads: "Place Check Source Here." Be sure the printed side of the source faces up. The meter should read approximately 2 MPC with this particular source. Check the instrument at least weekly to make sure it is still operational.

6. Press the RESET button on rear of instrument. MPC-HOURS and HOURS should read zero.

7. Place AUDIBLE ALARM switch in ON position, if desired.

8. The XenAlert is now ready to monitor and integrate the xenon-133 concentration in room air. Place the unit as close as possible to where you will be working with xenon.

9. At the end of the working day, place the instrument on standby by turning the INTEGRATE and BLOWER switches to TRAP/STANDBY. Record the readings in your logbook (Appendix A).

10. At the start of each week, or at 80 MPC-HOURS (whichever occurs first), reset the XenAlert to zero.

    Note: Do NOT unplug the XenAlert from its power source. Accumulated data is LOST when power is removed.

GAS TRAP MONITORING

1. To measure the concentration in the effluent from a gas trap, place one end of a 1" I.D. hose on the XenAlert's air intake and the other end over the gas trap exhaust port. Gas trap measurements should be made while xenon is being trapped, such as during the washout phase of a ventilation study.

2. Place the INTEGRATE and BLOWER switches on TRAP/STANDBY.

3. Place the METER MULTIPLIER switch on X1000. Proceed with the washout procedure and observe the MPC meter reading. If it reads less than 100 MPC, place the switch on X100.

4. Determine the activity (A) in the trap effluent by using the formula:

$$A = MPC \times 10^{-5} \times V \times T$$

    where A = effluent activity in µCi.
    MPC = reading from analog meter.
    10^{-5} = 1 MPC in µCi/ml.
    V = trap flow velocity in ml/minute.
    T = washout time in minutes.

5. Remove the gas trap hose connection.

6. Turn on the BLOWER until the MPC meter reads zero, which indicates that all the xenon from the trap is out of the XenAlert. This should take about 5 minutes.

7. Return the INTEGRATE switch to ON or ROOM AIR in order to continue monitoring room air.

8. Record the results (see Appendix B).

The graph on page 11 shows the total amount of xenon-133 that could excape from all sources and the total air flow volume that would be necessary to keep the average concentration for 40 HOURS below 10^{-6} µCi/ml or 0.1 MPC. Integrated over a 40-HOUR week, this would be equivalent to 4 MPC-HOURS. For example, if 34 mCi escaped during the course of a week, and the air flow volume of the room was 500 cubic feet per minute, the average concentration would be 10^{-6} uCi/ml or 0.1 MPC, which would correspond to 4 MPC-HOURS.

MAINTENANCE

Particulate-Matter Filter (36-753): It should be replaced or cleaned with soap and water once a week to prevent it from becoming clogged. Three front-panel thumbscrews permit access to the filter.

XENALERT ROOM AIR LOG

Week of _____

Day	No. of Studies	No. of mCi		MPC HRS	HRS
1.			Start		
			Finish		
			Difference		
2.			Start		
			Finish		
			Difference		
3.			Start		
			Finish		
			Difference		
4.			Start		
			Finish		
			Difference		
5.			Start		
			Finish		
			Difference		
6.			Start		
			Finish		
			Difference		
7.			Start		
			Finish		
			Difference		

7-26-83
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Atomlab

INSTRUCTION MANUAL

PULMONEX XENON SYSTEM

130-500

3-STEP SIMPLICITY OF OPERATION

1. Start: Set timer. Patient adjusts to breathing on system. Add oxygen. Set "Airflow" control. Switch handle to 2.

2. Single Breath-Equilibrium: Patient is breathing on closed loop. Inject Xenon at mouthpiece. Patient breathes until equilibrium (about 2 minutes). More oxygen may be added during 2, if necessary. Switch to 3.

3. Washout: Patient breathes room air through unit, exhales into trap. Study is complete.

Atomic Products Corporation

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

To thoroughly familiarize yourself with the equipment and methodology, it is suggested that you run through the procedure several times; first without any patient, then with a colleague as a "patient" without actually using xenon. When you are completely familiar with the routine, you can start doing xenon studies on a patient with confidence.

