| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>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 25 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

The Christ Hospital
2139 Auburn Avenue
Cincinnati, Ohio 45219

TELEPHONE NO.: AREA CODE (513) 369 - 2323

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

Licensed material is also used for in-vitro and animal studies at:
The James N. Gamble Institute of Medical Research
2141 Auburn Avenue
Cincinnati, Ohio 45219 (See amend. #33 6/1/84)

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Clifford G. Born, M.S.

TELEPHONE NO.: AREA CODE (513) 369 - 2323

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 34-03831-02

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

See Attachment A (Page 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.)*

Clifford G. Born, M.S.

See Attachment A (Page 4)

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

| RADIOACTIVE MATERIAL LISTED IN: | ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| 10 CFR 31.11 FOR IN VITRO STUDIES | X | See Page 5 |
| 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 | 6 Curies |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP V | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | X | 2.5 Curies |

| ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | | |
| 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 | 800 |

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 | Sealed Source<br><br>Technical operations Model 77302 or New England Model NER-570 | 165 mCi | For use in Technical Operations, Inc. Model 773 calibrator to calibrate radiation survey meters |





CONTROL NO. 78680

## 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 Page 6 | X | Appendix G Rules Followed; or |
| | Duties as in Appendix B; or *(Check One)* | | Equivalent Rules Attached |
| X | Equivalent Duties Attached Page 7 | 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 See Page 4 for individual users. | | Equivalent Procedures Attached |
| X | Supplement A Attached for RSO. See Page 4 for RSO. | 17. AREA SURVEY PROCEDURES *(Check One)* | |
| 9. INSTRUMENTATION *(Check One)* | | | Appendix I Procedures Followed; or |
| X | Appendix C Form Attached; ~~or~~ Page 8 | X | Equivalent Procedures Attached See Attachment I |
| | 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~~ Page 9 *(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 See Pages 10-13 *(Check One)* | | Appendix K Procedures Followed; or |
| | Equivalent Procedures Attached | X | Equivalent Procedures Attached See Attachment K |
| 11. FACILITIES AND EQUIPMENT | | 20. THERAPEUTIC USE OF SEALED SOURCES | |
| X | Description and Diagram Attached | X | Detailed Information Attached; and |
| 12. PERSONNEL TRAINING PROGRAM | | | Appendix L Procedures Followed; or *(Check One)* |
| X | Description of Training Attached | X | Equivalent Procedures Attached See Attachment L |
| 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 See Attachment M |
| 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)* | | 22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS | |
| | | | Detailed Information Attached |
| | Appendix F Procedures Followed; or | 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b | |
| X | Equivalent Procedures Attached | X | Detailed Information Attached |



CONTROL NO. 7 8 6 8 0

## 24. PERSONNEL MONITORING DEVICES

| TYPE (Check appropriate box) | | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | X | FILM | Siemans Gammasonics, Inc. | Monthly |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | X | TLD | Siemans Gammasonics, Inc. | Monthly |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

III

Applicant Approved
Check No. 38473
Amount Fee Category 7.C
Date Check Rec'd 4/18/85
Received By

## 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
7.c. Human use of by-product material

(2) LICENSE FEE ENCLOSED $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Jack M Cook

(1) NAME (Type or Print)
Jack M. Cook

(2) TITLE
President

c. DATE
March 22, 1985

RECEIVED
APR 08 1985
REGION III

NRC FORM 313M (9-81)

CONTROL NO. 78680

ATTACHMENT A

| INDIVIDUAL USERS | MATERIALS AND USES |
|---|---|
| Henry J. Kenkel, M.D. ✓ | All except Group VI |
| Vincent J. Seiwert, M.D. ✓ | Diagnosis |
| Ralph M. Scott, M.D. ✓ | Group VI |
| Sunantha Ploysongsang, M.D. ✓ | Group VI |
| Marcel Pons, Ph.D. ✓ | Non-human use |
| Olga M. Rochovansky, Ph.D. ✓ | Non-human use |
| Steven L. Wechsler, Ph.D. ✓ ltr. 8/5/81 | Non-human use |
| Ann B. Bjornson, Ph.D. ✓ | Non-human use |
| Charles G. Massion, M.D. ✓ | Non-human use |
| David C. Hohnadel, Ph.D. ✓ | Non-human use |
| Clifford G. Born, M.S. ✓ | Cesium-137 instrument calibrator |
| Joseph L. Hall, M.S. ✓ | Cesium-137 instrument calibrator |

All of the above named individuals, with the exception of Steven L. Wechsler, Ph.D., are presently listed as users on NRC license number 34-03811-02, amendment number 31, dated December 10, 1982. It is unknown why Dr. Wechsler's name was not included on this amendment when it was requested that his name be listed and all supporting documentation was submitted to the NRC in our letters of August 5, 1981, and October 1, 1982.

The Radiation Safety Officer is Clifford G. Born, M.S., who was certified by the American Board of Radiology in Diagnostic and Therapeutic Radiological Physics in June, 1975.

| BY-PRODUCT | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM POSSESSION LIMIT | AMENDMENT NUMBER |
|---|---|---|---|
| Carbon-14 | Any | 15 millicuries | 30 |
| Hydrogen-3 | Any | 240 millicuries | 31 |
| Iodine-125 | Any | 80 millicuries | 30 |
| Phosphorus-32 | Any | 50 millicuries | 30 |
| Selenium-75 | Any | 3 millicuries | 32 |
| Sulfur-35 | Any | 40 millicuries | 31 |

All of the above listed isotopes have been approved for use and are presently listed on NRC license number 34-03811-02.

RADIATION SAFETY COMMITTEE

MARCH 1, 1985

| ROSTER | DEPARTMENT OR SPECIALTY |
|---|---|
| Clifford G. Born | Radiation Medicine/Radiological Physics |
| Roger Deitchel | Administration |
| Joyce Ferrell, R.N. | Nursing |
| Robert Gorman, R.T. | Diagnostic Radiology |
| Joseph L. Hall, M.S. | Radiation Medicine/Radiological Physics |
| David Hohnadel, Ph.D. | Laboratory Medicine |
| John Houchin | Safety/Security |
| Henry J. Kenkel, M.D. | Nuclear Medicine |
| James G. Kereiakes, Ph.D. | Consulting Radiological Physicist |
| Dennis Lambert, Ph.D. | James N. Gamble Institute of Medical Research |
| James Masters, M.D. | Diagnostic Radiology |
| Elma Reigler, R.N., R.T. | Nuclear Medicine |
| James Tomaszewski | Administration |
| Richard Wendel, M.D. | Urology |

# RADIATION SAFETY COMMITTEE

Duties and Responsibilities:

The committee is established by authority of the hospital administrator as the administrative body responsible for the safe use of radioisotopes within the institution. The business of the Radiation Safety Committee is to review safety aspects of present programs and to consider special cases or problems. The Radiation Safety Committee does keep procedural records of committee meetings, actions, recommendations and decisions. The committee has delegated to the radiation safety officer the responsibility for day to day radiation safety programming. The committee does assure corrective action as is needed in cases of radiation safety violation. The committee does review the monthly radiation exposure records of all hospital personnel who have been provided with radiation monitoring devices.

The committee reviews the entire radiation safety program at least annually to determine that all activities are being conducted safely, and in accordance with NRC regulations and the conditions of our NRC license.

