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

St. Mary's Hospital
111 East Spring Street
Streator, Illinois 61364

TELEPHONE NO.: AREA CODE (815) 673 - 2311

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mr. Robert Gubbels

TELEPHONE NO.: AREA CODE (815) 673 - 2311

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 12-03391-01

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

See Attachment No. 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.)*

Theodore W. Wagenknecht, 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	X	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	2000
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	500

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	200

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
NONE			

RECEIVED BY LFMB
Date 9/27/84
Log Sept 18th
By
Orig. To

Applicant
Check No. 64664
Amount Fee Category 350
Type of Fee MC Renew
Date Check Rec'd 9/27/84
Received By

FORM NRC 313M
(8-78)

30-148

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		**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*	
X	Names and Specialties Attached; and		Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*	X	Equivalent Rules Attached
X	Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*	
8. TRAINING AND EXPERIENCE See Attachment #4			Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and	X	Equivalent Procedures Attached
	Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
	Appendix C Form Attached; or	X	Equivalent Procedures Attached
X	List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X	Equivalent Information Attached
X	Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*		Appendix K Procedures Followed; or
X	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		**20. THERAPEUTIC USE OF SEALED SOURCES**	
X	Description and Diagram Attached	X	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached	X	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**	
			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		Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer Jr. & Co.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer Jr. & Co.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

N/A

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 1C 5580 Renew

(2) LICENSE FEE ENCLOSED $ 580.00 Control No. 7 7 4 7 8

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*

(2) TITLE
Administrator

c. DATE
September 30, 1984

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RADIATION SAFETY COMMITTEE

7(a) RESPONSIBILITY:

The Committee is responsible for -

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience in accordance with NRC regulations and conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

DUTIES:

The Committee shall -

1. Be familiar with all pertinent NRC regulations, the terms of the license, the information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses readioactive material (including physicians, technologists, physicians, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by Section 19.12 or 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users and special monitoring procedures.

6. Review 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 the license. The reveiw shall include an examination of all records, reports from the Radiation Safety Officer, results of NRC inspection, written safety procedures and management control systems.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all Committee meetings, actions, recommendations and decisions.

9. Ensure that the Byproduct Material License is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel.

10. Review dosimetry reports with reference to the ALARA Program.

RADIATION SAFETY OFFICER -

Among the specific responsibilities of the Radiation Safety Officer, or his deputy, are the following:

(1) To assure that the institution is in compliance with all pertinent Federal, State and Local Regulations.

(2) To establish and supervise operating procedures and to review them periodically to assure their conformity with the recommendations.

(3) To instruct personnel in proper radiation protection practices.

(4) To conduct, or have conducted, radiation surveys and source leak tests where indicated and to keep records of such surveys and tests, including summaries of corrective measures recommended and/or instituted.

(5) To assure that personnel monitoring devices are used where indicated and that records are kept of the results of such monitoring.

(6) To investigate each known or suspected case of excessive or abnormal exposure to determine the cause and to take steps to prevent its recurrence.

The Radiation Safety Officer or his deputy will be available at the hospital during working hours and by phone for all emergency situations after normal working hours.

7(b) MEETING FREQUENCY

The Radiation Safety Committee shall meet as often as necessary to conduct its business, but not less than once in every calendar quarter.

ITEM 7(b)

[9/84]

RADIATION SAFETY COMMITTEE

W.E. Erkonen, M.D.	Physician licensed to use radioactive materials
T.W. Wagenknecht, M.D.	Radiation Safety Officer
Jim Lansford	Administrator or Representative
Linda Perry	Director of Nursing or Representative
Scott Graham	Chief Technologist, Nuclear Medicine
Robert Gubbels	Radiology Manager

INSTRUMENTATION

1. SURVEY METER
   - A. Manufacturer: Victoreen
   - B. Model Number: 498
   - C. Number of Instruments Available: one
   - D. Minimum Range: 0 - 1.0 mR/hr
   - E. Maximum Range: 0 - 1000 mR/hr

2. DOSE CALIBRATOR
   - A. Manufacturer: Capintec
   - B. Model Number: CRC-30
   - C. Number of Instruments Available: one

