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.*

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

VA Medical Center
Salisbury, North Carolina 28144

TELEPHONE NO. AREA CODE (704) 636-2351

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

William F. Lytle, Jr., M. D. Ext. 480

TELEPHONE NO. AREA CODE (704) 636-2351

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 32-15483-01

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

C. Douglas Maynard, M. D. (consultant)
William F. Lytle, Jr., M. D.
W. J. McBrine, Jr., M. D.

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

William F. Lytle, Jr., M. 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		
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
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100mCi
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	80mCi

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

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	
	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
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached Appendix E
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	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)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
	Detailed Information Attached Appendix M
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 [illegible]	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*

(2) TITLE

c. DATE

FORM NRC-313M (8-78)

LIST OF APPENDICES

Appendix

A. Acceptable Training and Experience for Medical Uses of Byproduct Material

B. Medical Isotopes Committee

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D. Calibration of Instruments

E. Procedures for Ordering and Accepting Delivery of Radioactive Material

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G. General Rules for Safe Use of Radioactive Material

H. Emergency Procedures

I. Area Survey Procedures

J. Waste Disposal

K. Radiation Safety Procedures for Therapeutic Use of Radiopharmaceuticals

L. Radiation Safety Procedures for Therapeutic Use of Sealed Sources

M. Procedures and Precautions for Use of Radioactive Gases (e.g., Xe-133)

N. Guidance on Requests for License Amendments and License Terminations

O. Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

APPENDIX A

Training and Experience For Medical Uses of Byproduct Material

1. Authorized Users

(a) C. Douglas Maynard, M. D. (NRC License Number 32-15483-01, dated March 21, 1973)

(b) William F. Lytle, Jr., M. D. (NRC License Number 32-15483-01, Amendment No. 04, dated June 23, 1976)

(c) William J. McBrine, Jr., M. D. (NRC License Number 32-15483-01, Amendment No. 08, dated April 22, 1983)

2. Board Certifications

All above doctors are certified by the American Board of Nuclear Medicine in addition to the American Board of Radiology.

APPENDIX B

Radiation Safety Committee

Responsibility

The Management of this medical center is committed to this program for keeping radiation exposures as low as reasonably achievable.

Duties

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

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

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

4. The Radiation Safety Committee will delegate authority to the Radiation Safety Officer for enforcement of the ALARA concept.

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

6. The Radiation Safety Committee will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

7. The Radiation Safety Committee will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I (Attachment A) are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

8. The Radiation Safety Committee will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the Radiation Safety Officer, authorized users, and workers as well as those of Management.

Meeting Frequency

The Radiation Safety Committee will meet quarterly at the call of the Chairman.

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Nuclear - Chicago

   Manufacturer's model number: 2651

   Number of instruments available: 1

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

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

   b. Manufacturer's name: Eberline Geiger Counter

   Manufacturer's model number: E-520

   Number of instruments available: 1

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

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

Dose calibrator

Manufacturer's name: Capintec, Inc.

Manufacturer's model number: CRC-10

Number of instruments available: 1

Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Technecare	Sigma 410

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

Uptake Probe & Well Counter	Nucleus, Inc.	187-290

APPENDIX D

CALIBRATION OF INSTRUMENTS

Section I

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.

2. The source activities or exposure rates at given distances shall be traceable by documented measurements to a standard source certified within 5 percent accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points located at approximately 1/3 and 2/3 of full scale.

5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10 percent at the two points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent for radiation protection purposes.

Note:

Sources of Cs-137, Ra-226, or Co-60* are appropriate for use in calibrations. Since these sources emit rather high-energy photons, they are not suitable for low-energy calibrations that may be required under special circumstances (see Item C below). The activity of the calibration standard should be sufficient to calibrate the survey meters on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Otherwise, a cautionary note that they have not been checked should be placed on the instrument.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, shall also be read at the time of the above calibration or as soon as the instrument is received from a calibration laboratory. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

If any reading with the same geometry is not within ±20 percent of the reading measured immediately after calibration, the instrument should be recalibrated (see Item A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and if the instrument is to be used for quantitative measurements in the Xe-133 or Tc-99m energy ranges.

The calibration may be done either:

1. As in Item A above with calibrated standards of radionuclides at or near the desired energies, or

2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

Alternatively, the manufacturer's energy response curve(s) may be used to correct instrument readings appropriately when lower-energy radiation is monitored.