# RADIATION SAFETY COMMITTEE

Staffing:

The Radiation Safety Committee includes a physician specialist from each department where radioactive materials are used for human use. In departments where radioactive materials are used only for in-vitro studies, such as Laboratory Medicine and the James N. Gamble Institute of Medical Research, a supervisory paramedical professional is included as a member of the committee. The committee's membership has not been modified to include physicians specializing in internal medicine, hematology, and pathology. Even though these specialties are available at the hospital, representatives from these specialties are unavailable to serve on the committee.

## APPENDIX C

## INSTRUMENTATION

Survey meters

a. Manufacturer's name: Victoreen Instrument Division

Manufacturer's model number: 498

Number of instruments available: 1

Minimum range: 0 mR/hr to 1.0 mR/hr

Maximum range: 0 mR/hr to 1000 mR/hr

b. Manufacturer's name: Victoreen Instrument Division

Manufacturer's model number: 40-F

Number of instruments available: 1

Minimum range: 0 mR/hr to 25 mR/hr

Maximum range: 0 mR/hr to 25000 mR/hr

Dose calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-30

Number of instruments available: 1

Instruments used for diagnostic procedures

| Type of Instrument | Manufacturer's Name | Model No. |
|---|---|---|

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

Item: 9

Page: 8

# NUCLEAR MEDICINE DIAGNOSTIC EQUIPMENT

| EQUIPMENT | MANUFACTURER | SERIAL NUMBER |
|---|---|---|
| LFOV I Console | Sieman's | 33645 |
| LFOV I Stand (ZLC upgrade) | Sieman's | MV347, 33615 |
| LFOV I Micro-Dot | Sieman's | 33996, 34227 |
| Display Scope Camera | Sieman's | 3147, 3155, 3156 |
| Persistent Scope | Sieman's | 1514A00395 |
| LFOV II Micro-Dot | Sieman's | 35228, 35270 |
| LFOV II Console | Sieman's | 33898 |
| LFOV II Stand | Sieman's | 33400 |
| LFOV II ZLC upgrade/Digitrac | Sieman's | To be delivered 4/85 |
| Thrombus Detector with probe | Technical Associates | Probe (28106) CCC4TP 78620-A |
| DeFibrillater/Monitor | Hewlett Packard | 1746A00498 |
| Squibb Q.C. Analyzer | Squibb/Bionucleonics | 3303 |
| XYZ Imaging Table | Atomic Products | 056-300 |
| ADAC Computer | ADAC Corporation | 60515 |
| ADAC Spinwriter | ADAC Corporation | NEC7715 |
| ADAC Format 9 Camera Mod. 303 | ADAC Corporation | S/N007388 |
| Ramtex Graphic Display System (color) | ADAC Corporation | S/N0020448 |
| (2) Gammex Alignment Systems | Gammex Corporation | |
| Pulmonex Xenon System )<br>I 131 Air Trap Monitor ) - | Nuclear Associates | S/N 8272 |
| Xenalert System | The Nucleus, Inc. | Mod. 36-751 |
| SurgiLift | Hamilton Industries | |
| (4) Series L Ratemeters | | 800921, 800922, 800923, 800924 |
| Jewett Undercounter Refrigerator | Jewett Refrigerator Company | Mod. UC-5-BC |
| Sears Refrigerator | Sears Roebuck Company | |
| ECG Monitoring System | Quinton Instruments | 0099-005-168 |
| 622A Scope & Recorder | Quinton Instruments | S/N 168 |
| Programmer | Quinton Instruments | 0093-005-719 |
| Uniwerk Ergometer & Bicycle 845B | Quinton Instruments | 008-001-327 |
| 133 Xenon Gas Trap | Nuclear Associates, Inc. | 36-020 |
| Scintiscan Table | Sieman's | S/N 930-932083 |
| (2) Hand Hold Stop/Start W/P Scope | Sieman's | 80337, 80338 |
| Physiological Synchronizer | Brattle Instrument Corporation | 202 |
| Polaroid M-P 3 Enlarger | Polaroid | MP-3 |
| Polaroid Boot Camera | Polaroid | |
| 400 AT Star Camera System | General Electric Corporation | |
| Array Processor for Star System | General Electric Corporation | |
| Storage Module 80MB | General Electric Corporation | |



March 1985 ER

| EQUIPMENT | MANUFACTURER | SERIAL NUMBER |
|---|---|---|
| BAIRD System I (Key Board Mod 76) | Baird Corporation | S/N 01679 |
| Hard Copier | Baird Corporation | S/N 87 |
| Fast Mag Tape | Ampex | |
| T.V. Color System Mod. 84 | Baird Corporation | |
| Whole Body Imaging Table | Baird Corporation | S/N BM056712 |
| Photo Monitor | Schiff Photo Mechanics | S/N 1051 |
| BAIRD System II | Baird Corporation | Mod. 056877 |
| Console Mod. 050301 | Baird Corporation | S/N 157 |
| Yoke & Pedestal | Baird Corporation | S/N 257 |
| One Set Exercise Hand Grips | Baird Corporation | Mod. 052392 |
| Dual Density Disc Drive | Baird Corporation | S/N 121 |
| Perkin Elmer Disc Drive | Baird Corporation | Mod. 059726-72C |
| Baird Hard Copier | Baird Corporation | Mod. 87 |
| Black & White Monitor | Sony | |
| 2300 Xerox Copier | Xerox Corporation | |
| Whole Body Imaging Table System (2) | Baird Corporation | |
| Spectroscaler | Sieman's | S/N 012318 |
| Scintillation Well (Floor Model) | Sieman's | S/N 008067 |
| Spectroscaler Thyro-uptake | Sieman's | S/N 028566 |
| Thyroid Uptake Probe | Sieman's | S/N 271 |
| Scintillation Well | Picker | S/N 255747 |
| Spectroscaler | Picker | S/N 225523 |
| RAD X Dose Calibrator | RAD X Corporation | S/N 409772 |
| Radioisotope Calibrator | Capintec, Inc. | CRC-30 |
| Centrifuge | Adams-Dynac | A.J. 4346 |
| Survey Meter | Victoreen | 740F |
| GM Survey Meter | Victoreen | Mod. 498 |
| ZLC 7500/ECT Processor | Sieman's | To be delivered 4/85 |
| Panasonic CT 1901 Monitor | Panasonic | S/N VG11357713 |
| Panasonic New Vicon 3150 Camera | Panasonic | S/N 12A03128 |
| Panasonic N.V. 8320 Video Cassette Recorder | Panasonic | S/N B15A61215 |

Item: 9
Page: 8.b.

## CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

Y 2. Calibration will be performed at least at two points on each scale used for radiation protection purposes.

The two points will be located at 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, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within ±10% for radiation protection purposes.

3. Survey instruments will be calibrated

____ a. By the manufacturer

X b. At the licensee's facility

(1) Using the calibration source described below:

Radionuclide CESIUM -137

Manufacturer's name TECHNICAL OPERATIONS, INC.

