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

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

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

Defiance Hospital, Inc.
1206 E. Second St.
Defiance, Ohio 43512

TELEPHONE NO.: AREA CODE (419) 782 6955

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

None

Applicant 027552 / 029685
Check No. 4130 / $430
Amount Fee Category 7C Ren
Type of Fee 2/16/84
Date Check Rec'd
Received By CP
Dep by Controller

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Dr. John A. Mitchell

TELEPHONE NO.: AREA CODE (419) 782 6955

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 34-15654-01

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

Dr. John A. Mitchell
Dr. Nilo V. Gomez

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.)*

Dr. John A. Mitchell
Chief, Department of Nuclear Medicine

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	1 mCi	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	2000 mCi	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED			
10 CFR 35.100, SCHEDULE A, GROUP VI			XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	x	200 mCi

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
Does not apply			

RECEIVED BY LFMB
Date 7/16/84
Log July 18th
By CP
Orig. To CP
Action Compl.

RECEIVED
JUL 12 1984

NRC FORM 313M (9-81)

Control No. 77113

8505280345 850507
REG3 LIC30
34-15654-01 PDR

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	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)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	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
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	ICN Dosimetry Service	
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST	X	FILM	ICN Dosimetry Service	
		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: 170.31 - 7B

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

Mike Reichfield

(1) NAME (Type or Print)

Mike Reichfield

(2) TITLE

Acting Administrator - Defiance Hosp.

c. DATE

5-11-84

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PRIVACY ACT STATEMENT

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

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

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

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

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

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

Item 7. Medical Isotope Committee:

The committee's duties, responsibilites, and the meeting frequency will be described in appendix B of the Regulatory Guide, Revision 1*, Oct. 1980.

Members of the committee include:

Dr. John A. Mitchell	- Diagnostic Radiology and Nuclear Medicine
Dr. Nilo V. Gomez	- Diagnostic Radiology and Nuclear Medicine
Dr. Isaac Cruz	- Pathology
Mr. Michael Reichfield	- Acting Administrator
Mr. Kerry Knuth	- Chief Laboratory Technologist
Mrs. Kathleen Horvath	- Director of Nursing
Mrs. Marie Salabsky	- Chief Nuclear Medicine Technologist (ARRT, NMTCB)

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Item 8. Training and Experience

A) Dr. John A. Mitchell and Dr. Nilo V. Gomez have been previously authorized to use the radioactive material requested in this application. Refer to License # 34-15654-01 of AEC.

B) Radiation Safety Officer - Dr. John A. Mitchell.

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APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victoreen Thyac 111

   Manufacturer's model number: 490

   Number of instruments available: 1

   Minimum range: .01 mR/hr to 0.2 mR/hr

   Maximum range: 20.0 mR/hr to 200 mR/hr

   b. Manufacturer's name: Picker Compac 120 (well counter) for wipe tests

   Manufacturer's model number: 630078-1

   Number of instruments available: 1

   Minimum range: _____ mR/hr to _____ mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

   Manufacturer's name: Mallinckrodt Nuclear

   Manufacturer's model number: None

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Radioisotope Camera	Technicare	Sigma 438
Spectrometer	Ludlum Measurements	261

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

Pulmonex - Xenon System	Atomic Products	130-500
Xenogard Xe 133 Room Air/Trap Monitor	Victoreen	36-751

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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

__X__ a. By the manufacturer *or*

_____ 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.

__X__ c. By a consultant or outside firm

(1) Name *Andrew J. Schneider (Physicist)*

(2) Location *Medical College of Ohio, Toledo, Ohio*

(3) Procedures and sources

__X__ have been approved by NRC and are on file in License No. *34-13011-05*

_____ 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.

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

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

ITEM: 10
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SURVEY METER CALIBRATION CERTIFICATE

Type _____ (e.g. end-window G.M.)

