

FORM NRC-313M

(8-78)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved:
GAO R0557

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.

RECEIVED BY LFMB

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

Danbury Hospital
24 Hospital Avenue
Danbury, CT, 06810

TELEPHONE NO.: AREA CODE (203) 797 7000

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

(same)

Log

By

Orig. To

Dec 14 1984
Brown2. PERSON TO CONTACT REGARDING THIS APPLICATION
Herbert W. Mower, Sc.D.

TELEPHONE NO.: AREA CODE (203) 797 7529

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

a. ☐ NEW LICENSEb. ☐ AMENDMENT TO LICENSE NO. _____c. ☒ RENEWAL OF LICENSE NO. 06-08544-01

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

See attached list, Item 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.)

Herbert W. Mower, Sc.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 mCi of each	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	3,500 mCi of each	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	700 mCi
10 CFR 35.100, SCHEDULE A, GROUP VI	X	3,000 mCi total			

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
Cesium 137	Encapsulated	200 mCi	Gamma survey instrument calib.
Cesium 137	Any	50 micro Ci	In vitro studies
Potassium 42	Any	40 mCi	In vitro studies
Sulfur 35	Any	5 mCi	In vitro studies

8505310521 850506
REG1 LIC30
06-08544-01

PDR

Amount, Fee Category

Type of Fee

Date Check Rec'd

Received By

87647
#150-7B 02014
Renewal
Brown

DEC 29 1983

FORM NRC-313M
(8-78)

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
X	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
X	Duties as in Appendix B; or (Check One)		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
X	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
X	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		X	Appendix I Procedures Followed; or
X	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or
X	Appendix D Procedures Followed for Survey Instruments; or (Check One)		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
X	Appendix D Procedures Followed for Dose Calibrator; or (Check One)	X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached	X	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		X	Appendix L Procedures Followed; or (Check One)
X	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
		NA	Detailed Information Attached
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached	---	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	R. S. Landauer, Jr. & Co.	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER <i>(Specify)</i>		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	R. S. Landauer, Jr. & Co.	Monthly
	<input type="checkbox"/> OTHER <i>(Specify)</i>		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER <i>(Specify)</i>		

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)

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type of Print)*
Morris Gross

(1) LICENSE FEE CATEGORY:
7. B. Renewal

(2) TITLE
Director of Operations

(2) LICENSE FEE ENCLOSED: \$ 150.00

c. DATE
December 20, 1983

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 Form NRC-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.

INDIVIDUAL USERS

Nilo E. Herrera, M.D.	Groups I, II, III, IV, and V <u>In vitro</u> studies Xenon 133
William Goldstein, M.D.	ALL
David S. Berger, M.D.	Groups IV, V, and VI
Joseph J. Belsky, M.D.	Groups I, II, and III <u>In vitro</u> studies Xenon 133 Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction
Ramon N. Kranwinkel, M.D.	Groups I, II, and III <u>In vitro</u> studies Xenon 133
Shiv Gupta, M.D.	Groups I, II, III, IV, and V <u>In vitro</u> studies Xenon 133 Iodine 125 sealed sources for bone mineral analysis
Jonathan Alexander, M.D.	Technetium 99 M radiopharmaceuticals in Groups I, II, and III for cardiac imaging and diagnosis of cardiac function.

RADIATION SAFETY COMMITTEE

<u>Name</u>	<u>Specialty</u>
Nilo E. Herrera, M. D.	Chairman, Department of Laboratory Medicine and Nuclear Medicine
Jonathan Alexander, M. D.	Cardiologist
Joseph L. Belsky, M. D.	Chief, Endocrinology and Metabolism
David S. Berger, M. D.	Radiation Therapist
William B. Goldstein, M. D.	Chairman, Department of Radiology
George Terranova, M. D.	Chairman, Emergency/Primary Care Department
Herbert W. Mower, Sc.D.	Radiation Physicist, R.S.O.
Diane Allen, R.N.	Head Nurse
Richard Cochrane, R.P.T.	Assistant Director, Medical Affairs
Joseph Daley	Manager, Department of Radiology
Tom Davies	Supervisor, Nuclear Medicine
James P. Gravius, Jr.	Director, Security and Safety
Morris Gross	Director, Operations

TRAINING AND EXPERIENCE

For:

Refer to:

Nilo E. Herrera, M.D.	#06-08544-01 Renewal 1/19/79 & Amendment 57 (6/16/82)
William Goldstein, M.D.	#06-08544-01 Renewal 1/19/79
David S. Berger, M.D.	#06-08544-01 Renewal 1/19/79
Joseph J. Belsky, M.D.	#06-08544-01 Renewal 1/19/79
Ramon N. Kranwinkel, M.D.	#06-08544-01 Renewal 1/19/79
Shiv Gupta, M.D.	#06-08544-01 Amendments 56 (10/22/81) & 57 (6/16/82)
Jonathan Alexander, M.D.	#06-08544-01 Amendment 56 (10/22/81)
Herbert W. Mower, Sc.D.	#24-00128-03 Amendment 33 (3/23/79) #06-08544-02 Renewal application (October, 1983)

APPENDIX C INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: Ludlum
 Manufacturer's model number: 3
 Number of instruments available: 3
 Minimum range: 0.0 mR/hr to 0.2 mR/hr
 Maximum range: 0 mR/hr to 200 mR/hr
- b. Manufacturer's name: Victoreen
 Manufacturer's model number: 740-G Cutie Pie
 Number of instruments available: 1
 Minimum range: 0 mR/hr to 100 mR/hr
 Maximum range: 0 mR/hr to 100,000 mR/hr