Model No. 773

Activity (e.g., millicuries) or exposure rate output (e.g., R/hr at 1 meter) 151mCi AS OF 1-7-83

Accuracy ± 1

X (2) Following the calibration procedures in this appendix.

or

____ (3) Following the step-by-step procedures, including radiation safety procedures, that are attached.

## CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Lincarity Test

(Check as appropriate)

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

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

| Radionuclide | Suggested Activity (mCi) | Activity (mCi) | Accuracy |
|---|---|---|---|
| Co-57 | 3-5 | 0.583 (10/1/84) | ± 4.5% |
| Ba-133 | 0.1-0.5 | _____ | _____ |
| Cs-137 | 0.1-0.2 | 0.181 (10/1/84) | ± 4.5% |
| Ra-226 | 1-2 | _____ | _____ |
| _____ | | _____ | _____ |

C. __X__ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator (See Pages 11-13)

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.

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

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

A. Test for the following:

1. Instrument linearity (at installation and quarterly thereafter)

2. Geometrical variation (at installation)

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

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

C. Daily or before each use of the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment, or recalibration.

2. Measure and record the apparent activity of a long-lived standard radionuclide such as Cs-137 or Ra-226 at all the commonly used radionuclide settings (when the unit was first calibrated against NBS-traceable standards). Choose a source with activity in the 100 μCi range.

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 utilize 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:

| Assay Time (hr) | Correction Factor |
|---|---|
| 0 | 32 |
| 6 | 16 |
| 24 | 2 |
| 30 | 1 |
| 48 | 0.125 |

Example: If the net activity measured at 30 hours was 15.625 mCi, the predicted activity for 6 and 48 hours would be 15.625 mCi x 16 = 250 mCi and 15.625 mCi x 0.125 = 1.95 mCi, respectively.

4. Plot the measured net activity for each time interval versus the predicted activity on log-log graph paper.

5. The activities plotted should be within ±5% of the predicted curve if the instrument is linear and functioning properly. Errors greater than ±5% 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 either assay an aliquot of the eluate that can be accurately measured or to use the graph constructed in step 4 to relate measured activities to true 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% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, a 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.

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,

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

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:

   True Activity = Measured Activity x 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% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

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

G. Test For Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Ba-133 using appropriate reference standards whose activity is traceable to NBS. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower-energy reference standards (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% 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% indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated with the NBS-traceable 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 NBS-traceable standards. Keep a log of these initial and subsequent readings.

H. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument.

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.
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 semi-log graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ±5% limits on the graph as illustrated.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ±5% 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.

## DESCRIPTION OF FACILITIES AND EQUIPMENT

Detailed diagrams of both the Nuclear Medicine Department (Page 16) and the hot lab (Page 17) are following.

The hot lab is the area which has been assigned for the receipt, storage, short term waste storage, and preparation of radioactive materials. The measurement of radioactive materials for patient dosage is conducted in the uptake and low level room. The detailed drawing of the hot lab (Page 17) indicates the type, dimensions, position, and thickness of the shielding that will be used for:

a. Use of Tc-99m generators. (In addition to the standard shielding provided by the manufacturer of the Mo/Tc generators, a lead shield of a minimum of 1/2" lead thickness is provided as an external shield which surrounds the generators. The Tc milking vials are held in 5/16" thick lead shields during the milking process and are kept in these shields until placed into the shielded waste containers.)

b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

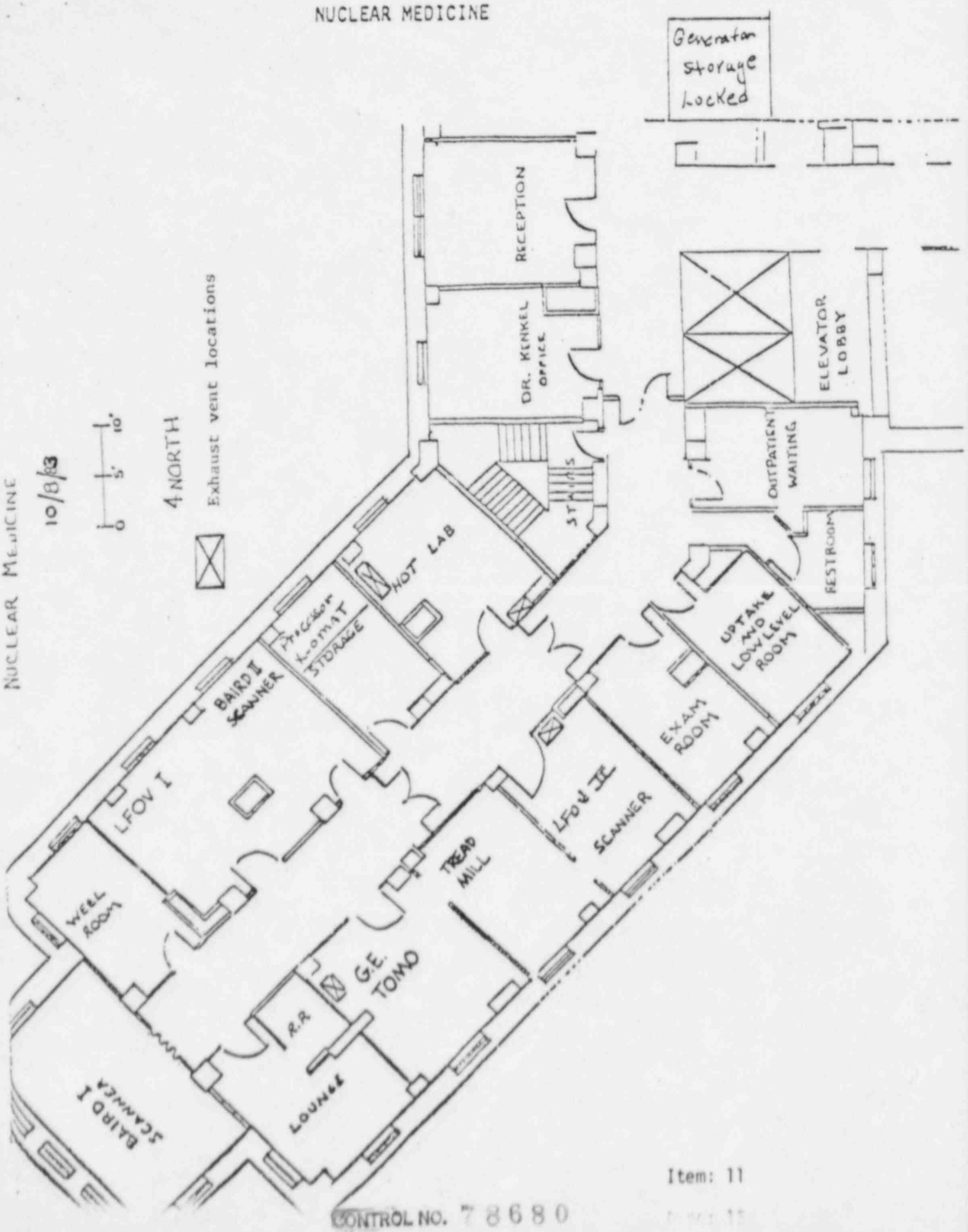
c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. There are two additional radioactive waste storage areas. One of these areas is indicated on the departmental floor plan (Page 16) and is identified as "generator storage, locked". It is surveyed weekly. The other storage area is a long term storage vault constructed of concrete block and located in a remote area on the hospital grounds. The doors to both the generator storage room and the long term storage vault are locked except when access to these areas is necessary. The only hospital personnel to whom access to these areas is permitted are nuclear medicine personnel, radiation safety personnel, and safety-security personnel. Radioactive materials are not placed into the generator storage room or the long term storage vault in such a manner as would cause the exposure level outside these areas to exceed 2 mR/hr. If there is any likelihood of such an exposure rate outside either of these two areas, one of the following options would be taken:

    1. Additional shielding would be placed around the radioactive material in question inside the storage area to reduce this exposure rate outside the storage area to less than 2 mR/hr.