Owner _____

Mfg. _____

_____

Max. Reading _____

Meter Model # _____

Batteries _____

Meter Serial # _____

_____

Probe Model # _____

_____

Probe Serial # _____

Check Source _____

Speaker Model # _____

_____

Speaker Serial # _____

_____

Speaker Batt. _____

☐ Time Constant ☐ Ear Plugs ☐ Head Set ☐ Integrate

Calibration Source: 96 millicuries ^{137}Cs -- See Other Side

Full-Scale Range (mR)	Meter Value (mR)	Known Value (mR)	Correction Factor (Multiplier)

Geometry Conditions _____

_____

Comments _____

_____

Recalibration Due By: _____

_____ Physicist

_____ Date

THIS REPORT MUST BE SAVED--SEE OTHER SIDE

SOME TIPS ABOUT SURVEYING

1. Always use a "check source" to verify meter is working.
2. Always check background before entering radiation area.
3. For G-M, if needle is not moving either the meter is broken or it can be saturated from high radiation levels.
4. A speaker will respond to radiation more quickly than the needle, so use the speaker to locate "hot" areas.
5. When counting beta radiation, record values from the CPM scale.
6. Be aware of energy dependence. Obtain energy response curves from the manufacturer or calibrate the meter for the radionuclide in use.
7. Be aware of geometry conditions.
8. Always allow the needle to stabilize before recording value.
9. Most reliable readings will be obtained if needle is approximately mid-scale.
10. A survey meter should be calibrated semi-annually.

CALIBRATION FACILITY

The survey meter calibration source used for this calibration was 96 mCi of Cs-137 at 10-4-76. The output of this source was determined by measurement with a Victoreen "R" chamber under those scatter conditions used during actual calibration. The accuracy of the roentgen output is believed to be known within $\pm$ 3%.

Item 10: Calibration of Instruments

A. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy and constancy. They will consist of:

Nuclide	Manufacturer	Model #	Activity (mCi)
Cs-137	Mallinckrodt	045-4DZ	1.0 on 5-1-74
Co-57	Amersham	CTC-VI	5.527 on 3-1-83
Co-60	NEN		Approx. 0.200

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standards sources.

3. The calibration procedure will be as follows:

a) The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in item 1 above.

The activity displaed by the dose calibrator must agree with the stated assay within ± 5%. This error may increase to ± 10% but correction factors will be determined. If the unit displays readings with an error greater than ± 10%, it will be repaired or adjusted.

b) The dose calibrator will be checked for constancy each day of use. This will be accomplished using the Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5% of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check.

The acceptable range of error for the constancy checks may be extended to ± 10%, however correction factors will be determined. If variation greater than ± 10% are noted, the unit will be repaired or adjusted.

c) The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the first elution from a new Mo/Tc generator. After assay of the entire

contents, the concentration will be determined and an aliquot containing 40 mCi will be drawn. The aliquot will be assayed for agreement with the calculated activity. In this way, the accuracy of the unit will be assured in the measurement of activities from the maximum on hand to the quantity approximating the maximum dose used for a patient study.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check can be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluant can be determined by dividing the displayed activity by the volume in the syringe. A 40 mCi aliquot contained in the proper volume can be withdrawn from the elution vial and used for the linearity test. In this way, the accuracy of the dose calibrator will be assured in the measurement of activities approximating the maximum doses used for patient studies.

Stating that from .5 - 1 ml vol. measured act the vol. for 40 mCi can be figured out.

The linearity test will be continued by repeating the assay of the 40 mCi aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is less than the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for patient studies. In the event Technetium generator systems are not used, the linearity test described above will be performed using a source (instant technetium or radiopharmacy supplied) with an activity equal to or exceeding the maximum anticipated activity received for the performance of the clinical studies.

The above linearity test will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 5% but may increase to 10% between which correction factors will be determined. If measurements indicate an error greater than ± 10% the unit will be adjusted or repaired.

d) The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or linear repair or replacement. This test will be performed by placing an amount of activity of Tc-99m in a vial made of the same material and in the same volume as the Co-57 standard. This vial will be assayed. Aliquots of activity will be removed using syringes and volumes representative of those to be used and drawn for patient studies. In addition, aliquots will be drawn and transferred to kit vials representative of those kits to be employed in synthesizing various Technetium compounds. The syring aliquots and kit vials will be assayed.