2. Dose calibrator

- Manufacturer's name: Capintec Capintec (spare)
 Manufacturer's model number: CRC-30 CRC-6
 Number of instruments available: 1 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Computer	Technicare	556
Portable Gamma Camera	Technicare	420-550
Spectroscaler with well and probe	Pickar	628486
Bone densitometer	Norland	278
Gamma Camera	Baird	050301
Gamma Camera (2)	General Electric	400 T and 400 TA
Xenon Lung Unit	Nuclear Associates	
4. Other (e.g., liquid scintillation counter, area monitor, velometer)		
Area Monitor	Pickar	60081
Velometer	Alnor	
* Survey Instrument Calibrator	Nuclear Associates	64-773
Xenon Gas Trap	Nuclear Associates	36-022

(* to be added)

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

- X 1. Survey instruments will be calibrated at least annually and following repair.
- X 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
- X b. At the licensee's facility

(1) Calibration source

Manufacturer's name Nuclear Associates

Model no. 64-773

Activity in millicuries 165

or

Exposure rate at a specified distance

Accuracy $\pm 5\%$

Traceability to primary standard NBS

- X (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.

X c. By a consultant or outside firm

- (1) Name Radiation Protection Services
- (2) Location Darien, CT, 06820
- (3) Procedures and sources

X have been approved by NRC and are on file in License No. 29-09701-02 on July 22, 1982 (Riverview Hospital, Redbank, NJ)

 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.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

 Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

<u>Radionuclide</u>	<u>Suggested Activity (mCi)</u>	<u>Activity (mCi)</u>	<u>Accuracy</u>
Co-57	3-5	<u>5.75</u>	<u>3 %</u>
Ba-133	0.1-0.5	<u>0.27</u>	<u>4 %</u>
Cs-137	0.1-0.2	<u>0.24</u>	<u>3 %</u>
Ra-226	1-2	<u>----</u>	<u>----</u>
<u> </u>		<u> </u>	<u> </u>

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

or

 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.

FACILITIES AND EQUIPMENT

Attached are four diagrams which show the Nuclear Medicine Department, an enlargement of the hot lab and in-department storage area, the remote storage area (waste storage), and the brachytherapy source storage area.

The cesium-137 brachytherapy sources are stored in a secured corridor on the north end of the Radiation Therapy Department. The west access is locked with keys issued to the Radiation Therapist and the Radiation Physicist. The east access is an emergency exit from the corridor with no access from the east. The cesium is stored in one of two commercial cesium safes, which are also secured. Safe #1 is within a 2" leak block area which also serves as the preparation area for brachytherapy sources. Sources are transported to the patient's room in a commercial carrier designed for brachytherapy sources. The carrier remains in the patient's room until the sources are removed from the patient and returned to the safe therein.

The remote waste storage area is located in a secured room in a back corner of a mechanical equipment room, which is also secured. The mechanical equipment room is not an occupied area. Keys for the waste storage area are in the possession of the chief Nuclear Medicine Technologist and the Radiation Safety Officer. All items being held for decay prior to disposal are stored in this area. Items are transported to this area in a special lead-lined (1/16") cart. This area is surveyed weekly by the Radiation Safety Officer or his designee.

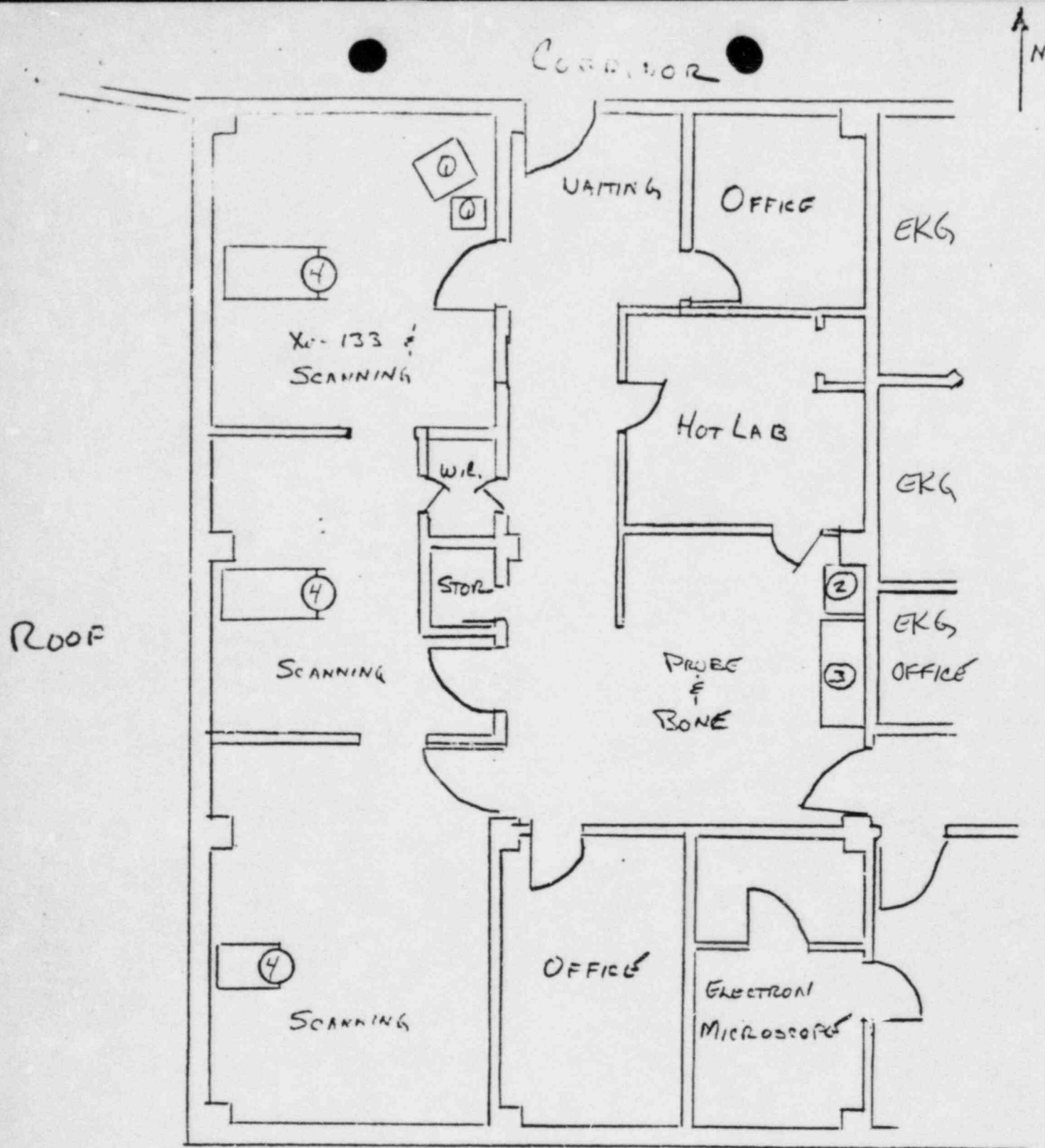
The separate storage area within the Nuclear Medicine Department is used to store flood sources and some calibration sources. Items in route to the remote storage area may also be held temporarily in this secured room.