    2. The radioactive materials would be distributed to the various storage areas in such a fashion as to insure that the exposure rates exterior to either of the two storage areas in question would be less than 2 mR/hr.

d. Preparation and dispensing of Group III kit radiopharmaceuticals.

# NUCLEAR MEDICINE

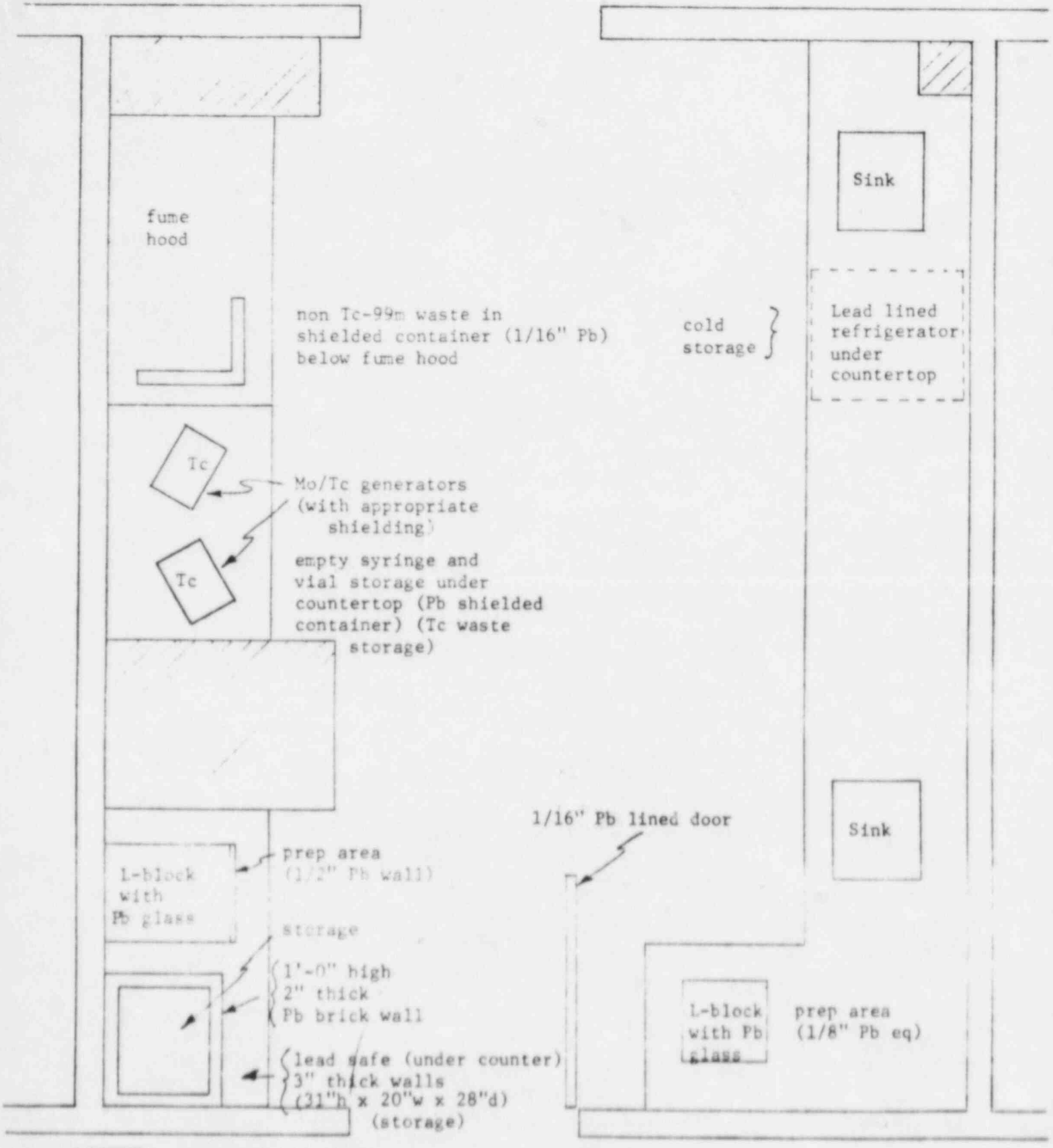



Item: 11

CONTROL NO. 78680

The Christ Hospital

Nuclear Medicine Department




Hot Lab

Scale: 1/2" = 1'-0"

Licensed material is also used at The Christ Hospital in the Department of Laboratory Medicine under the supervision of Drs. Massion and Hohnadel and at the James N. Gamble Institute of Medical Research under the supervision of Drs. Pons, Rochovansky, Wechsler and Bjornson. In both areas licensed materials are designated for non-human use only.

Due to the voluminous quantity of documentary material submitted in the letter of October 1, 1982, for both the Department of Laboratory Medicine and the Institute of Medical Research, that documentation is hereby referenced with regard to our license renewal request.

As specified in amendment number 34, licensed material is disposed of by incineration according to license condition 21. Please incorporate into this renewal request the letters from The Christ Hospital dated September 23, 1983, December 1, 1983, and February 27, 1984, as supporting documentation to continue our authorization to dispose of licensed material by incineration.

Personnel Training Program.

Continuing education will be provided for the Staff Technologists. The program is provided for by Henry J. Kenkel, M.D., Director of the Department of Nuclear Medicine and Clifford Born, Radiation Safety Officer. Monthly sessions are given over a twelve month period. Subjects pertinent to upgrading of nuclear medicine technology are given in addition to radiation safety.

Technologists are given the opportunity to attend workshops and seminars so as to qualify for continuing education points.

Periodicals and journals are subscribed to for the benefit of the personnel.

Inservice education will be given to other personnel in the hospital to include clerical, nursing, housekeeping, and security personnel. Instructions will be given pertinent to their participation in the department. The programs will be given on an annual basis before assuming duties within the vicinity of radioactive materials, or whenever there is a significant change in any of our regulations or duties.

Procedure for Ordering and Receiving Radioactive Material.

1. The Chief Nuclear Medicine Technologist must place all orders or delegate the Technical Clerk to order under his supervision the radioactive materials and must 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 must be instructed to deliver radioactive packages directly to the receiving area. The receiving area in turn notifies the Nuclear Medicine Department of its arrival.

3. During off-duty hours, security personnel must accept delivery of any packages containing radioactive material that arrive between 5 p.m. and 7 a.m. or on Sundays. The packages must be signed for by the security officer on duty and taken immediately to the Nuclear Medicine Department, unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

4. If the package is wet or appears 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.

Procedures for Safely Opening Packages Containing Radioactive Material

1. Put on gloves to prevent hand contamination.
2. Visually inspect package for any sign of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
3. Measure surface exposure rate and record. If greater than 200 mR/hr., stop procedure and notify Radiation Safety Officer or his designee. Where appliable.
4. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container ( inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.
5. Wipe external surface of final source container with moistened cotton swab or filter paper. Assay and record. (Assay may be performed with thin window B-M survey meter.) Where applicable.
6. Monitor the packing material for contamination before discarding.
    a. If contaminated, treat as radioactive waste.
    b. If not contaminated obliterate radiation labels before discarding in regular trash.
7. Maintain records of the results of this testing in an appropriate manner.