The stock vial volume will be returned to its original volume using water after each withdrawal. The activity reduction in the stock vial determined on re-assay will be assumed quantitively transferred to the syringe aliquot or the kit vial. Correction factors for various geometries will be determined if the calculated vs. measured activities exceed ± 2% and will be considered in the setting of dose schedules for Technetium-99m.

Initial geometrical correction factors will be established for other nuclides beside Tc-99m which will be received bearing a manufacturer's assay. These sources, in such configuration as capsules, ampules, cartridges & etc, will be assayed and the initial correction factors will be established for source to be received in geometries such as capsules, ampules, cartridges, etc. These correction factors will be determined using the displayed assay vs. the manufacturer's assay at the time of receipt.

Acceptable correction factors may be on the order of ±50% due to the unusual configurations associated with these geometries. The manufacturer's assay will be assumed to be correct, however, and the correction factor will be used only as a constancy value to be compared to future shipments of these nuclides. In the event the constancy value varies by greater than ±10%, the dose calibrator will be adjusted or repaired.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of one or more of the following plans:

1- A substitute dose calibrator will be acquired.

2- The manufacturer's assay of precalibrated activities will be relied upon.

3- Technetium eluents will be assayed and the Mo-99 contaminent will be determined using a dose calibrator located at the nearest cooperating institution having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

B. Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and uniform flood check will be performed each day of use. A quarterly calibration and preventive maintenance program is done by the manufacturer.

THIS SOURCE WAS TESTED FOR
EXTERNAL CONTAMINATION OR LEAKAGE
DATE 2-28-77 MICROCURIES <.005 BY P.R.
DATE 2-28-77 MICROCURIES <.005 BY P.R.

Standards Laboratory Report

GAMMA RAY SOURCE CALIBRATION

Technical Operations, Incorporated OPERATIONS INC.