All other radioactive materials, including Tc-99m generators, are stored in the generator and storage area within the hot lab. This area is within a fume hood. Refrigerated radiopharmaceuticals are stored below the fume hood in a secured refrigerator that is lead lined.

Radiopharmaceuticals are prepared behind the "L" block which is between the fume hood (storage) and hot sink. It is also adjacent to the well for the dose calibrator. This reduces movement within the hot lab and radiation exposure to personnel.

Areas within the Department and adjacent to it are surveyed to assure that the limits of 20.105 (b) of 10 CFR Part 20 are not exceeded. All areas outside the Nuclear Medicine Department and the Radiation Therapy Department, except those below grade, are assumed to have a non-controlled occupancy of 1.

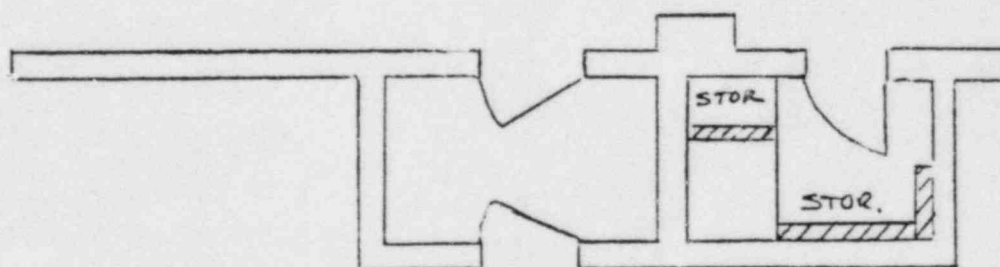
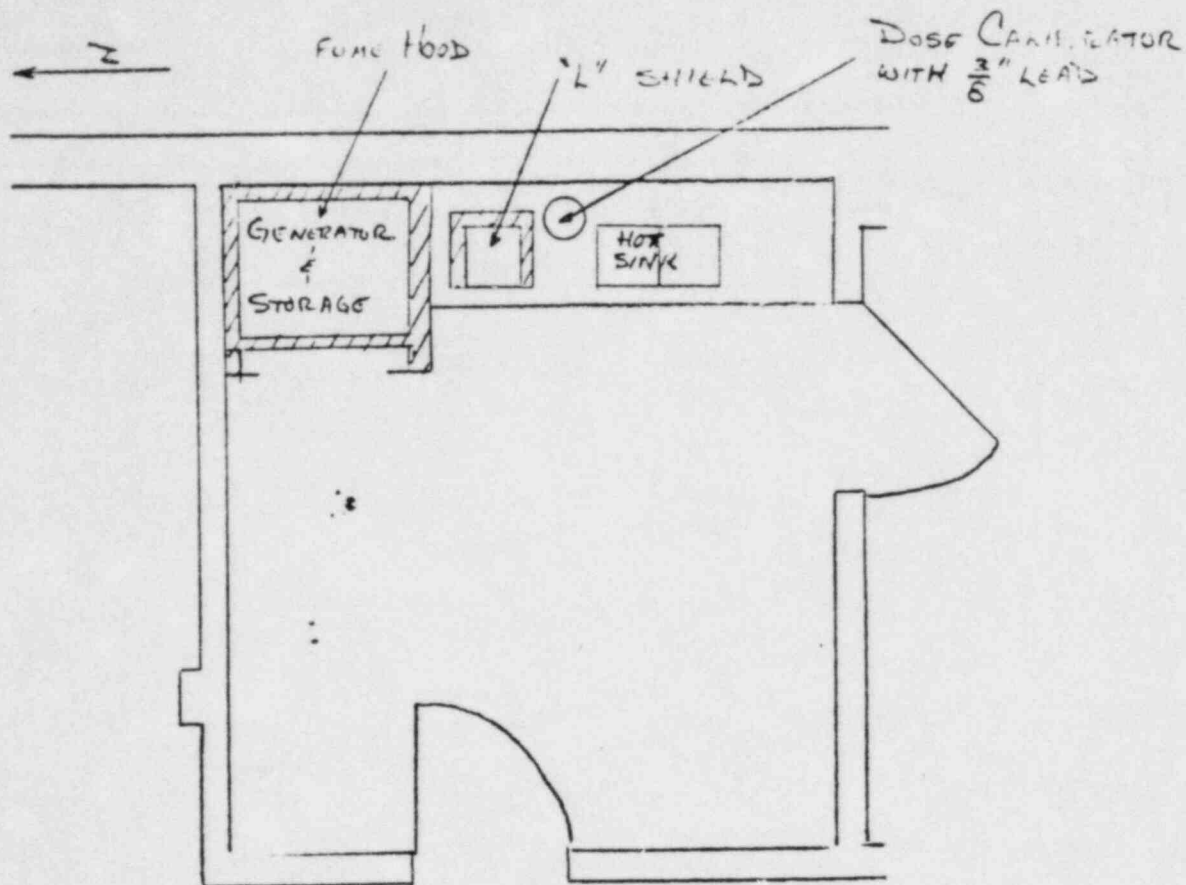
Information relative to Xenon-133 is contained in item 21.