Rev. 3/85

Attachment I

AREA SURVEY PROCEDURES

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

2. Laboratory areas where only small quantities of radioactive material are used (less than 100 uCi) will be surveyed monthly.

3. All other laboratory areas will be surveyed weekly.

4. a. The weekly and monthly survey will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.

   b. A series of wipe tests to measure contamination levels will be performed according to the attached procedure entitled, "Radioactive Contamination Control Wipe Testing". The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 $cm^2$ for the contaminant involved.

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

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

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features.

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

   e. Corrective action taken in the case of excessive exposure rates, reduced 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.

RADIOACTIVE CONTAMINATION CONTROL

WIPE TESTING

Wipe Testing for the purpose of determining the amount of removable contamination in the appropriate department shall be done by the Radiation Safety Officer of his designee. This test shall be made by using a 1.5 inch diameter, numbered filter paper to wipe, with moderate pressure, an area of approximately 100-150 square centimeters. This filter paper shall then be counted in the Packard Auto Well. The energy level windows shall be set for the radioisotopes for which it is expected that contamination might be found. A background count rate will be measured and will be subtracted from the gross count rate. The net count rate of the sample will be compared to the net count rate of a standard reference source to determine the activity of the sample and, hence, the removable contamination in disintegrations per minute (dpm) of the sample.

The wipe test samples shall be taken from random locations throughout the appropriate department. These samples shall be taken at least bi-weekly or at a more frequent interval if the test results indicate that more frequent testing is necessary in order to keep removable contamination within established limits.

The test results shall be reported in writing to the Medical and Technical Directors of the appropriate department and to the Radiation Safety Officer on a form similar to that which has been attached. The report shall include but not be limited to:

1) the background count rate for each of the radioisotope window settings
2) the activities and count rates of each of the standard reference sources or the counting efficiency of the standard
3) the location where each test sample was obtained
4) the gross sample count rate
5) the net (gross-background) sample count rate
6) the removable activity in disintegrations per minute or μCi
7) space for an evaluation of the test and a description of any necessary remedial action

The level of removable contamination at which clean up must be initiated shall be set at 200 dpm (disintegrations per minute). At 1000 dpm a contamination zone shall be established until the contamination has been removed or has decayed to acceptable limits. These limits are guidelines (not Federal Regulations)

which have been recommended by the Nuclear Regulatory Commission, Radioisotope Licensing Branch, Division of Material Safety and Fuel Cycle Licensing, Washington D.C., in a draft entitled, "A Guide for Preparation of Applications for Medical Programs", February 1976.

If any removable contamination is found which exceeds the limits which have been set, it shall be the responsibility of the Technical Director of the appropriate department to ensure that the recommended remedial action has been accomplished, to make written notice of this fact, and to institute and record precautions to prevent similar occurrences.

All test results, remedial action taken, preventive measures instituted, and general correspondence dealing with wipe testing shall be kept in a notebook in the appropriate department entitled "Wipe Test Results and Correspondence". Copies of the remedial action taken and the preventive measures instituted shall also be sent to the Director of the appropriate department and the Radiation Safety Officer.

# Radiation Safety - Wipe Test Results

Date of test:_____ Time:_____

Department:_____ Hospital:_____

Physician in charge:_____

Number of wipe samples obtained:_____ Wet or dry:_____

Counting instrument:_____ Bkgrd cnt rate:_____

Comparison source standards used

| Source | calibrated activity uCi | date of calibration | test date activity uCi | net count rate c/m | control settings LL | W or UL |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Test results

| sample number | location where test sample was obtained | average gross count rate c/ m | | | net count rate c/m | | | removable activity | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | Control | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

(all wipe samples encompassed areas of 100 $cm^2$ unless specified otherwise)

Comment:

APPENDIX J

WASTE DISPOSAL

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

___ By commercial waste disposal service (see also item 4 below)

X In sanitary sewer system in accordance with 20.303 of 10 CFR Part 20

X Other (specify): Decay-in-storage method

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

X Returned to the manufacturer for disposal.

X Held for decay until radiation levels, as measured 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 disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

___ Disposed of by commercial waste disposal service (see also item 4 below).

X Other (specify): Shipped to licensed burial facility via common carrier

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

X Held for decay until radiation levels, as measured 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).

X Other (specify): Shipped to licensed burial facility via common carrier.

4. The commercial waste disposal service used will be

(Name) (City, State)

NRC/Agreement State License No. _____

There are three radioactive waste storage areas avaialble. Radioactive material will be held for decay in the particular storage area which has been determined to be the most appropriate dependent upon exposure rate, half-life, activity, etc. of the material being stored. The three storage areas are as follows:

1. Hot Lab, lead safe, with two inch thick walls,

2. Generator Storage Room, locked, ceramic block walls, with minimal occupancy in the near vicinity,

3. Long Term Storage. This is a locked concrete block vault on the hospital grounds. Occupancy within 25 feet of the vault is minimal.

ATTACHMENT K

Therapeutic Use of Radiopharmaceuticals

1. All persons treated with iodine-131 or gold-198 will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination to be expected. Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.

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

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, 3 feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. All linens will be surveyed for contamination and, if necessary, will be held for decay.

6. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

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

8. Vomitus from iodine-131 therapy patients will be stored for decay in the radioactive waste storage area and disposed of according to procedures specified in Appendix J.

9. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated

10. Nursing Instructions

a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department with any questions about the care of these patients.

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

c. Patients must remain in bed while visitors are in the room and visitors should remain at least six (6) feet from the patient.

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

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

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

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

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

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

j. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressing dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For iodine-131 patients:

(1) Urine from iodine-131 patients will not be collected unless so requested, in which case it will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

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

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, 369-2323
Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) All vomitus and any contaminated linens will be stored in plastic bags and must be kept in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).

l. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or his designee.

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

n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

o. When the patient is discharged, call the Radiation Safety Officer or his designess or the Nuclear Medicine Department, and request that the room be surveyed for contamination before turning over to housekeeping for cleaning.

ATTACHMENT L

THERAPEUTIC USE OF SEALED SOURCES

A. Sealed sources are stored in a room that has been designated solely for the purpose of storage of sealed sources. A floor plan of the room is included (Page 35) which shows:

1. The placement and thickness of shielding; and

2. proximity of the storage area to occupiable areas.

The exposure rate in the hallway outside the storage room is less than 2 Mr/hr. The door to the storage area is double locked and has an intrusion alarm and a "High Radiation Area" sign on the door. The sealed sources in the storage room are housed in lead vaults.

B. When handling sealed sources, suitable forceps and shielding are used whenever possible.

C. TLD finger monitoring devices are used to determine the radiation doses to the extremities of personnel handling sealed sources.

D. There are several devices which are used for transporting sources from the storage site to the place of use. Among these devices are the intracavity 18-channel source container from nuclear associates mounted on a cart and the model number 50100 Ernst Carrier and Heyman Carrier with cart.