3. DIAGNOSTIC INSTRUMENTS
   - A. Type of Instrument: Scintillation Camera
   - B. Manufacturer: Searle
   - C. Model Number: LFOV

4. OTHER INSTRUMENTS

   Automatic Multiple Sample Scintillation Well Counter

   Manufacturer: Tracor Analytic

   Model No.: 11902

ITEM #9

CALIBRATION OF INSTRUMENTS
Methods, Frequency, Standards

SURVEY INSTRUMENTS:

Calibration and repair of survey instruments will be done annually by Health Physics Associates, Ltd., 3304 Commercial Avenue, Northbrook, Illinois 60062.

The procedure used to calibrate survey meters is on file with the Nuclear Regulatory Commission, under Health Physics Associates Ltd.'s license No. 12-09160-01. When a survey meter is sent for repair or calibration, a "loaner" survey meter will be supplied by Health Physics Associates, Ltd.

Cs-137 reference standard will be used to check the constancy of the GM survey meter prior to use. If a reading with the same geometry is not within ±20% of the reading measured after calibration, the instrument will be recalibrated.

DOSE CALIBRATOR:

The following checks will be performed on the dose calibrator:

A. Constancy - Daily
B. Linearity - Quarterly
C. Accuracy - Annually
D. Geometrical Variation - At installation and after chamber replacement

A. Constancy

A Cs-137 standard, consisting approximately 200 µCi of activity will be assayed in the dose calibrator daily in the Cs-137 setting on the instrument. The standard used will be traceable to the National Bureau of Standards. The dose calibrator initial assay of the standard should not differ by more than ±5% from the anticipated range of activity of the standard.

The Cs-137 source will be assayed daily in other radionuclide settings routinely used in the department. The assay of the sources will not vary by more than ±5% from week to week. Once a week, the Cs-137 source will be assayed in other radionuclide settings occasionally used in the department and the readings should not vary by more than ±5% from week to week.

B. Linearity will be performed using one of the following two methods

1] The linearity of the instrument will be established quarterly. The procedure employed will be such that it will cover the entire range of activity that the department may use. The maximum quantity of radioactivity that we may have on hand in a single container would be elution from Mo99/Tc99m generator (Tc99m pertechnetate).

Knowing the volume in the vial, the concentration of the activity can be calculated. One milliliter of eluent is drawn precisely into a syringe and it is assayed in the dose calibrator. The reading should be within ±5% to be acceptable.

Further linearity will be determined as follows: The same syringe is then further assayed at approximately 6 hours, 24 hours, 30 hours and 48 hours after the activity was drawn into the syringe. For acceptable linearity, all the assay results must be within ±5% of the calculated values.

2] We may use the "Calicheck Kit" from Calcorp, Inc., P.O. Box 25589, Cleveland, Ohio 44125-0589. A copy of the brochure is attached. The initial linearity of the dose calibrator will be confirmed using the decay method as indicated above. The "Calicheck Kit" will be used according to the instructions from the supplier of the kit.

C. Accuracy

The accuracy of the dose calibrator at various energy levels will be confirmed at installation, after repairs, and once a year thereafter, using three reference standards whose activity is traceable to the National Bureau of Standards. These standards are obtained from New England Nuclear.

RADIONUCLIDE	CATALOG No.	APPROXIMATE ACTIVITY	SOURCE TYPE
Cs-137	NES-356	200 µCi	Vial E
Ba-133	NES-358	250 µCi	Vial E
Co-57	NES-206	5.0 mCi	Vial E

Each standard will be assayed in the appropriate settings three times and the average of the three settings will be calculated. After subtracting the room backgrounds, the average source assay should be within ±5% of the anticipated range of activity of each source. The sources are possessed by IML Imaging Inc., for the specific purpose of annual calibration of the dose calibrator. The sources will not be stored on site at the hospital.

D. Geometrical Variation - At Installation and After Chamber Replacement

As explained in paragraph "B" above, the geometrical independence between the vial and the syringe is first established. The activity in the syringe is then further diluted 0.5 ml at a time, mixed properly, and the syringe assayed after every step. In this manner, a series of readings of the same activity in different volumes are obtained. If the assay result in any volume is above ±2% of the mean value, a corrective value will be determined.