FOLLOW THESE SIMPLE STEPS CAREFULLY:

A. Setting Up Your Pulmonex

1. Open the top rear door. Inspect the interior. All hoses should be connected to their respective ports. Bags should be lying flat. The elbows on the bags should be in their wall brackets. Hoses should not be kinked.
2. Open the lower front door. All hoses should be connected to their respective ports.
3. Remove the empty plastic cartridge that hangs in the lower compartment. Fill the cartridge about 1/4 to 1/3 full with the blue drierite (139-101) and return the cartridge. This serves as a moisture trap for the air going into the charcoal cartridge. Close the lower compartment. Replace the drierite when it changes color (from blue to pink). *Failure to change the drierite will significantly shorten the life of the charcoal cartridge.*
4. Remove the empty plastic cartridge that is within the top compartment. Fill 1/4 to 1/3 full with white granule soda-lime (Model #130-019). Reconnect to the hoses. This soda-lime serves as a carbon dioxide trap. Close the top rear door. Change the soda-lime between each patient. *Failure to change the soda-lime will cause the patient to rebreathe too much carbon dioxide thus causing hyperventilation.*
5. Bring the unit to the area of operation. Make sure the timer is on "0" and plug into a nearby electrical outlet.
6. At the rear of the unit, there are two white hose connections, side by side. Attach the breathing tubes/Y Fitting/bacteria filter/mouthpiece assembly to the hose connections. The plastic plug and warning label on the Y fitting must be facing up.

> **Note:** Keep the breathing tubes as short as possible. If a patient is supine bring the system to the bedside. Never add a length of tubing to the patient side of the Y fitting. If you need more tubing length replace both breathing tubes. The distance from the Y to the patient must be as short as possible.

It is advisable to use hose clamps to tightly fasten the breathing hoses to the hose connections. As a safety precaution you can connect a hose from your room vent to the exhaust port on the Pulmonex. This exhaust port is located on the patient side of the Pulmonex just below the overhang.

> **Caution:** Some patients are sensitive to oxygen. Consult a physician before using oxygen. If the physician prefers, substitute room air for oxygen.

7. To add oxygen connect and clamp a 1/4" oxygen hose from your oxygen supply to the oxygen inlet port on the Pulmonex front panel. Turn the oxygen valve to 5 psi or 6-8 liters/minute and leave it on. If possible, use a pediatric regulator on the oxygen tank.

> **Note:** Use a flow regulator, not a flow meter. Flow rates can be high (up to 50 liters/min.) but pressure must be low, 5 psi.

B. Performing a Study.

8. Using a source, position the patient in front of the scintillation camera. See that both the lungs are within the crystal area.
9. Set the camera for Xe-133. Record all data on tape.
10. Place the Pulmonex as close to the patient as possible and set the handle to the "Start" position. The number "1" will appear under the handle.
11. Set the "Air Flow" control to 30 (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).
12. Press the button on the front panel to add oxygen to the "To Patient" bag. Only add a small amount of oxygen, about 1/4 full. (The bag will only move slightly, do not fill it up.) More oxygen can be added later if the patient requires. In many cases, it is possible not to add any oxygen and perform the entire study on ambient air. In all cases, the oxygen is only to enrich the air in the circuit.

    To do a study with ambient air, before connecting the patient to the system, turn the Pulmonex on and go to position #2. When the "To Patient" bag is 1/4 full, switch the handle back to position #1. Now the system is ready to use.
13. Set the timer to 9 minutes (an arbitrary figure that can be changed at any time depending on the study procedure you prefer).
14. Place the mouthpiece in the patient's mouth. Clamp the patient's nose closed. A face mask may be used, if preferred. Place a vertex cape (#055-101) on the patient.
15. Have the patient breathe briefly on "Start" to become accustomed to breathing with a mouthpiece. The "from patient" bag will move slightly as the patient exhales.
16. Switch the handle to "Single Breath, Equilibium, #2". With a NEN Gun or syringe filled with xenon, puncture the mouthpiece's rubber with the needle and add the xenon as you have the patient take a deep inspiration. Have the patient hold his breath for as long as possible and then continue to breathe normally. Increase the "Air Flow" control to about 70, (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).