E and F. A log of all sources leaving and returning to the storage area is kept. The date, type, number and strength of sources and the person's initials are logged. In addition to this, a source count survey is made on each patient when sources are inserted and when sources are removed. A source inventory is considered as having been completed whenever all sources have been "signed in" which is usually no less than monthly.

G. A survey of the patient will be conducted as soon as practical after the sources are implanted or inserted. The exposure rate will be measured at one meter from the body surface area nearest to the sight of implant or interstitial application. The radiation safety officer or his designee will then determine how long a person may remain at a position which is six feet or more from the patient and indicate this time on the radiation precaution notice which is placed on the patient's door. The exposure rate at one meter from the patient will also be indicated on the patient's chart.

H. At the conclusion of the treatment, a survey will be performed in accordance with paragraph 10CFR35.14(b)(5)(vii) to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in any other area occupied by the patient. At that time all radiation precaution notices will be removed. If the patient is to be discharged, the final survey will also determine that the activity remaining in the patient meets conditions for release from the hospital.

I. Instruction to Nurses:

See Christ Hospital policy R Med. 11.126 which is immediately following.

Approved by Clifford Born
Supersedes 12/1/81
Effective date 3/1/85

Originated by C. Born
Reviewed by C. Born
Edited by J. Hall

SUBJECT: SPECIAL NURSING INSTRUCTIONS FOR PATIENTS WITH RADIUM, CESIUM OR OTHER BRACHYTHERAPY SOURCES

POLICY: Provide complete radiation therapy services of the highest quality for patients referred for treatment.

RESPONSIBILITY: Department of Radiation Medicine, Nursing Service Personnel

PROCEDURE:

1. In this section, nursing personnel will be concerned with hermetically sealed radioactive sources. These brachytherapy sources may be used for intracavitary insertions and interstitial implants both permanent and temporary. Since there are a variety of applications and amounts of radioactive material used, the nursing personnel must refer to the "Radium/Cesium Orders" found in the patient's chart for each individual case.

2. The personnel monitoring devices, when provided, should be worn while tending the patient.

3. Every patient receiving intracavitary or interstitial brachytherapy treatment is to be placed in a priviate room and restricted to bed, unless, due to the nature of the treatment or the exposure rate at one meter from the patient, the radiation safety officer or his designee has determined that these precautions are unnecessary.

4. The chart, room and wrist of the patient should be marked with radiation precaution notices indicating the presence of brachytherapy sources.

5. Nurses should spend only the adequate amount of time near the patient required for ordinary nursing care. Typical examples are:

| | |
|---|---|
| Within 2 feet | 15 minutes |
| Within 3 feet | 30 minutes |
| Within 5 feet | 60 minutes |
| Within 6 feet | 2 hours |

However, this depends on the exposure rate from the patient which is indicated on the patient's chart.

6. Patients are allowed visitors in accordance with the usual hospital rules unless other instructions are given. They should, however, sit at least 6 feet away from the patient. Children and expectant mothers should be excluded.

7. Instruments and containers used to handle sealed radioactive sources DO NOT become contaminated (radioactive). Special instruments are used only to simplify handling and to maintain appropriate distances from the hands to the sources.

8. No special precautions are needed for sputum, urine, vomitus, feces, dishes, instruments, utensils or bedding.

9. If radioactive source capsules or containers become loose or fall out, do not try to replace them. Call the attending physician and the Radiation Medicine Department (Ext. 2323).

10. Notify the Radiation Medicine Department when the radioactive sources have been removed from the patient. The radiation safety officer or his designee will come to remove them from the patient's room and perform the required room survey.

11. If there is reason to suspect that a disruption of a sealed source has occurred, proper precautions, taken immediately, will help to protect health and minimize financial loss. Contact the radiation safety officer or physician immediately at ext. 2323. Untrained persons shall not attempt to examine or clean up spilled radioactive material. The following emergency measures should be carried out at once.

    A. All windows should be closed and fans and air conditioners should be shut off in order to prevent airborne spread of contamination.

    B. All persons should leave the room and all doors should be closed and locked. No immediate attempt should be made to clean up the spill.

    C. Entrance to the contaminated area shall be prohibited until authorized by the radiation safety officer.

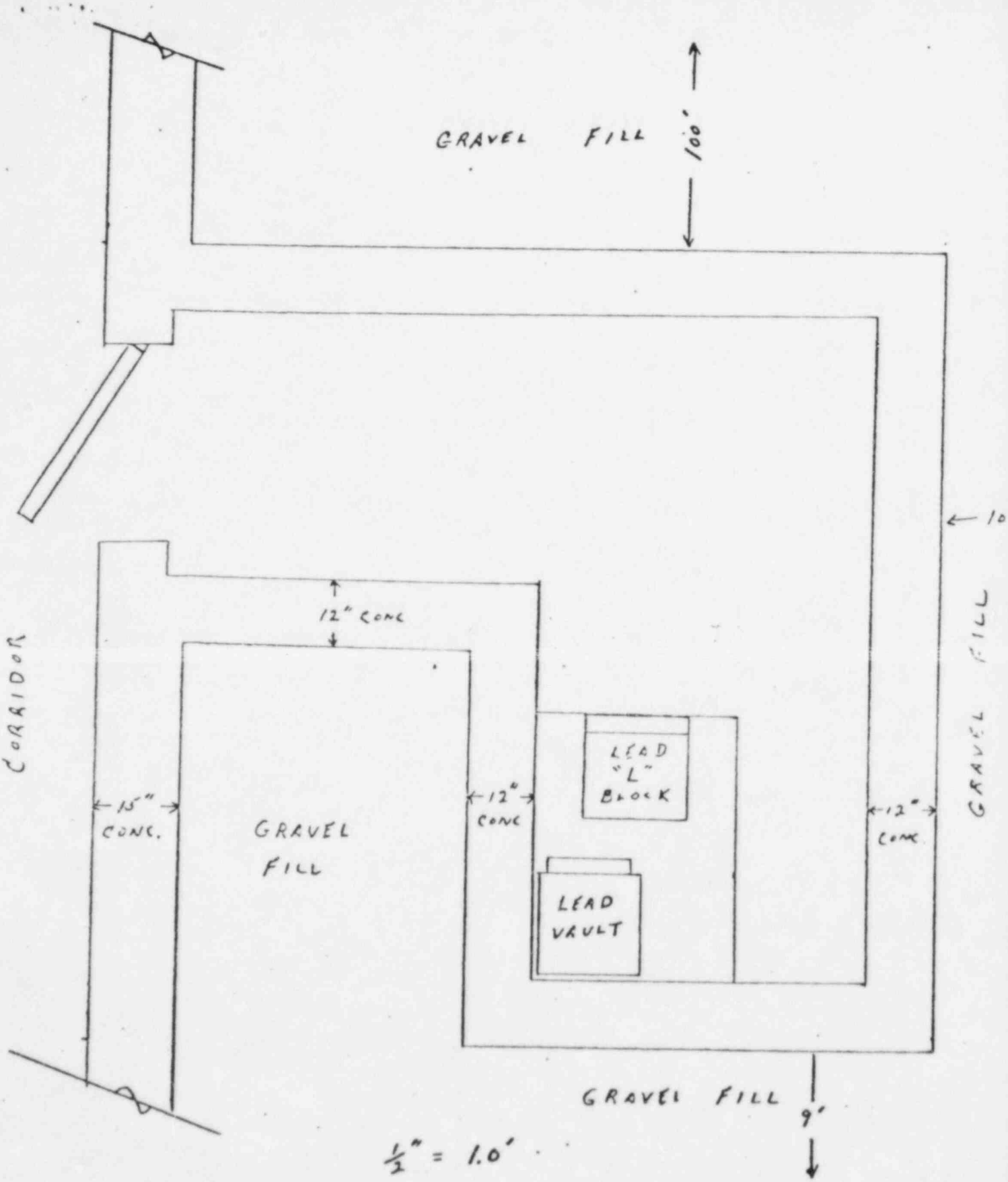
    D. All persons suspected of having been contaminated shall be surveyed. Such persons should be confined to a restricted area so as to reduce the possibility of spreading contamination throughout the building.