D. Records of the above Items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its exposure rate at a given distance.

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* Minimum activities of typical sources are 85 mCi of Cs-137, 3 mCi of Co-60, and 34 mCi of Ra-226 (to give at least 700 mR/hr @ 1 cm).

or its activity, measured on a specified date by the manufacturer or NBS.

a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

b. The Radioactive Decay Law may be used to calculate the exposure rates or source activities at times other than the calibration date.

2. Inverse Square Law

Consider a "point"* source of radiation at position S, as shown in Figure D-1. Then, the relationship between exposure rates R_1 and R_2 at detector positions P_1 and P_2, which are at distances D_1 and D_2 from S, respectively, is given by the following equation:

$$R_2 = \frac{D_1^2}{D_2^2} \times R_1$$

where R_1 and R_2 are exposure rates in the same units (e.g., mR/hr, R/hr), and D_1 and D_2 are the distances in Figure D-1 in the same units (e.g., m, cm, ft).

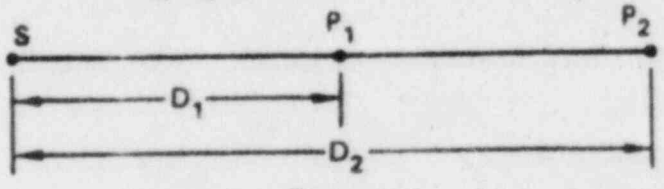

Figure D-1

3. Radioactive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-\left[\frac{0.693}{T_{1/2}} \times t\right]}$$

where

R_o and R_t are in the same units (e.g., mR/hr or R/hr).

R_o is exposure rate on the specified calibration date.

R_t is exposure rate t units of time later.

$T_{1/2}$ and t are in the same units (years, months, days, etc.).

$T_{1/2}$ is radionuclide half-life.

t is number of units of time elapsed between calibration and present time.

4. *Example*: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

$$= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 1977.}$$

b. Output at 3 feet, 2.0 years after calibration date:

$$R_3 \text{ feet} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr}$$

$$= \frac{1}{9} \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration.}$$

* A source may be considered a "point" source when the source and the radiation detector are small, in any dimension, compared to the distances at which radiation is to be measured. The center of the detector should be at distances D_1 or D_2 as shown in Figure D-1.

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

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

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

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

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ±5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ±5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

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

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

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* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 018).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective state agency should be consulted to determine its requirements for possessing this material.

Assay Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

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

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

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

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

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

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

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

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

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

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

$$\text{True Activity} = \text{Measured Activity} \times \text{Correction Factor}$$

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

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

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

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

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133 using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented

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* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

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

2. Repeat step 1 for a total of 3 determinations, and average results.

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

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

5. Keep a log of these calibration checks.

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

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

RADIATION PHYSICS CONSULTANTS

P. O. Box 5874
Winston-Salem, N.C. 27103
(919)765-4318

Calibration of survey meters are performed as outlined in Section I of Appendix D of NRC regulations.

A Cs-137 source (3M company, model 6D6-CC, serial # 0142) having an activity of 26.5 mCi (10.6 mg Ra equivalent) on 15 March 1974 is used.

This source was calibrated by 3M company (certificate # 211841) on 15 March 197 by direct comparison with an NBS calibrated source and has an accuracy of 5%.

The calibration sticker which we affix to the instrument is attached.

RADIATION PHYSICS CONSULTANTS, INC.
FINLEY C. WATTS, PH.D. ROBERT L. DIXON, PH.D.
KENNETH E. EASTRAND, PH.D.
LICENSED MEDICAL PHYSICISTS
919/765-4318 — P. O. BOX 5874
WINSTON-SALEM, N. C. 27103

SURVEY INSTRUMENT CALIBRATION

MANUFACTURER _____ SERIAL NO. _____

DATE OF CALIB. _____ BY _____

NEXT CALIBRATION DUE _____

R L Dixon

Robert L. Dixon, Ph.D.
Certified Radiological Physicist

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.

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% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to 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 _____
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 Physics Consultants

(2) Location Winston-Salem, N.C. 27103

(3) Procedures and sources

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

X are 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

Radionuclide	Activity (mCi)	Accuracy
Co-57	~~0.68~~ 3.0	±5%
Ba-133		
Cs-137	0.49	±5%

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.

*Must be equivalent to the highest activity used.

Facilities and Equipment

1. Nuclear Medicine consists of three rooms located between Physical Therapy and Radiology Service. One large room is equipped with a Technecare Gamma Camera and VIP computer.

2. The second large room is equipped with an uptake probe-well counter combination made by Nucleus, Inc. There are also two ultrasound units in this room.