Radiation Products Division
Burlington, Massachusetts 01803

Isotope	Test No.	Control No. 7-113	Date Measured
Cs^{137}	98033		10-4-76

Source Identification	Roentgens/Hr. at 1 Meter	Curies
S-207	.03072	.0960

Source decay correction factors

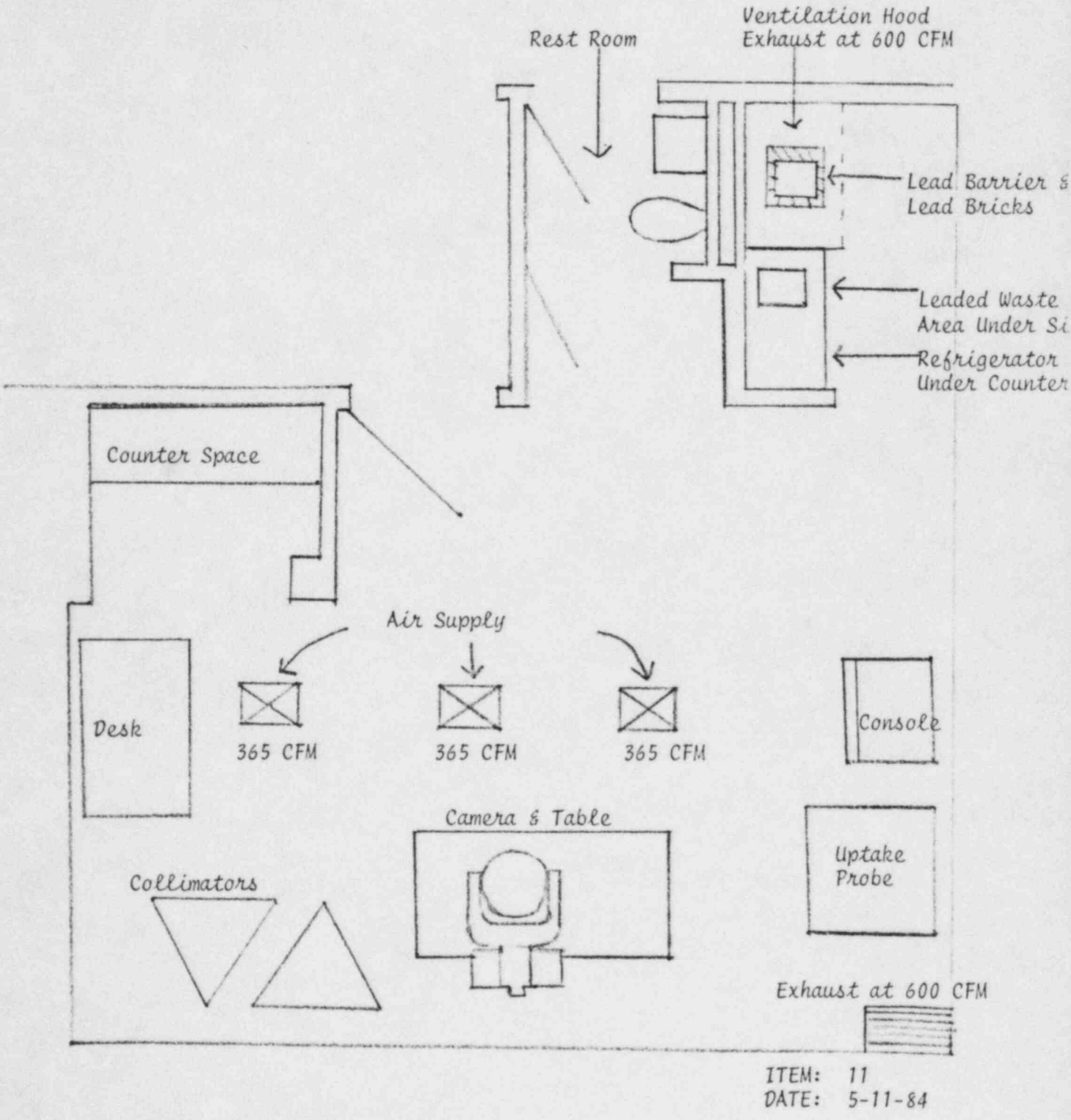
Age in:	Cobalt-60 years	Cobalt-60 mos	Iridium-192 weeks	Iridium-192 days	Cesium-137 years
0	1.000	1.000	1.000	1.000	1.000
1	.877	.989	.937	.991	.977
2	.768	.978	.877	.981	.955
3	.674	.967	.821	.972	.933
4	.590	.957	.769	.963	.912
5	.518	.946	.721	.954	.892
6	.454	.936	.675	.945	.871
7	.398	.926	.632	.937	.852
8	.349	.916	.592		.832
9	.306	.905	.554		.813
10	.268	.895	.519		.795
11	.235	.886	.486		.777
12	.206	.877	.455		.759
$T_{\frac{1}{2}}$	5.26y		74.0d		30.2y
Rhm/ci	1.30		0.55		0.32

The gamma-ray emission of the sealed source herein described was intercompared with the radiation from a reference standard cobalt-60 source whose intensity had been established relative to a National Bureau of Standards calibrated cobalt-60 source. Comparison was made either with an uncollimated plastic-lined ionization chamber encased in a 3-mm thick aluminum container sealed against atmospheric pressure, or with an NBS-calibrated Victoreen R-meter whose readings were compensated for atmospheric pressure and temperature. All readings were corrected for air scattering and absorption. The source was measured with its axis of symmetry parallel with/perpendicular to the line joining source and detector. The reported output is believed to be accurate within ± 3 percent, the stated uncertainty of the reference NBS sources. Precision is believed to be better than ± 1 percent.

Signed Paul R. Landeau

Calibration performed for: Medical College of Ohio
Prod. # 726 S/N 126
945 S. Detroit Ave.
Toledo, Ohio

Item 11: Facilities and Equipment



Item 12: Personnel Training Program

All personnel involved directly with the Nuclear Medicine department (technicians, maintainance, housekeeping) will be given instructions, upon their employment, on the locations where Radioactive materials are stored and the hazards involved with the unsafe handling of such materials.