    Advise the patient to breathe slowly and normally. Observe both breathing bags moving through the front panel windows. Add oxygen if the patient requires it. An alternative to puncturing the mouthpiece is to use the luer adapter plug provided with the system.

A common problem is the xenon not getting into the patient for single breath. If this happens, try again with these changes:

A. Lower the "Air Flow" control to 20 or 10 five seconds before xenon administration.

B. Puncture the mouthpiece closer to the patient.

C. Have the patient take a deeper breath.

17. When the patient reaches equilibrium (1 or 2 minutes, the counting rate on the camera stabilizes), switch to "Washout, #3". Take washout data on the camera (typical framing: first picture, 15 seconds; second, 30 seconds; third, 60 seconds). Have the patient breathe normally slowly.

18. Carefully watch the "from patient" bag. If it starts blowing up, the patient is breathing too fast. Advise him to normalize his breathing and increase the "Air Flow" speed. If the bag continues to expand up towards the glass, the patient will feel back pressure and resistance. To relieve this effect, open the lower cabinet. In the center there is a motor control. Turn it clockwise until the breathing bag deflates. Return the control to about 1/2 of its range when the study is complete. The use of this motor control will be a rare occurence. Do not adjust it unless it is absolutely necessary. If it is used, be sure to return it to its original position. To be effective, the increase in motor speed must be done before the bag is full so watch the "From Patient" bag carefully during washout.

19. When the washout is complete, remove the patient and let the system run for a few more seconds or until both bags are empty.

To prolong the life expectancy of your charcoal cartridge, do the following:

1. When the patient has completed the washout, do not leave the system running for more than 10 seconds.
2. Check the lower blower motor. It should be set on 50-60 and not increased unless a specific patient needs the extra evacuation power.
3. Make sure the drierite is replaced before it changes color.
4. Do not leave the Pulmonex in Position #3 when not in use.
5. Monitor the trap effluent at regular intervals and keep a formal record.
6. Spread studies out. If you perform all your studies in one day, xenon may break through.

Additional routine for maintenance program:

1. Remove the two breathing tubes on the back of the unit. Take one short tube about 8" and connect the two ports on the back of the unit together so that there is a C configuration made by the single tube. Place the handle in position #2 and press the oxygen button filling the unit with oxygen. Both bags should be blown up tight against the glass windows. They should remain tight for about two minutes. If they do not blow up tight or sag, you may have a leak somewhere in the system. Call us if this happens.

TEST PROCEDURE FOR MONITORING TRAP EXHAUST

Trap exhaust is monitored by using the gamma camera without a collimator. The following simple technique is used:

1. Remove the collimator from the camera.
2. With a 5 percent window, calibrate for Xe-133.
3. Fill a large plastic bag with a known volume of air (typically, 50 liters).
4. Inject a known quantity of Xe-133 (such as 100uCi) into the bag. The concentration will be 2×10^{-3} uCi cm^3).
5. Place the bag in front of the crystal and count for a known period of time. The c/m obtained is a measure of the efficiency.
6. Collect the exhaust of a typical study in another bag of the same volume (50 liters) and count as defined in Step #5.
7. Ratio the count rates to the standard taken to determine exhaust concentration.

   For example:

   If 2×10^{-3} uCi/cm^3 yielded 600,000 c/m above background, and collected effluent from the patient study was 150 c/m above background, then:

$$\text{Ratio} = \frac{1.5 \times 10^2 \text{ c/m}}{6 \times 10^5} = 2.5 \times 10^{-4}$$