Similarily, a 20 mCi activity in a vial is assayed in different volumes and correction factors computed when necessary.

If a dose calibrator does not meet your specifications in sub-items A-D above, replacement dose calibrator will be obtained while the instrument is shipped for repairs.

Patient Doses

All patient doses will be assayed prior to administration to ensure that they are within ±10% of the prescribed dose.

New!

Now meet governmental regs in 4 minutes ...not days!

Fast

Now with the newly developed Calicheck™ dose calibrator activity linearity test kit†, you can meet N.R.C. Regulatory Guide 10.8, appendix D., Section 2E or your state's equivalent requirement in just 4 minutes — not days.* You can complete the test in one short sitting and check for linearity virtually at a glance. Plus you eliminate the frustration of having to start the test all over simply because you forgot to take a reading on time. † (Patent pending)

Accurate and Reliable

The new Calicheck kit is designed to attenuate radiation by known values — accurate using a high yield generator eluant or a unit dose.

A Calicheck kit provides for seven successive measurements simulating the decay of ^{99m}Tc at approximately 0, 6, 12, 21, 31, 41 and 51 hours from the initial assay.

Complete Yet Reusable

Your Calicheck kit comes to you complete with its own storage container, a unique arrangement of seven color-coded lead-wrapped tubes, work/record keeping sheets, instructions for use including specific correction factors, and a license amendment form (if needed.)

Your Calicheck kit is completely reusable for an indefinite period of time. There is nothing to wear out or use up. If damage should cause a tube to malfunction, individual replacements are available.

Safe

Your use of a Calicheck kit eliminates the need to fractionate eluants or decay the elution for several days while periodically collecting data to determine linearity. Time of potential exposure to radiation is drastically reduced, thereby maintaining exposures ALARA.

Lowers Department Costs

When you test with a Calicheck kit, both the source activity and dose calibrator can be returned to active service in just minutes. This savings alone can pay for a Calicheck kit in just three to four linearity tests. A Calicheck kit lets you return to active service too!

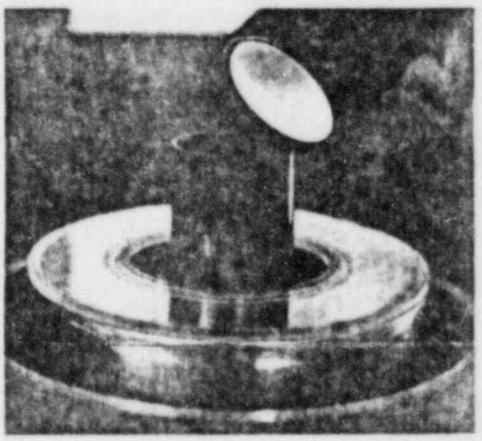
Can Improve Patient Care

A Calicheck kit is so fast, efficient and easy to use, you may wish to check dose calibrator linearity more frequently. Lets you spot trouble before it becomes serious.

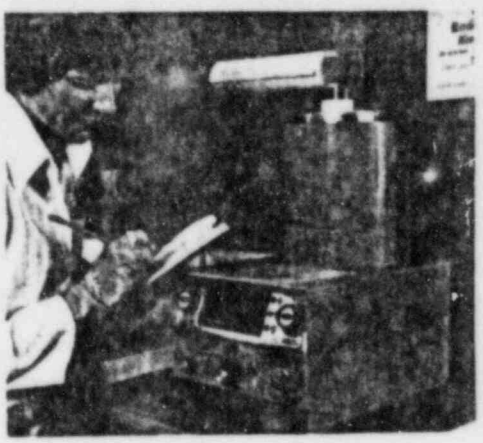
Low Price

A Calicheck dose calibrator activity linearity test kit is just $325.00 shipping included.

Just complete and return the card with your check or call (216) 663-1773.