These persons will also be lectured on the importance of reporting any unsafe conditions or violations that they may see. This will also include what they should do in case of an emergency and whom to contact.

In addition, all Technicians who are directly involved with the use of radiopharmaceuticals and the equipment will be instructed in the use of the survey meter and calibrator. They will be shown how to do calibration checks on all the equipment involved and what to do or whom to contact if there is a variance from the normal.

They will also be informed of all the NRC regulations pertinent to their job and further instructed when new regulations are adopted.

These lectures will be given annually to all personnel involved. They will also be given anytime new personnel begin, and all will be urged to attend these lectures as a refresher course.

ITEM: 12
DATE: 5-11-84

Item 13: Procedures for Ordering and Receiving Radioactive Material

It is the policy and procedure of this department to follow these steps listed when ordering and receiving Radioactive Material.

1. The Nuclear Medicine Technologist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
3. During off-duty hours, the radiologic technologist on duty will accept delivery of radioactive material. The technologist will unlock the door to the department and allow the case to be placed in the ventilation hood and relock the door upon exit.

   If the case is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. If unable to contact the Radiation Safety Officer, call either the Radiologist or the Nuclear Medicine Technologist. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Radiation Safety Officer: John A. Mitchell, M.D. 784-5943
Radiologist: Nilo Gomez, M.D. 899-4142
Nuclear Medicine Technologist: Marie Salabsky, R.T. 782-7207

ITEM: 13
DATE: 5-11-84

Item 14: Procedures for Safely Opening Packages Containing Radioactive Materials

It is the policy and procedure of this department to follow the steps listed below when receiving a radioactive package:

1. Visually inspect package for any signs of damage. If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Measure exposure rate at 3 feet from case surface and record reading. If more than 10 mR/hr, stop procedure and notify Radiation Safety Officer.
3. Measure surface exposure rate and record reading. If more than 200 mR/hr, stop procedure and notify Radiation Safety Officer.
4. Put on gloves.
5. Open case and wipe external surface of each lead container with a cotton swab and record reading.
6. Check all Record of Receipt slips and compare with order requisition. Check also that shipment does not exceed possession limits. Inspect lead containers for breakage and loss of liquid.
7. Monitor the case for contamination and store for repackaging. All lead containers received (used and unused) will be returned to the radiopharmacy.

ITEM: 14
DATE: 5-11-84

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

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

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

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

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

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

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: J. Mitchell, M.D.
OFFICE PHONE: 782-6955 ext. 216
HOME PHONE: 784-5943

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Nilo Gomez, M.D. 899-4142
Marie Salabsky, R.T. 782-7207

*The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

ITEM: 16
DATE: 5-11-84

Control No. 77113

Item 17: Area Survey Procedures

1. Area surveys and wipe tests will be performed weekly or in any case where contamination is suspected.
2. The weekly surveys will consist of:
   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.
3. A permanent record will be kept of all survey results, including negative results. The record will include:
   a. Location, date and identification of equipment used, including the serial number and pertinent counting efficiencies.
   b. Name of person conducting the survey.
   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
   e. Detected contamination levels, keyed to locations on drawing.
   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
4. Area will be cleaned if the contamination level exceeds 200 dpm/100cm^2.