   Exhaust Concentration

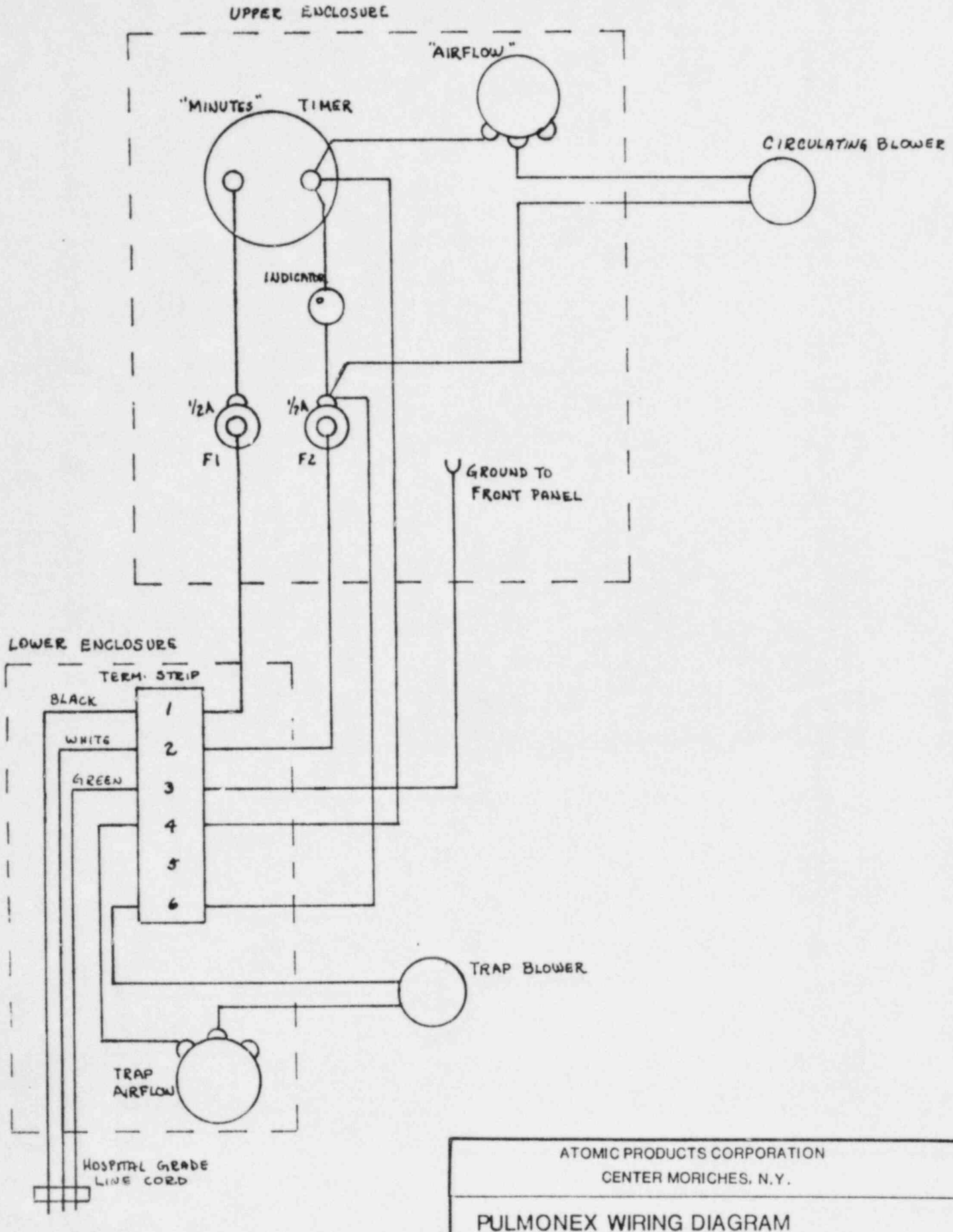
$$= R\ (2 \times 10^{-3}\ uCi/cm^3)$$

$$= (2.5 \times 10^{-4})\ (2 \times 10^{-3})$$

$$= 5 \times 10^{-7}\ uCi/cm^3 *$$

*MPC Xe-133 controlled area should not exceed 1×10^{-5} uCi/cm^3.

> Only perform the trap test when a patient is being tested on the system.



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MAT.	A090-419
DR. C.A.L. / DATE 3-18-78	
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XENON SYSTEM

Notes—

Here are a few ideas that will be helpful when performing Xenon studies. Most of them are covered in the instruction manual for the Pulmonex Xenon System.