- NOTES:
- ① Xe-133 UNIT
 - ② WORK & PROBE
 - ③ BONE UNIT
 - ④ CAMERA

ROOF

NUCLEAR
MEDICINE
1/8" = 1'
ITEM 11
DECEMBER 1983



NOTES: 1)  = 2 INCH LEAD

(NUCLEAR MEDICINE)

HOT LAB &

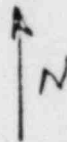
STORAGE

1/4" = 1'

HEIN //

DECEMBER, 1983

BELOW GRADE



FOUNDATION

BELOW
GRADE

FOUNDATION

RADIOACTIVE
WASTE
STORAGE

8" CONCRETE
BLOCK

8" BRICK

MECHANICAL EQUIPMENT
(SECURED AREA)

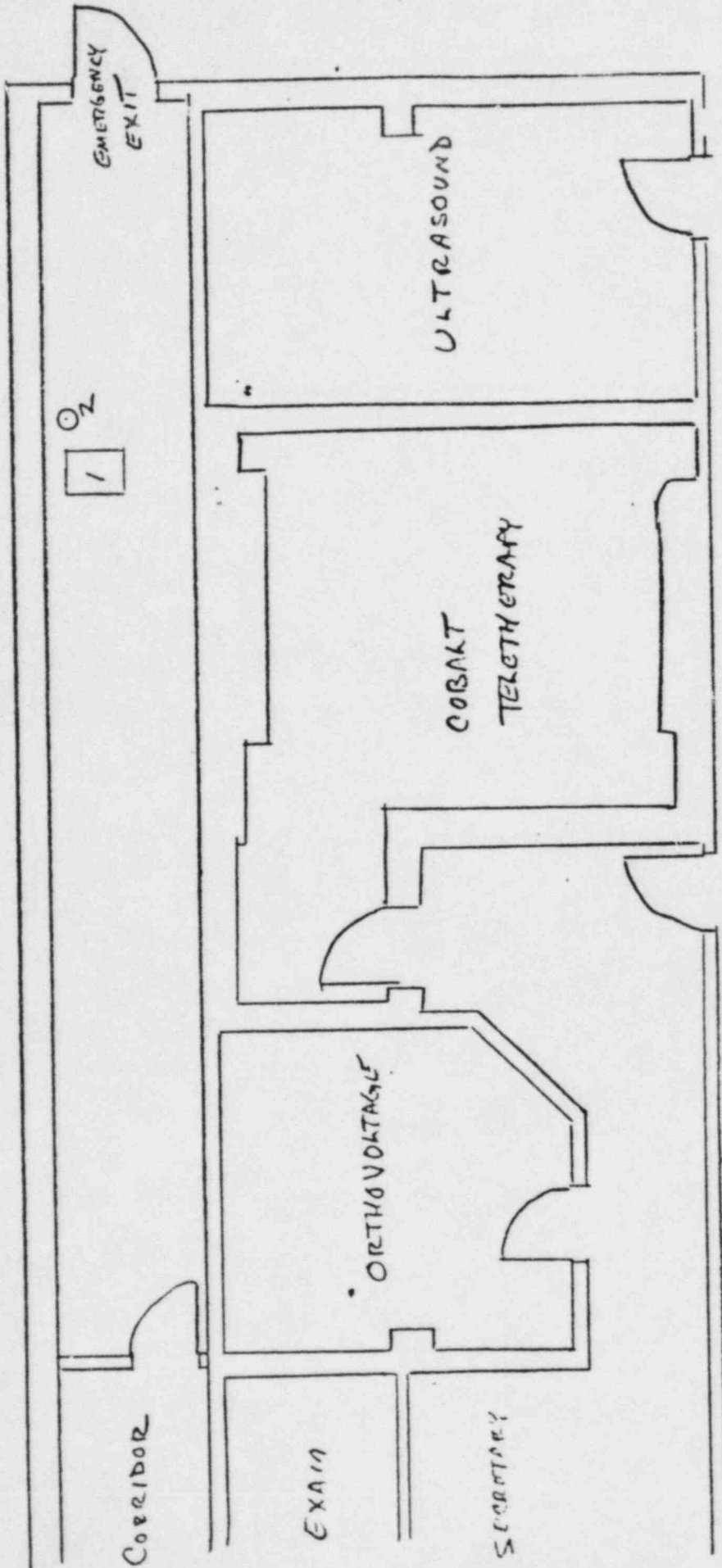
WASTE STORAGE

1/8" = 1'

ITEM 11

DECEMBER, 1983

BELOW GRADE



CORRIDOR

- NOTES: 1) 3 M CESIUM SAFE WITH
"L" BLOCK AND 2" LEAD ADDED
- 2) NUCLEAR ASSOCIATES STORAGE
INCLUDING 3" LEAD

BRACHYTHERAPY
STORAGE
1/8" = 1'

ITEM 11
DECEMBER, 1933

PERSONNEL TRAINING PROGRAM

I. Nuclear Medicine Technologists

All new technologists will be graduates of an accredited program for nuclear medicine technologists and will be certified.