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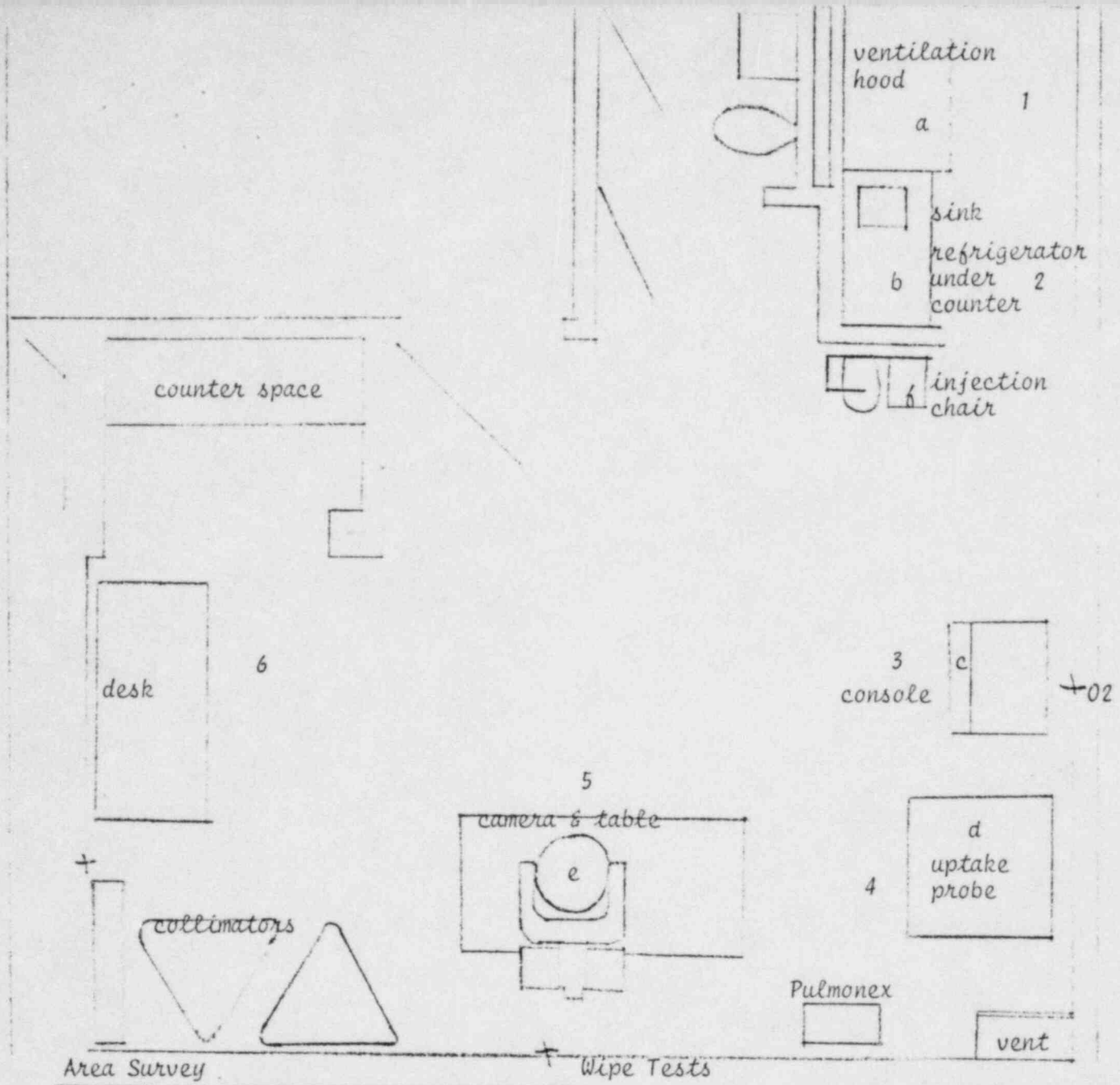

Area Survey	Wipe Tests
1	a
2	b
3	c
4	d
5	e
6	f

Date: _____

Name: _____

Instruments: _____

ITEM: 17
DATE: 5-11-84

Item 18: Waste Disposal

All waste will be disposed of by Syncore, Inc., of Toledo, Ohio.
NRC Number 34-16654-01MD .

ITEM: 18
DATE: 5-11-84

Item 21: Procedures and Precautions for Use of Radioactive Gases

1. Quantities to be used: 10 Patients/week
   10 mCi/patient
   5200 mCi/year
   Possession Limit: 200 mCi

2. Xenon will be used in the single camera room as shown on the drawing in Item 11. Xenon will be stored in the fume hood in the hot lab in its shielded lead shipping container. Spent Xenon filters (from the delivery system) will also be stored in the fume hood behind lead bricks.