1. Turn the top motor speed down before the initial Xenon Bolus injection. Keep it no higher than 20. After the Xenon is in the patient you can increase the speed to approximately 60. Do not increase the length of tubes that are supplied with the system. It is preferable to do patients sitting up with the 9 inch tubes that are supplied. If you must do a supine patient use no more than 24 inch tubes. Do not place an extension tube between the Y connector and the bacteria filter. This will create dead space. If you must increase tube lengths, increase both sides leading to the Y fitting.

2. If a patient is tired during a wash out, purchase Model # 185-302 Y connector with extra one-way valve. During the wash out you can open the top port on the Y and allow more room air to the patient. It makes wash out breathing easier.

3. Although a leur lock fitting is supplied for use at the Y connector we still recommend administering the Xenon closer to the patient. Consider injecting the Xenon either with a gun and a needle, through the mouth piece or attach a needle to the end of the automatic Xenon dispenser tube and place that needle into the mouth piece. Having the Xenon enter at the mouth piece always insures a good bolus for single breath.

4. Keep an eye on the breathing bags during the study. If during the initial breath a patient collapses the "to" p tient bag, add more oxygen so that in his next breath there is a reserve to draw on. Note: do not completely fill the to patient bag with oxygen. If you do you will create an air bound situation. Just add a small amount if required. During the wash out, be sure that the "from" patient bag is not filling up. If it is filling, speed up the air flow control. If this is still not enough, there is a wash out assist blower in the lower cabinet. Speed up the lower blower to help empty the from patient bag.

5. Be sure to test your trap effluent on a regular basis. It's required by law. The best way to test your trap is by using one of our Xenon monitors. If you do not have a monitor, follow the instructions for trap testing in your instruction manual.

6. Here are a number of ideas to prolong the life expectancy of your charcoal cartridge.

   a. When the patient has completed the wash out, do not leave the system running for more than ten seconds.

   b. Check the lower blower motor, it should be set around 70 and not increased unless a specific patient needs the extra evacuation power.

   c. Make sure the drierite is replaced when it changes color. The cartridge should be half full.

   d. Do not leave the Pulmonex in position 3 when not in use.

   e. Monitor trap effluent at regular intervals and keep a formal record.

7. Again, remember to keep the tubing on the outside of the Pulmonex as short as possible. The longer the tubing the harder it is to breath.

8. Fill the soda lime cartridge only 1/2 to 1/3 full and change for every patient. This will cut resistance.

AUTOMATIC XENON DISPENSER

It is recommended that periodically you clear the needles on the 150-310 AXD. The procedure is fast and simple. Please note that the 150-310 AXD can be used only with the 130-500 Pulmonex and NEN Calidose Gun.

1. Remove the Xenon vial and plunger from the AXD.

2. Hook the oxygen hose to the oxygen input on the AXD.

3. Press the AXD "Add Xenon" button and slowly increase the oxygen pressure. The oxygen will flow out one needle in the center of the dispenser. Continue the flow for about 10 seconds.

4. Disconnect the tube connecting the AXD to the leur lock plug.

5. Connect the oxygen hose to the leur loc fitting on the side of the AXD. Turn the oxygen on. Slowly increase the oxygen pressure. Oxygen will flow out the other needle in the center of the AXD. Continue the flow for about 10 seconds.

6. Reset the AXD.

Atomic Products Corporation
ATOMLAB DIVISION • ESTABLISHED 1949
P.O. BOX 657 CENTER MORICHES, NEW YORK 11934 USA
(516) 878-1074
TWX #510-228-0449

SUPPLEMENT TO ITEM 23, NRC-313M

Details for the use of the 153 Gadolinium source have been given in the Amendment request dated March 18, 1985. The only additional safety precautions required would be the usual leak testing for a sealed source. This will be performed as a wipe test on a monthly basis. 169 Ytterbium DTPA requires no additional safety precaution other than what we already use in all of our radiopharmaceuticals. The depleted Uranium is used in the Radiation Therapy Department as shielding material.