12. All linen, dressings, clothing, equipment and trash containers shall be kept within the room of a patient until released by the radiation safety officer or until all sources are accounted for. The indication that all sources have been accounted for and that the radiation safety precautions are no longer in effect shall be the removal of the radiation precaution notice from the door to the patient's room by the radiation safety officer or his designee.

13. Any loss of a source shall be reported immediately to the radiation safety officer. Call extension 2323.

14. If a patient dies before the brachytherapy is complete, the radiation safety officer and attending physician shall be called immediately (Ext. 2323).

# SEALED SOURCES STORAGE AREA




½" = 1.0'

NOTE: STORAGE ROOM IS BUILT ON GROUND LEVEL AND THERE IS 12' OF FILL ABOVE ROOM.

ATTACHMENT M

1. Quantity to be used:

   a. Patient Information

      1) We anticipate a maximum of 15 patients per week.
      2) The individual patient dose is approximately 10 mCi.

   b. We request a possession limit of 800 mCi.

2. Use and Storage

   a. A diagram of the new Nuclear Medicine Department is attached. The only unrestricted areas in the department are the Outpatient Waiting Room and adjacent outpatient restroom.
   The Xenon is stored in the Hot Lab behind a wall of two inch thick lead bricks and used in the gamma camera room labeled LFOV II.

   b. The location and measured air flow rates of all of the supply and exhaust vents in areas where Xe-133 is used are shown on the attached floor plan. None of the exhaust air is recirculated.

   c. All areas where Xenon is used are under negative pressure. Air flow rates are measured semiannually with an Alnor Velometer Model 2-08 to ascertain that air flow rates are maintained at the appropriate level.

3. Procedures for Routine Use

   a. Subject: Pulmonary Ventilation Xe-133

      Indications: Pulmonary emboli, Bronchogenic carcinoma, Chronic obstructive disease, Acute obstructive airways disease

      Patient Preparation: Explain the test fully to allay any fears, take time so patient feels relaxed. A "Dry Run" is performed to determine if any problems will be encountered.

      Collination: LEAP (low energy all purpose) Collinator

      Dynamic: The Xenon is injected into the flexible tubing as the patient is instructed to take a deep breath, blow it all out and then take another deep breath. The patient is then instructed to breath normally into the Xenon apparatus. Obtain 10 second posterior images for five minutes as the patient breathes 10 mCi Xe-133 in $O_2$ and three second images for approximately 5 - 7 minutes as the patient resumes breathing room air. These two portions of the study are termed "Wash In" and "Wash Out" respectively. (Right and left

posterior oblique views are needed.

Static: For a Ventilation Perfusion/VQ Study the above is followed by a routine Lung Perfusion Image using Tc-99m MAA 6mCi given IV. Images are done 3-5 minutes after injection.

b. A Pulmonex Xenon System Model 130-500 is used for the administration and collection of the Xenon. The system has disposable charcoal traps. Exhaled Xenon is gently pulled through activated charcoal contained within a "U" shaped cartridge, shielded with 1/8" lead, by an induction vacuum pump. The control panel timer and airflow pressure dial regulation of the trap pump assures complete patient and system purging. Only a minimal amount of Xenon is present in the trap exit port effluent. The gas trap cartridge is easily replaced when expended. After each study the trap effluent is monitored. Normally room background is approximately 0.05 mR/hr. If the exposure rate of the effluent exceeds 0.5 mR.hr, the trap would be considered to be malfunctioning and/or the filter saturated. The filter would be replaced and a 10 mCi sample would be run through the system to determine the trapping efficiency.

The saturated charcoal traps are stored for decay in the radioactive waste storage area. When the measured exposure rate reaches background, the traps are disposed of as normal trash.

4. Emergency Procedures

Possible leakage from the gas trap or from a noncooperative patient will be constantly monitored by the Nuclear Associates Xen-Alert. In the event that the room concentration of Xenon exceeds the MPC for a restricted area, as indicated by the Xen-Alert alarm, the room will be vacated and the door will be closed. The room exhaust fans are routinely set to the high level for all Xenon procedures. The room will not be used until the concentration of Xenon has fallen below the MPC as indicated by the Xen-Alert.

The amount of time which the room will be remain vacant is given by the following formula:

$$T = -\frac{V}{v} \ln \left[ \frac{\rho\ (t=T)}{\rho\ (t=o)} \right]$$

Where:

T = time to ventilate the room to the MPC of Xenon-133 for a restricted area
V = room volume: 16' x 17' x 8' = 2,176 $ft^3$
v = rate of air exhaust from the room
$\rho\ (t=o)$ = concentration of Xenon-133 in room at time zero (time of Xenon release into the room)
$\rho\ (t=T)$ = maximum permissible concentration of Xenon in room ($1 \times 10^{-3}$ $\mu Ci$ / ml) which occurs at time T.

$$T = -\frac{2{,}176\ ft^3}{2{,}593\ CFM}\ \ln\left\{\frac{1 \times 10^{-5}\ \mu Ci/ml}{\left[\frac{1 \times 10^{4}\ \mu Ci}{(2{,}176\ ft^3)(2.832 \times 10^{4}\ ml/ft^3)}\right]}\right\}$$

$T = 2.34$ minutes

After waiting two and a half minutes, the room will be surveyed to confirm the ventilation of the Xenon gas.

5. Air Concentration of Xe-133 in Restricted Areas

The Xen-Alert is used to monitor the concentration of Xenon in the room. An alarm is activated if the concentration exceeds the MPC for Xenon in which case the room is evacuated.

A calculation is performed below to indicate the minimum exhaust rate required to maintain the concentration of Xenon below the MPC for a restricted area. The following assumptions are made: maximum of 25% leakage of administered doses, maximum of 15 patient studies per week, and a normal dose rate of 10 mCi per patient.

$$\left(\frac{A}{V}\right)(f) \leq 1 \times 10^{-5}\ \mu Ci/ml$$

$$A = (10\ mCi/patient)\ (15\ patients/week)\ (1 \times 10^{3}\ \mu Ci/mCi)$$

$$A = 1.5 \times 10^{5}\ \mu Ci/week$$

$$f = .25$$

$$V = (A)\ (f)/(1 \times 10^{-5}\ \mu Ci/ml) = 3.75 \times 10^{9}\ ml/week$$

The minimum room ventilation rate necessary is

$$\left(\frac{3.75 \times 10^{9}\ ml/week}{40\ hrs/week}\right)\left(\frac{1\ CFM}{1.699 \times 10^{6}\ ml/hr.}\right) = 55.2\ CFM$$

This is well below the measured air exhaust rates of 2593 CFM.