   The hot lab fume hood will run 168 hours per week at 600 CFM. The camera room will exhaust 168 hours per week at a rate of 600 CFM. There will be no recirculation of the exhaust air from the hot lab hood or the camera room. The air supply to the hot lab will be 550 CFM, the air supply to the camera room will be 550 CFM. The remainder, (100 CFM) will be provided by leakage around the door. The nuclear medicine area will be under negative pressure. The exhaust for the nuclear medicine area will be vented outside through a stack which is located 35 feet horizontally away and 20 feet above the nearest air intake for the hospital.

   The air flow rates into and out of the nuclear medicine area will be measured semiannually to assure that they are as stated above.

3. Procedure for Routine use:
   a. Peak the gamma camera for Xenon. Set stool in front of camera and bring over Pulmonex system. Turn on oxygen 3 to 5 psi. Bring in patient, close all doors, and plug in Pulmonex. Position patient in front of camera. Instruct patient as to what he/she will be doing. Have a trail run with the mask and nose clips. Be sure to check seal and air flow. Turn on Pulmonex system by setting the time to 14 minutes. Set Pulmonex to 2 and allow a small amount of O_2 into the bag (½ full), attach Xenon gun or hose. Air flow at 20. Next have the patient take in a deep breath, blow it out, and take in another deep breath while injecting the Xenon. The patient should hold his breath while the pictures are started. Continue with rebreath. If using the Xenon injection system, be sure to hold in the button until Xenon is seen in the lungs. Air flow to 60. Turn the handle of the Pulmonex to 3 to start washout. If the patient's bag gets too full, turn up the air flow of the motor located in the lower trap. After the study is completed, turn off the Pulmonex. Views: initial breath, 3 rebreaths, and 3 washouts or until lungs are clear.
   b. The Xenogard (or equivalent) air monitor will be used to measure the concentration of Xenon in the room air. The air monitor will be used each day Xenon is in the department and during each ventilation study. The results of the monitoring will be recorded.

c. The Xenon-133 traps will be tested monthly for trapping efficiency with the XenGard (or equivalent) monitor.
d. Manufacturers instructions will be followed.

4. Emergency Procedures
If there is an accidental release of Xe-133, the following procedures will be done:
a. Notify all persons in the area to evacuate the room. Take survey meter out of room with you.
b. Notify the Radiation Safety Officer.
c. The door will be sealed with wide adhesive tape and locked to prevent entry.
d. The room will not be re-entered until the exposure levels at the door are 0.5 mR/hr. Immediately upon entering the room, the XenGard will be checked to assert that the Xe-133 air concentrations are below the MPC.

5. Air Concentrations of Xe-133 in Restricted Areas → 1.0×10^{-5} uci/ml MPC App B 10CFR 20
a. Hot Lab
100 mCi per week
0.25 escape fraction
600 CFM exhausted

C = (A x F)/V
C = (100 mCi/week x 1000 uCi/mCi x 0.25)/
(600 CFM x 2.854×10^{8} ml/wk CFM) ✓ 168 hrs week.
C = 1.5×10^{-7} uCi/ml which is below the MPC for restricted areas.

b. Camera Room
The activity, escape fraction and air exhaust volume are the same as the hot lab, resulting in the same concentration of Xe-133.

6. Air Concentration of Xe-133 in unrestricted areas
a. The majority of Xe-133 used for ventilation studies will be absorbed on traps of the delivery system. Assuming an escape fraction of 0.25:
C = (A x F)/V
C = (5200 mCi/year x 1000 uCi/mCi x 0.25)/
(1200 CFM x 1.44×10^{10} uCi/ml)
C = 7.5×10^{-8} uCi/ ml which is below the MCP for unrestricted areas. → 3×10^{-7} uci/ml MPC App B 10CFR 20

b. A XenGard (or equivalent) air monitor will be used to test for efficiency of the Xenon traps of the delivery system. All manufacturers instructions will be followed. Saturated Xenon filters will be returned to the Radiopharmacy for disposal.

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