New technologists, during their first week of employment, will work under the guidance of a senior technologist on the staff. During this interval, under the supervision of the Director of Nuclear Medicine or the Radiation Safety Officer, they will receive instruction including:

- handling of radioactive materials
- procedures utilized in our Department
- storage, transfer, and use of radioactive materials
- controlled and non-controlled areas
- radiation biology
- radiation precautions
- ALARA
- location and provisions of our license
- location of posting of personnel exposures
- radiation safety
- radiation spills and emergencies

All technologists will participate in a weekly in-service program. The format will alternate between lectures and departmental discussions. The lectures will be presented by members of the staff, professionals within the Hospital, and invited lecturers. All of the topics noted above will be covered annually. The departmental discussions will provide a forum for covering procedures, problems, and other topics of concern to the technologists.

II. Ancillary Personnel

Ancillary personnel includes all employees who may come in contact with radioactive materials, radiation areas, or patients containing radioactive materials. This includes, but is not limited to: security, nurses, housekeeping, cardiology technicians, and dietary personnel.

All new employees, as a part of their indoctrination, will receive instruction on basic radiation safety as it relates to their area. This will be an audio-visual presentation with names to contact for further information.

Personnel who may come in contact with radioactive materials or radiation areas will receive annual refresher courses. Several sessions will be conducted each year at different times to allow employees on all shifts to attend at least one session. These sessions will use audio-visual programs as well as professionals trained in radiation protection.

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY
OF RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist or his designee will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive materials will be maintained. This system consists of the following:

a. Ordering of routinely used materials

(1) Written records that identify the isotope, compound, activity levels, and supplier will be used.

(2) The written records will be referenced when opening or storing radioactive shipments.

b. Ordering of specially used materials (e.g., therapeutic uses)

(1) A request will be obtained from the physician who will perform the procedure.

(2) Persons ordering the materials will reference the physician's request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

(3) The physician's request will be referenced when receiving, opening, or storing the radioactive material.

c. It is essential that written records be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty hours, security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in the memorandum attached.

Danbury Hospital the community health center
Danbury, Connecticut 06810 Telephone 203-797-7000

December 1, 1983

To: Security Personnel

From: Herbert W. Mower, Sc.D., Radiation Safety Officer

Subject: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive when the Nuclear Medicine Department is closed shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package inside the Department waiting area, and relock the door.

If the package is wet or appears to be damaged, IMMEDIATELY contact the Radiation Safety Officer, Nuclear Medicine Supervisor, or the Nuclear Medicine Technologist on Call. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

	Supervisor	Tech-on-call	R.S.O.
	Tom Davies		Dr. Mower
Office:	x3192	x7222	x7529
Home:	274-7261	Beeper 630	354-1155

ITEM 13
DECEMBER 1983

APPENDIX J
WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

☒ In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

☐ By commercial waste disposal service (see also Item 4 below).

☐ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

☐ Returned to the manufacturer for disposal.

☒ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

☐ Disposed of by commercial waste disposal service (see also Item 4 below).

☐ Other (specify): _____

3. Other solid waste will be (check as appropriate)

☒ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

☐ Disposed of by commercial waste disposal service (see also Item 4 below).

☐ Other (specify): _____

4. The commercial waste disposal service used will be

(Name)

(City, State)

NRC/Agreement State License No. _____

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

All operations with radioisotopes will be performed using laboratory coats and disposable gloves. Chemical procedures must be performed over absorbent paper or in trays. The transfer of radioactive materials must be done in trays or other suitable vessels.

Work with volatile substances or particulate matter must be performed in the fume hood.

Skin contamination, ingestion, or inhalation of radioactive material can be avoided by practicing good housekeeping, clean work habits, and frequent hand washing. Radioactive materials shall not be allowed to come into contact with the skin. Gloves should be worn whenever working with such materials.

PROCEDURES FOR THE USE OF THERAPEUTIC QUANTITIES OF IODINE-131 CAPSULES

To prevent possible exposure of the technologist to volatile I-131 and subsequent internal contamination:

1. Upon receipt of a package containing a therapeutic quantity of I-131, the technologist will put on latex examination gloves and open the package in accordance with departmental procedures.
2. The lead container holding the I-131 should be placed inside the fume hood for storage until it is ready to be used.
3. Prior to patient administration, the container will be opened and allowed to sit inside the fume hood for a period of five (5) minutes.
4. At such time, the capsule will be assayed and administered to the patient. During the entire procedure, the technologist handling the I-131 capsule will wear a pair of latex examination gloves.
5. After capsule administration, monitor the exterior and interior of the container. If less than 0.5 mR/hr, the container can be disposed. If radiation levels are in excess of 0.5 mR/hr, save the container for evaluation by the Radiation Safety Officer.
6. After handling the I-131 container, remove gloves, place in "hot" trash, and wash hands thoroughly.
7. Monitor both hands with the area monitor; if contaminated, re-wash and repeat procedure.

Note: All personnel handling doses of I-131 in excess of 10 mCi will have a thyroid uptake 24 hours after handling the I-131. Technologist's neck counts and background will be recorded and saved for the evaluation of the Radiation Safety Officer.