As simple as 1, 2, 3, 4, 5, 6, 7. Place red central tube in dose calibrator. Place source in red tube and take a reading. Then sequentially place color-coded tubes over red tube. Additional readings are taken immediately, converted with a given factor and you can see the degree of linearity virtually at a glance.



*As presented in a scientific paper before the 28th Annual Meeting of the Society of Nuclear Medicine, 1981, Las Vegas, Nevada.

CALCORP, INC.
P.O. Box 25589
Cleveland, Ohio 44125-0589

Phone No. (216) 663-1773

[9/84]

Item #10

DOSE CALIBRATOR CHECKS

HOSPITAL ____

DOSE CALIBRATOR MAKE & MODEL # ______________________________

CALIBRATOR SOURCE ____________ ACTIVITY ________ DATE ________ S/N ______

DATE	Cs-137	Tc-99m	Mo99	I-131	I-123	Ga-67	Xe-133	Tl-201		

[9/84]

ITEM #10

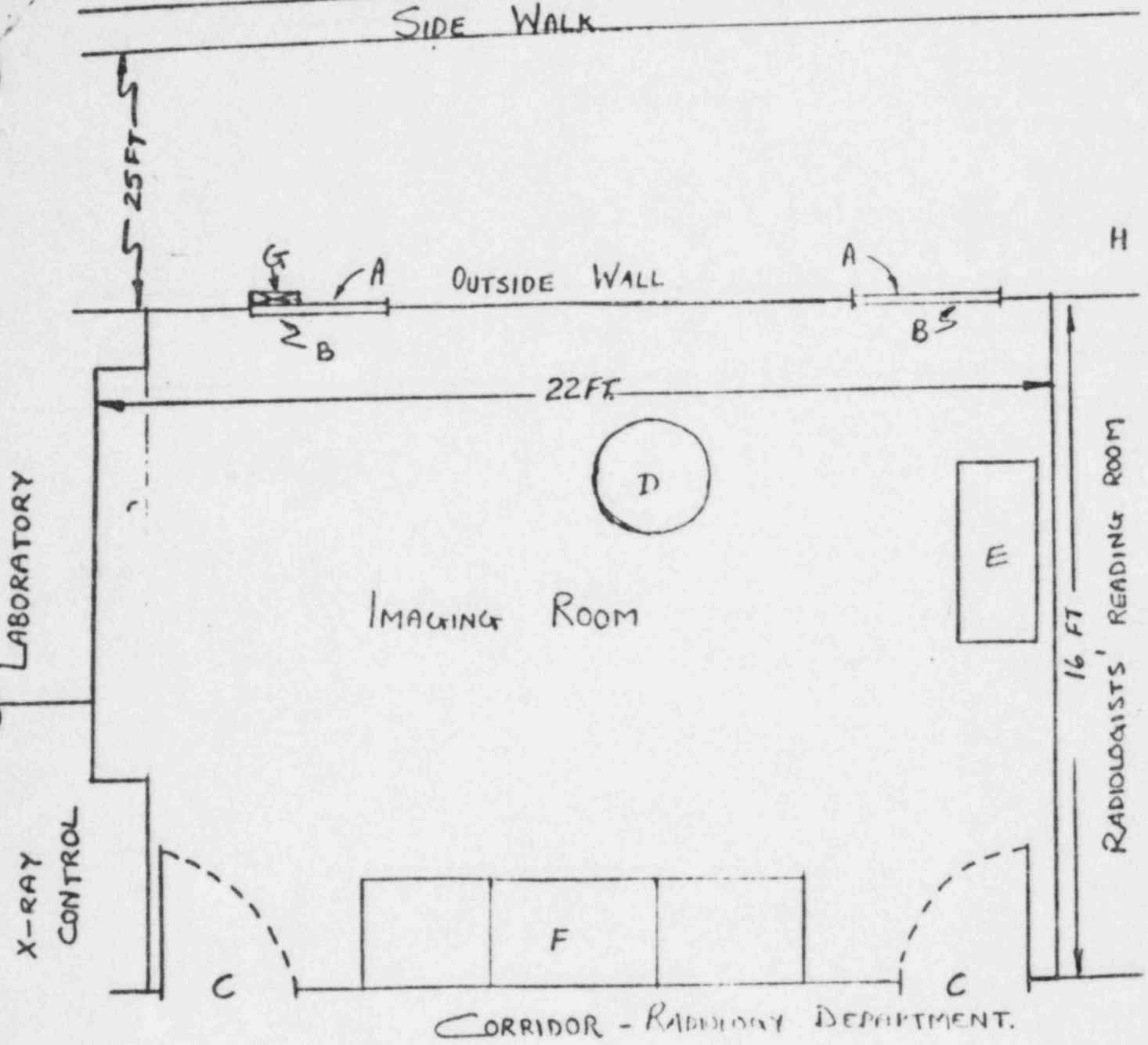
QC-2

FACILITIES AND EQUIPMENT

Attached are diagrams of our Nuclear Medicine Department and Radioactive Materials Storage Areas.

All areas in the Nuclear Medicine Department and all storage areas are lockable. Shielding of all radioactive materials storage areas will be adequately thick enough to reduce exposures to 2 mR/hr or less.

St. Mary's Hospital Streator, IL
ROAD 12-03391-01



A - WINDOWS: MINIMUM 10 FT ABOVE GROUND LEVEL

B - FRESH AIR SUPPLY, EACH AT 60 CFM (TOTAL 120 CFM).

C - SECURED DOORS

D - CAMERA DETECTOR

E - CAMERA CONSOLE

F - STORAGE CLOSET - LINEN, ETC.

G - WINDOW MOUNTED AUXILLIARY EXHAUST FAN

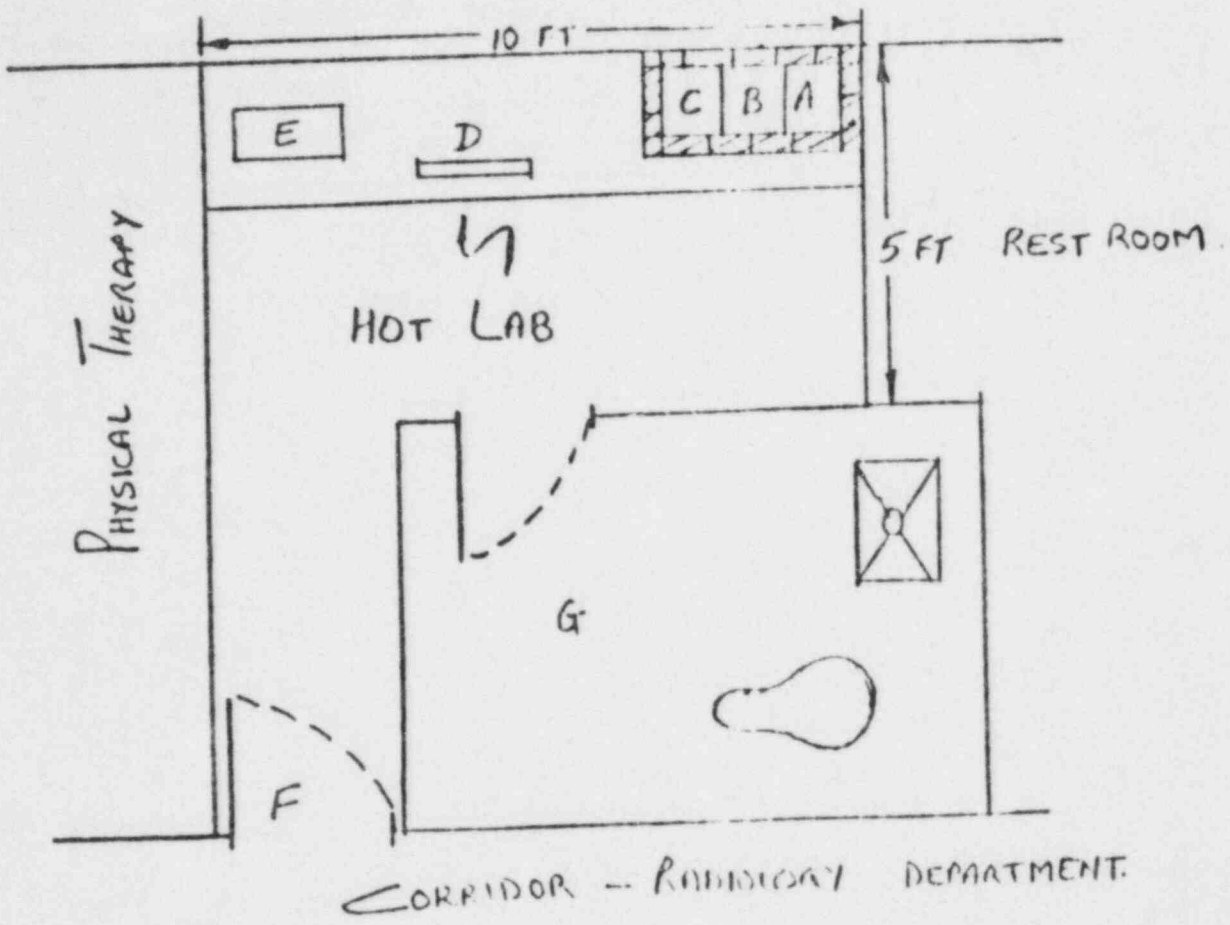
H - FRESH AIR INTAKE UNITS AT MINIMUM 30 FT.