3. A smaller room is located next to the scanning room. It is designated exclusively for the storage and preparation of all radiopharmaceuticals. This room has a stainless steel working bench and sink. A refrigerator for the storage of particular radionuclides is also located here. There are 22 lead bricks placed strategically on the working bench to enclose all radioactive materials and to cut down on background around the dose calibrator.

4. All radioactive waste is stored in the "hot" lab until it reaches background levels. Then it is discarded.

5. It has been arranged that all radioisotopes delivered to the hospital before and after regular working hours will be received and checked in by the hospital police and then immediately taken directly to the Nuclear Medicine Department for careful storage.

6. There is a sketch of the room enclosed.

REF
8
SINK
5
7
Floor
3
HOOD
1
6
DESK
STRETCHER
10
11
Floor
15
VIP
CONSOLE
13
SINK
12
15.
BACKGROUND
DATE
BY

Personnel Training Program

1. The basic training for all users of isotopes includes a minimum of thirty hours of instruction in the principles and practice of radiological protection, measurements of radioactivity, and standardization, handling, and monitoring techniques.

2. Access to all areas where isotopes are either stored or used is limited to personnel with proper training in radiation safety as described.

3. All housekeeping is performed by the members of Nuclear Medicine except for cleaning of floors.

4. Personnel monitoring of radiation exposure is performed in accordance with applicable NRC regulations. Permanent records of radiation exposure to radiation workers are taken and kept in Radiology Service for employee information.

5. In addition, in all areas where isotopes are either used or stored, appropriate measures for assistance in emergency situations are posted.

APPENDIX E

Procedures for Ordering and Accepting Delivery of Radioactive Material

1. The Lead Nuclear Medicine Technologist 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. During normal working hours carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours the hospital police will accept delivery of radioactive packages in accordance with the procedures outlined below:

a. Any packages containing radioactive material that arrive between 4:00 p.m. and 7:30 a.m. or on Saturdays, Sundays, and holidays, shall be signed for by the Hospital Policeman on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package in the "hot" lab, and relock the door.

b. If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

c. RADIATION SAFETY OFFICER: William F. Lytle, Jr., M. D.
OFFICE PHONE: 636-2351 Ext. 227
HOME PHONE: 636-3035

APPENDIX F

Procedures for Safely Opening Packages Containing Radioactive Material

1. Visually inspect package for any sign of damage (e. g., wetness, crushed.) If damage is noted, stop procedure and notify Radiation Safety Officer.

2. Measure surface exposure rate and record. If greater than 200 mR/hr--stop procedure and notify Radiation Safety Officer.

3. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle), check integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material.) Check also that shipment does not exceed possession limits.

4. Monitor the packing material and packages for contamination before discarding:

    a. If contaminated, treat as radioactive waste.
    b. If not, obliterate radiation labels before discarding in regular trash.

APPENDIX G

General Rules for Safe Use of Radioactive Material

1. Wear disposable gloves at all times while handling radioactive materials.

2. Monitor hands and clothing for contamination at the end of each working day.

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

4. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

5. Wear personnel monitoring devices (Film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist levels.

6. Wear wrist badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

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

8. Never pipette by mouth.

9. Survey generator and kit preparation areas for contamination at the end of each day. Decontaminate if necessary.

10. Confine radioactive solutions in lead containers plainly identified.

11. Always transport radioactive material in shielded containers.

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. Include all other contaminated materials such as disposable gloves.

4. Survey: With a G. M. Survey Meter, check the area around the spill, your 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: William F. Lytle, Jr., M. D.
OFFICE PHONE: 636-2351 Ext. 227
HOME PHONE: 636-3035

APPENDIX I

Area Survey Procedures

1. All elution and preparation areas will be surveyed daily with a G-M survey meter and decontaminated if necessary.

2. All other laboratory areas will be surveyed weekly.

3. The weekly survey will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

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

   a. Location and date.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as elution and preparation areas, etc.

   d. Measured exposure rates, keyed to location on 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.

NOTE: For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded.

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)

X 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.

X 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.**

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

____ Other (specify): _____

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

X 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. _____

* 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.

APPENDIX K

Therapeutic Use of Radiopharmaceuticals

1. Treatment of hyperthyroidism will be the only therapy employed by this Nuclear Medicine Service.

2. Iodine-131 is the radioisotope used for this therapy.

3. The average dose employed for this procedure will be 6-12 mCi with the maximum administered dose not to exceed 30 mCi.