For air concentration in the hot lab where the Xenon is stored, it is assumed that 50% leakage occurs.

$$\left(\frac{A}{V}\right)(f) \leq 1 \times 10^{-5}\ \mu Ci/ml$$

$A = (10\ mCi/patient)\ (15\ patients/week)\ (1 \times 10^{3}\ \mu Ci/mCi)$

$A = 1.5 \times 10^{5}\ \mu Ci/week$

$f = .50$

$V = (1.5 \times 10^{5}\ \mu Ci/week)\ (.50)/(1 \times 10^{-5}\ \mu Ci/ml) = 7.5 \times 10^{9}\ ml/week$

The minimum room ventilation rate necessary is

$$\left(\frac{7.5 \times 10^{9}\ ml/wk}{40\ hrs/wk}\right)\left(\frac{1\ CFM}{1.699 \times 10^{6}\ ml/hr}\right) = 110\ CFM$$

This is well below the measured exhaust rate of 1878 CFM.

6. Air Concentraion in Unrestricted Areas

a. The following calculations will demonstrate that even without the gas trap, the exhaust from the camera room will be below the MPC for a nonrestricted area ($3 \times 10^{-7}\ \mu Ci/ml$).

Maximum weekly patient load = 15
Normal patient dose = 10 mCi
Weekly Xenon Usage = 150 mCi
Annual Xenon Usage = 7800 mCi/yr = $7.8 \times 10^{6}\ \mu Ci/yr$

The camera room exhaust rate is 2593 CFM

$$(2593\ CFM)\left[(1.484 \times 10^{10}\ ml/yr)/(1CFM)\right] = 3.84 \times 10^{13}\ ml/yr$$

$$\frac{\text{Total Xenon-133 Usage}}{\text{Total Ventilation}} = \frac{7.8 \times 10^{6}\ \mu Ci/yr}{3.84 \times 10^{13}\ ml/yr} = 2.03 \times 10^{-7}\ \mu Ci/ml$$

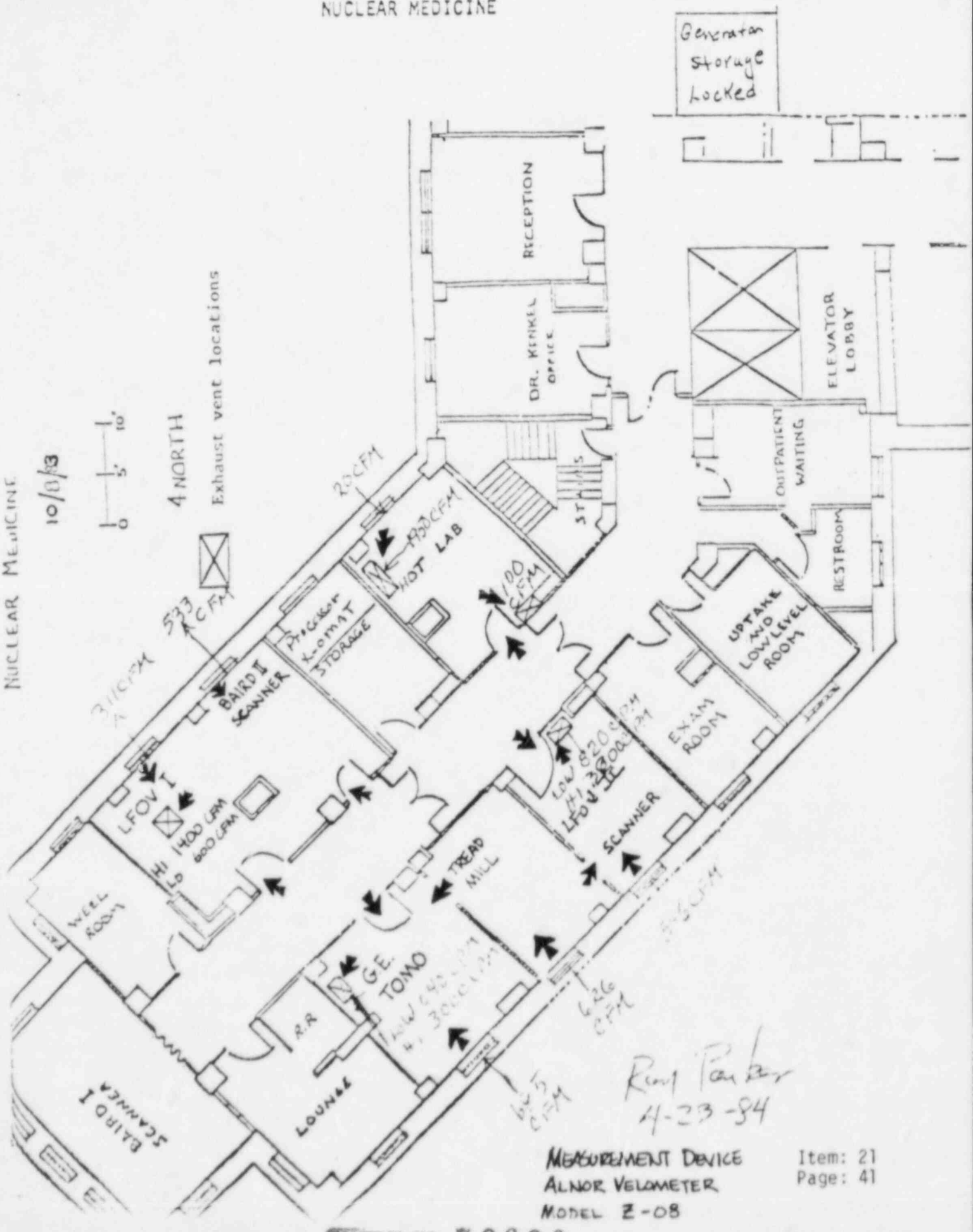
Therefore even without the gas trap, the concentration of Xenon would be below the MPC for a non-restricted area.

b. Handling of Xe-133 Charcoal Traps

As indicated above the effluent from the trap is monitored after each Xe-133 procedure. When the exposure rate of the effluent exceeds 0.5 mR/hr, the trap will be replaced. The Xen-Alert also serves as an indicator of trapping efficiency.

When a saturated trap is removed from the Xenon system, it is placed in the outside locked concrete storage bin for decay. When the exposure rate measures background, the trap will be disposed of with the normal hospital waste.

NUCLEAR MEDICINE




Rem Tanner
4-23-84

MEASUREMENT DEVICE
ALNOR VELOMETER
MODEL 2-08

Item: 21
Page: 41

CONTROL NO. 78680

PROCEDURES AND PRECAUTIONS FOR THE USE OF INSTRUMENT CALIBRATION SOURCE

1. The source is to be used only at the licensee's facility.

2. The source is to be used for the purpose of calibration of survey meters.

3. The source is to be leak tested every six months.

4. The source is to be used only by or under the supervision of a radiological physicist who is certified by the American Board of Radiology in Radiological Physics or Therapeutic Radiological Physics.

5. When not in use, this source is to be stored in the area which is designated for the storage of sealed sources used in radiation therapy.

Item: 23

Page: 42