ITEM # 11 (9/84)

ST MARY'S HOSPITAL, STREATOR, ILL

12-03391-01

PHYSICAL THERAPY



A – Mo^{99}/Tc^{99m} NEW GENERATOR – SHIELDED BY 2" THICK

B – " ONE WEEK OLD " " " "

C – RADIOACTIVE MATERIALS STORAGE " " "

D – DOSE PREPARATION AREA: L-BLOCK

E – DOSE CALIBRATOR

F – SECURED DOOR

G – REST ROOM

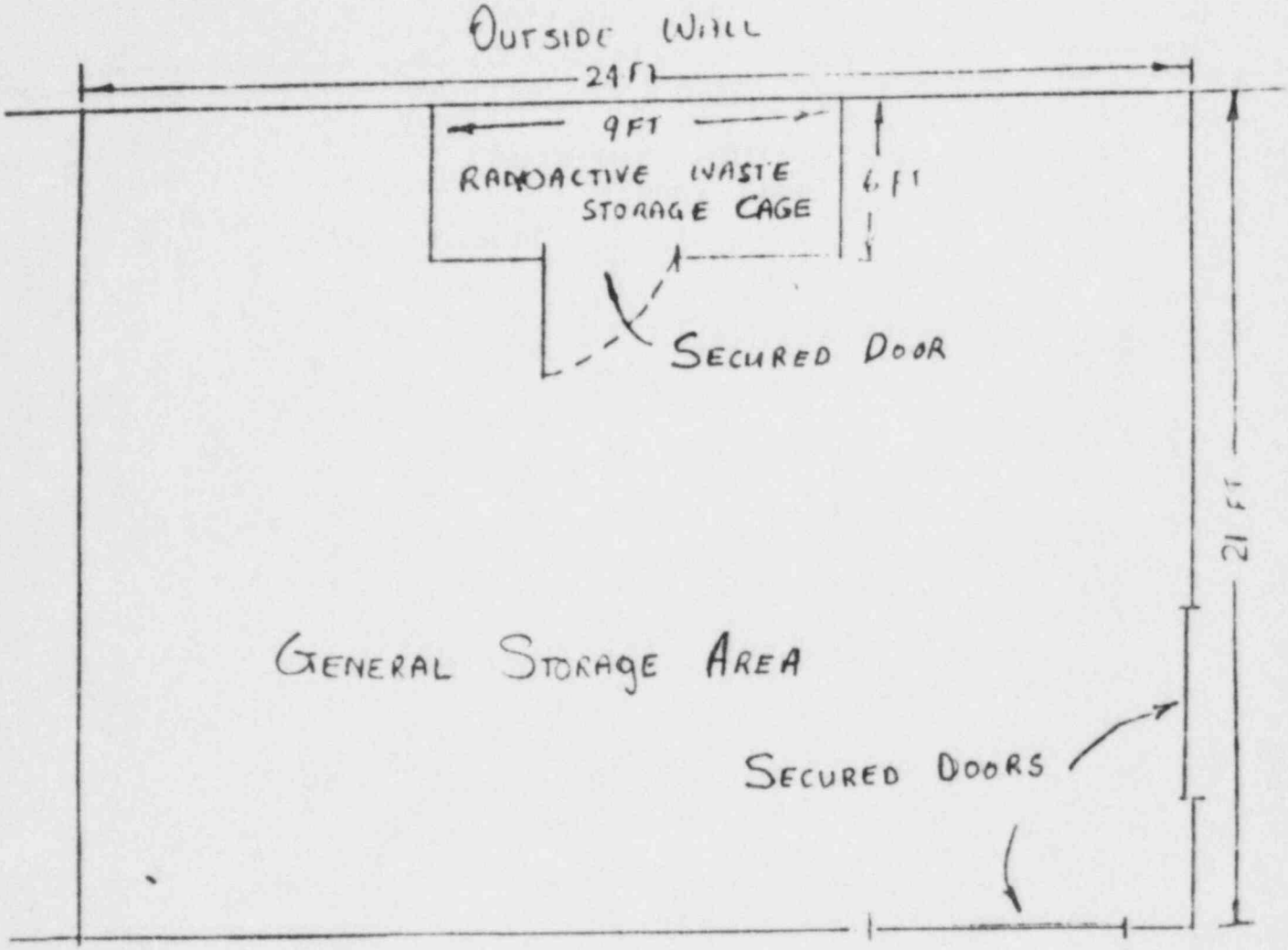
ITEM # 11

(9/84)

St Mary's Hospital, Streator, Ill

12-03391-01

Subbasement Area



(9/84)