BIOASSAY OF PERSONNEL FOLLOWING THERAPEUTIC I-131

For all therapeutic I-131 administrations with activities in excess of 10 mCi (370 MBq) the technologists involved in the preparation and assay of the Iodine-131 capsule will have their thyroid monitored at 24 hours post capsule administration.

Procedure:

1. Device - Picker Spectroscaler 4 with Uptake probe
2. Window - 330 keV - 402 keV
3. Position -
 - a. Background count - use standard neck phantom, remove positioning bar and position phantom at face of collimator
 - b. Technologist - seat the technologist in a comfortable chair and position the face of the uptake probe on the technologist's neck
4. Counting time - 10 minutes for background and technologist study.
5. Record total background counts and total technologist neck counts. Save results for Radiation Safety Officer.
6. Minimal detectable uptake limit is 2.01 nCi.

THERAPEUTIC USE OF SEALED SOURCES

Group VI sources are stored in the Brachytherapy Storage Area (see attached sketch). This is a secured corridor on the north end of the Radiation Therapy Department. The west access is locked with keys issued to the Radiation Therapist and the Radiation Physicist. The east access is an emergency exit from the corridor with no access from the east. The cesium is stored in one of the two commercial safes, which are also secured. Safe #1 is within a 2 inch lead brick area which also serves as the preparation area for brachytherapy sources. Other group VI sources, as gold-198, iridium-192, are ordered individually for each application. These are stored in the 2 inch lead brick area adjacent to safe #1. Following the therapeutic procedure, unused and removed sources are returned to the vendor.

The Storage Area, Orthovoltage Room, and Cobalt Teletherapy Room are all controlled areas. Radiation levels in and adjacent to the Brachytherapy Storage Area for 3000 mCi of cesium-137 (maximum anticipated at any given time) are:

	mR/hr	mR/week *
(A) At emergency exit	.04	6.7
(B) One foot in front of "L" block	.22	37.0
(C) 2 meters from safe	.15	25.2
(D) Secured entrance	.04	6.7
(E) Northeast corner of Orthovoltage Room	.04	6.7
(F) Northeast corner of Cobalt Room	.19	32.0
(G) Northwest Corner of Ultrasound Room	.04	6.7

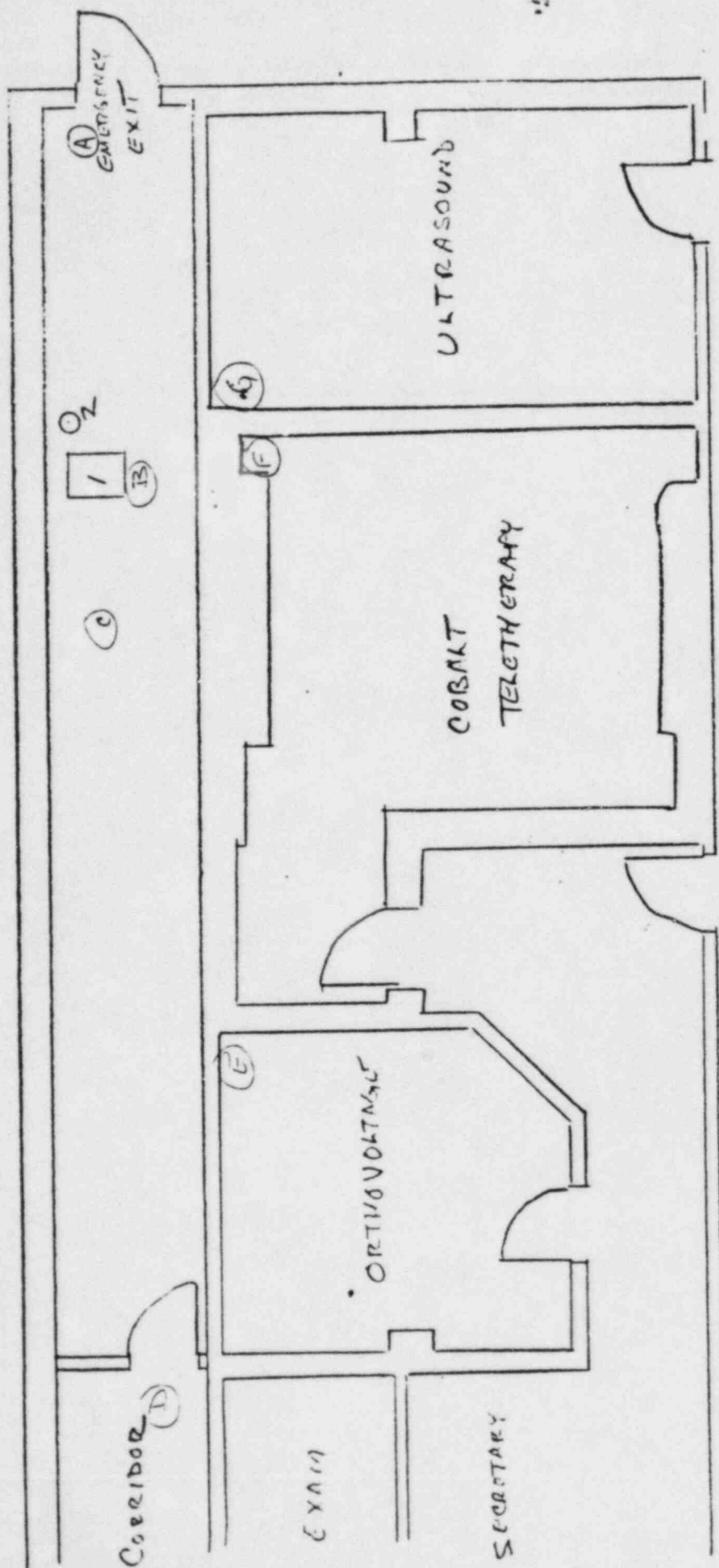
* mR/week are based on 168 hours per week. Areas (E) and (F) are occupied 40 hours per week, (D) and (G) are 50 hours per week. No area is found to be above 2 mR/hr or 100 mR/week.