4. All radiation safety procedures will be followed according to the NCRP report number 37.

APPENDIX M

Procedures and Precautions for Use of Radioactive Gases

1. Quantities to be used

   a. Patient information

      (1) Number of studies to be performed weekly - 5

      (2) Average activity per patient - 20 millicuries

      (3) The requested possession limit is 80 mCi

2. Use and storage areas

   a. Xenon-133 will be used in the nuclear medicine imaging area. A diagram of the nuclear medicine department is attached.

   b. The ventilation in this area is shown in the attached diagram. The ventilation rates (air supply and exhaust) will be measured semi-annually by qualified personnel of the VA Medical Center's Biomedical Engineering Department. The measuring instrument will be the Floret Model M1E Air Flow Indicator.

   c. Negative air flow will be ensured by the continuous operation of the air exhaust hood during imaging.

3. Procedures for routine use

   a. Xenon-133 will be obtained from an FDA approved manufacturer as an NDA radiopharmaceutical. Upon receipt Xenon-133 will be assayed, the units and activity received will be recorded and the Xenon-133 will then be placed into the exhaust hood for storage behind lead bricks. Prior to patient imaging, the Xenon-133 will be assayed and the activity dispensed will be recorded. The Xenon-133 will be obtained in unit dose form.

   b. The RADX Corporation Ventil-Con II will be used. The unit contains a built-in charcoal trap.

   c. Either a full-face mask or mouthpiece with nose clamp will be used to reduce any possible leakage. In all instances, extreme care will be taken to prevent leaks of Xenon-133 from occurring.

4. Emergency Procedure

In the unlikely event of an accidental release of Xenon-133, the personnel will be immediately evacuated and the room sealed. A sign stating DO NOT ENTER will be placed onto the door and the Radiation Safety Officer will be immediately notified. The room will be re-entered no sooner than 18 minutes after the spill has occurred. (Calculations follow). Before personnel re-enter, the Radiation Safety Officer will establish that safe levels of

exposure have been reached by surveying with a low level GM survey meter.

(The evaluation time represents approximately 5 room air changes).

Room air volume = $5{,}929\ ft^3$ (RAV)

Exhaust rate = $1{,}200\ ft^3/min$ (ER)

Rate of Air Change = $\frac{RAV}{ER} = \frac{5{,}929\ ft^3}{1{,}200\ ft^3/min} = 4.9$

5. Air concentration of Xenon-133 in restricted areas.

The following calculations have been used to determine the necessary parameters for use of Xenon-133 in the quantities and studies requested.

It is anticipated that no more than 6 patients per week might be studied (adult dose = 20 mCi).

A = maximum amount of activity used per week

$$A = \frac{20\ mCi}{patient} \times \frac{6\ patients}{week} \times 1 \times 10^3\ \frac{uCi}{week}$$

Assuming a lost rate of 20% (f),

$$V = \frac{A \times f}{1 \times 10^{-3}\ uCi/ml}$$

$$= \frac{(1.2 \times 10^5\ uCi/week) \times 20\%}{1 \times 10^{-5}\ uCi/ml}$$

$$= 2.4 \times 10^9\ ml/week$$

The required ventilation rate is:

$$= \frac{2.4 \times 10^9\ ml/week}{40\ hour\ week} \cdot \frac{1.7 \times 10^6\ ml/hr}{ft^3/min}$$

$$= 3.5 \times 10^1\ ft^3 min$$

The ventilation rate in the nuclear medicine department is:

$1.26 \times 10^3\ ft^3/min$

$C = A/V$

$$C = \frac{1.9 \times 10^6 mCi/yr}{1.78 \times 10^{13} ml/yr}$$

$C = 1.06 \times 10^{-7} uCi/ml$

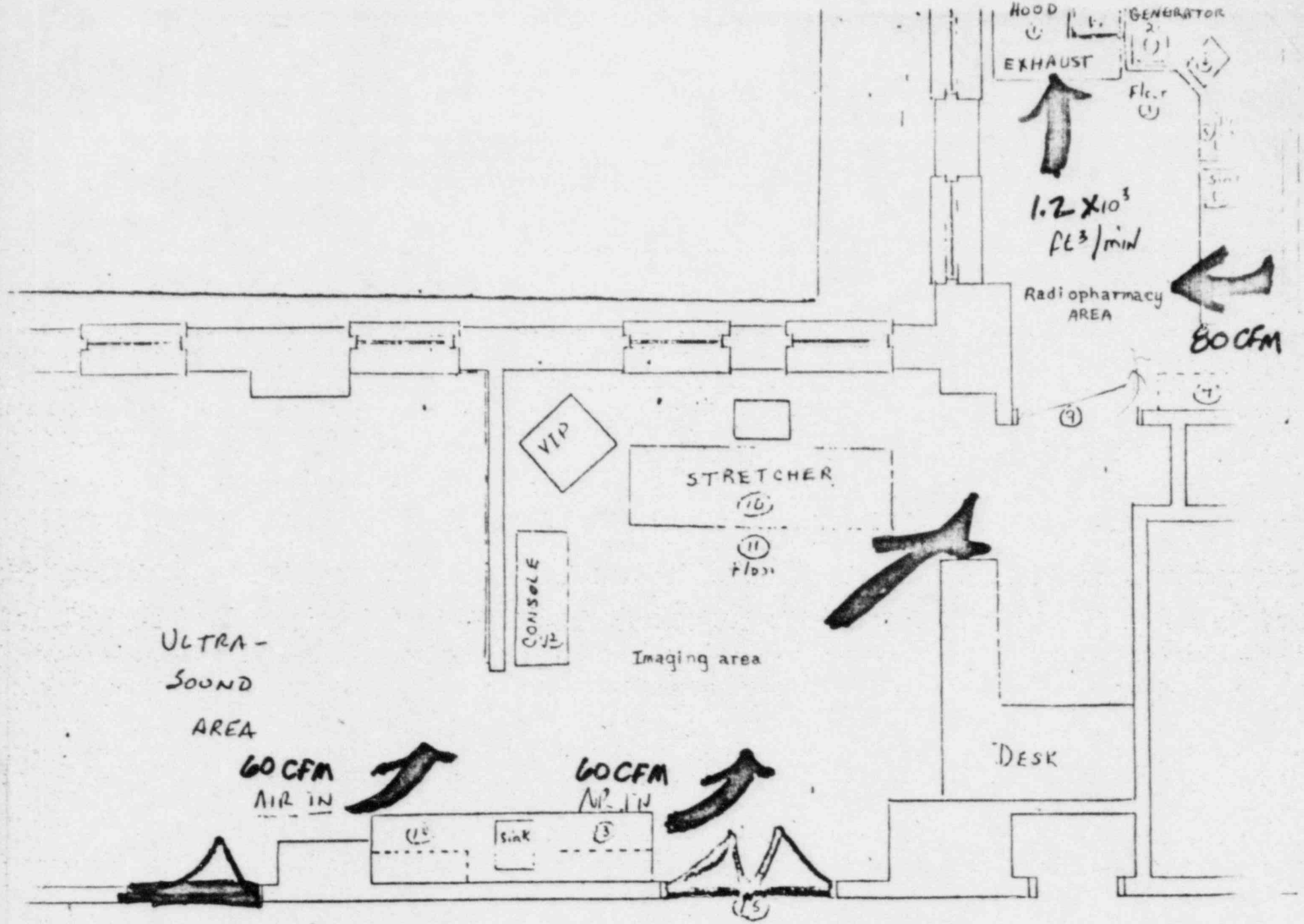
The concentration C occurs at a point approximately 20 ft. above a restricted access roof level. (Maintenance only, etc.). No air intakes are located

within 100 feet of this point. This value calculated for C represents an activity level considerably less than 3×10^{-7}uCi/ml.

We are very much aware of the effect of moisture, gaseous contaminants, etc. upon the adhesion of Xenon onto charcoal. In the situation where the trapping efficiency is greatly compromised by the presence of contaminating gases or water, hot air drying shall be employed after sufficient decay before reuse. Otherwise, new charcoal traps may be necessary. We shall make extra effort to ensure that our Xenon Alarm is properly calibrated and in working order at all times. A test audible alarm is part of the system.

6. Methods of Xenon-133 Disposal

The method employed shall be chromatographic adsorption onto charcoal. The Ventil-Con II Xenon system employs a built-in trap and alarm system. The alarm will register when Xenon-133 released at the terminal end of the trap exceeds 1×10^{-2} uCi/ml of air. At that time, the charcoal trap cartridge will be removed and sealed at each end. It will be allowed to set for at least 12 X 5.3 days ($T_{1/2}$ Xenon-133) before reuse. During storage for decay, the cartridge will be placed into the exhaust hood in case any leaks might occur.



* Calculations from Mr. Bill Ward, Biomedical Engineering Department