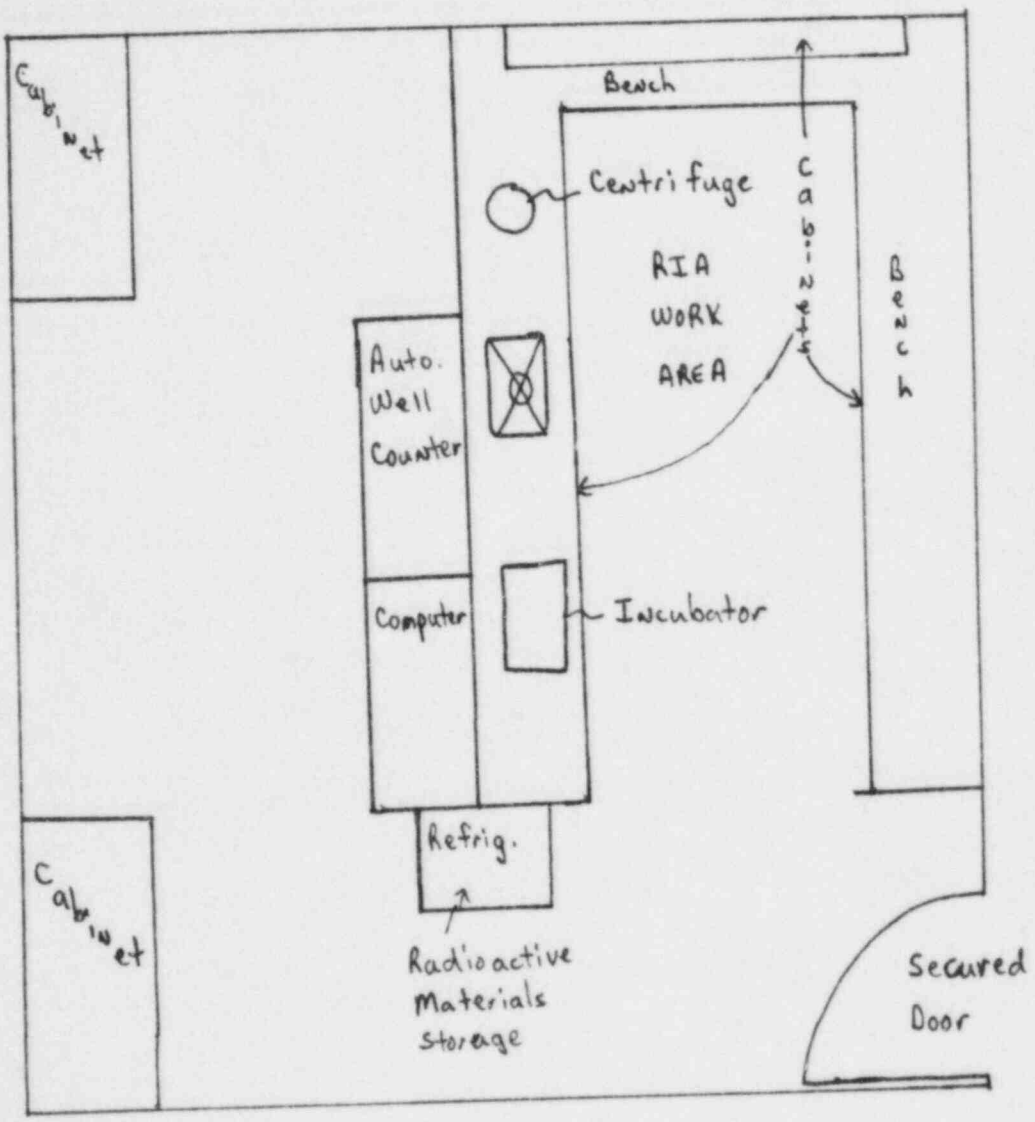
St. Mary's Hospital

Streator, Illinois

RIA LAB

(Basement of Hospital)

12-03391-01



Item #11 (9/84)

PERSONNEL TRAINING PROGRAM

In accordance with State Regulations, instructions to workers will be carried out in the following manner:

1. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer or use of radioactive materials or of radiation in such portions of the restricted area.

2. All individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to such radioactive materials, in precautions or procedures to minimize exposure, and in the proceses and functions of protective devises employed.

3. All individuals working in or frequenting any portion of a restricted area shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the Commission to radiation or radioactive materials occuring in such areas.

4. All individuals working in or frequenting any portion of a restricted area shall be instructed of their responsibility to report promptly to the licensee, any conditions which may lead to or cause a violation of Commission Regulations and Licensee of unnecessary exposure to radiation or to radioactive material.

5. All individuals working in or frequenting any portion of a restricted area shall be instructed in the appropriate response to warnings made in the event of any unusual occurence or malfunction that may involve exposure to radiation or radioactive material.

The Nuclear Medicine Technologist will be classified as occupational employees. These individuals perform their duties from the radiation safety viewpoint under the direction of the physician at the hospital named on the license application.