Long forceps are used when handling sources. Sources are prepared behind the "L" block and within the shielded area. Personnel handling brachytherapy sources are issued ring badges to monitor the dose to the extremities. Sources are transported in a commercial wheeled carrier with 1 inch of lead shielding.

Sources are accounted for in three ways. First, a quarterly inventory is carried out to assure that all sources are present or accounted for. Second, whenever sources are removed from the storage area, the sources removed are noted on a blackboard in the area. When the sources are returned, they are removed from the board. Third, sources are logged-out and logged-in in a log book. This record includes date, time, sources, quantity, patient, and patient location. When any sources are returned to the storage area, all sources are counted to assure that all sources are accounted for.

When sources are administered to a patient, a survey is made to determine the exposure levels at the patient's bedside, one meter from the patient, at the room entrance, and at adjacent patient locations. Brachytherapy patients are always assigned a single room at the end of the corridor. When the sources are removed, a physical count is taken immediately to assure that all sources have been removed. The sources are moved away from the patient and a survey of the patient and environs is made to verify that no sources have been left behind or in the patient. The results of these surveys becomes a part of the patient's permanent record.

Below Grade



CORRIDOR

- NOTES: 1) 3'4" CESIUM SAFE WITH "L" BLOCK AND 2" LEAD ADDED
- 2) NUCLEAR ASSOCIATES STORAGE INCLUDING 3" LEAD

BRACHYTHERAPY
STORAGE
1/8" = 1'

ITEM 20
DECEMBER, 1992

1. Quantities to be used

Patients per week: 7 average; 15 maximum
Activity per patient: 12 mCi average; 20 mCi maximum
Desired possession limit of 700 mCi

2. Use and storage areas

The Xenon-133 will be stored in the manufacturer's lead storage containers in the exhaust hood of the Nuclear Medicine Department's hot lab. The Xenon-133 will be used in the north scanning room. See attached diagram of these areas.

The ventilation of the Nuclear Medicine Department is a system with all exhaust vents leading directly outside. There is no recirculation of air to other parts of the hospital.

This ventilation system is a negative pressure system. In case of accidental release of Xenon-133, all doors to adjacent areas will be immediately closed to ensure that the only escape route for the released Xenon-133 is through the established ventilation system. The theoretical clearance half-time for the north scanning room is just under 2 minutes. Thus 10 half-times is about 20 minutes. Ventilation measurements are performed quarterly by the Engineering Department and reviewed by the Radiation Safety Officer.

3. Procedures for routine use

Before the ampoule of Xenon-133 is injected into the closed Xenon system, an unruly patient will not be injected or allowed to inhale the dose and the study cancelled.

A special apparatus is utilized for the administration and collection of Xenon-133 at Danbury Hospital. The unit which is used is a Nuclear Associates Inc. Xenon Lung Functioning Unit.

During the administration of Xenon-133, the patient will be breathing through a specially designed mouthpiece with a clamp placed over his/her nose. In this manner, all Xenon-133 utilized during the procedure will be collected and contained by the trap with no Xenon-133 being released into the atmosphere under normal operating conditions.

4. Emergency procedures

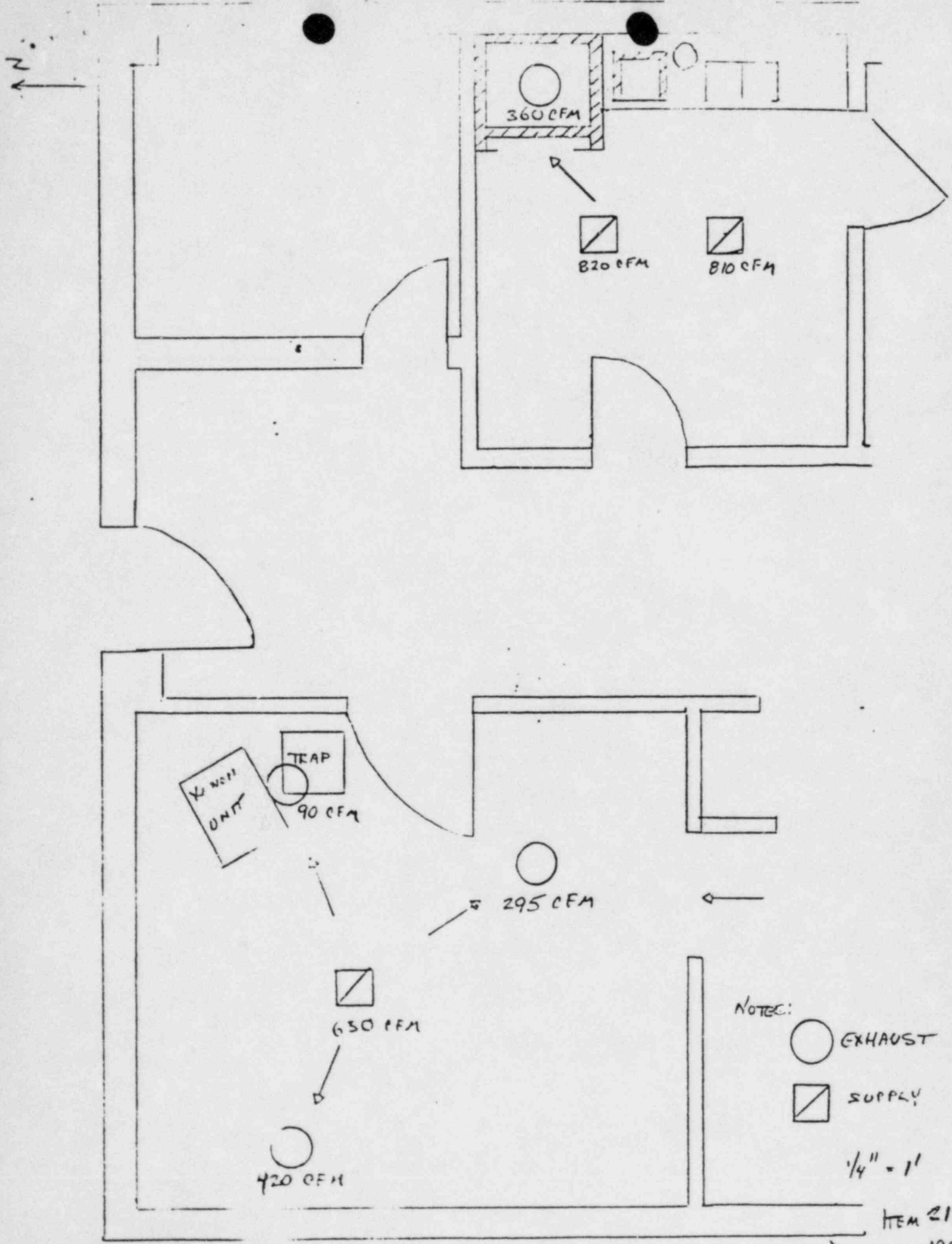
All personnel and will be removed from the north and middle scanning rooms if Xenon-133 is released into the scanning room.

Upon exiting the room, all doors will be closed to insure maximum ventilatory capacity of the room, and this room shall be sealed off to prevent unauthorized entry.

The Radiation Safety Officer shall immediately be notified.

Upon arrival of the Radiation Safety Officer, he shall assess the radiological danger.

Decontamination procedures will be started under his direction, if any personnel are found to be contaminated.



ITEM 21
DRAFTING, 1982

At regular intervals, starting at 20 minutes post release, the RSO will survey the accident area to determine when safe re-entry is possible.

Re-entry to the contaminated area will be allowed only under the direction of the RSO.

Upon re-entry, an assessment of the underlying causes behind this release will be undertaken by the Chief Nuclear Medicine Technologist and, if appropriate, recommendations will be made at the next meeting of the Radiation Safety Committee.

5. Air concentrations of Xenon-133 in restricted areas

Maximum activity to be used per week (A):

$$A = 20 \text{ mCi/patient} \times 15 \text{ patients/week} \times 10^3 \text{ uCi/mCi} = 3 \times 10^5 \text{ uCi/week}$$

Loss rate (f) of 20%

Required ventilation rate is:

$$\frac{A \times f}{10^{-5} \text{ uCi/ml}} \times \frac{\text{ft}^3/\text{min}}{1.7 \times 10^6 \text{ ml/hr}} \times \frac{1}{70 \text{ hrs/week}} = \frac{(3 \times 10^5) \times (.20)}{(10^{-5}) \times (1.7 \times 10^6) \times (70)} = 50 \text{ CFM}$$

Thus a ventilation rate of 50 CFM (minimum) is required. As shown on the accompanying diagram, the ventilation rate averages 175 CFM. Since the average dose per patient is closer to 12 mCi and the average patient load is closer to 7 per week, we are well within acceptable limits.

6. Air concentration of Xenon-133 in unrestricted areas

The disposal of Xenon-133 is by method of a charcoal absorbant trap supplied with the Nuclear Associates delivery system and collection system described earlier.

Leakage will be assumed to be approximately 10% of the absorbed Xenon-133 per year. Therefore:

$$A = 7 \text{ patients/week} \times 12 \text{ mCi/patient} \times 10^3 \text{ uCi/mCi} \times 52 \text{ weeks} \times .10 \\ = 4.37 \times 10^5 \text{ uCi/year leakage from the trap}$$

The ventilation rate per year is:

$$V = 175 \text{ CFM} \times 1.484 \times 10^{10} \text{ ml/yr/CFM} = 2.60 \times 10^{12} \text{ ml/year}$$

Therefore, the yearly concentration of Xenon-133 is:

$$C = (4.37 \times 10^5) / (2.60 \times 10^{12}) = 1.68 \times 10^{-7} \text{ uCi/ml}$$

This is well below the allowable 3×10^{-7} uCi/ml.

After each use of the Xenon-133 delivery system and gas trap, it will be monitored with a GM meter to insure that there are no leaks in the system. The survey of the unit will check all connections between the delivery and collection tubing and that of the machine. Leakage will be assumed to have occurred if the reading shows exposure levels significantly greater than background (usually five times background with background usually being 0.05 mR/hour or less).

* The manufacturer of the traps estimates a life-time of approximately one year at the present workload. Saturated traps will be stored in the radioactive waste storage area of the Nuclear Medicine department for a time period of seven half-lives (approx 40 days). At this time, the spent gas traps can be discarded in the normal hospital trash.

Saturation of the filter is monitored by the release from the exit port of the trap following wash-out of a known volume of Xenon-133. Samples are compared with a known standard in the well counter. Acceptable level is less than

5×10^{-2} uCi from the exit port per 10 mCi administered dose.