Every effort will be made to find technologists educated in Nuclear Medicine Technology in an institution approved by the American Medical Association. Such employees will be certified or eligible for certification in Nuclear Medicine Technology and for licensure by IDNS. Orientation of radiation safety and techniques of such personnel, for one or two days by the Radiation Safety Officer, will be considered sufficient.

All Nuclear Medicine Technologists will be instructed before assuming duties and annually thereafter by the Radiation Safety Officer or the Chief Technologist in the following areas:

(a) New procedures and radiopharmaceuticals in Nuclear Medicine

(b) Radiation Safety Techniques

(c) NRC and State Rules and Regulations for the use of radioactive materials.

(d) Location of regulations, license, license applications, regulatory notices and dosimetry and bioassay reports. All of these documents and reports are available for employee inspection upon request to the R.S.O.

With regard to non-occupational personnel at hospitals and their contact with the Nuclear Medicine Department, the Staff Technologist will be instructed to restrict access to the department to those people having business there.

NON-OCCUPATIONAL PERSONNEL WHEN REQUIRED TO ASSIST THE TECHNOLOGIST WITH A PATIENT, WILL NEVER BE ALLOWED TO HANDLE ANY RADIOACTIVE MATERIAL.

Any person requested to assist with a patient will do so under the direction of the Nuclear Medicine Technologist who will ensure that the exposure to these persons is held to a minimum (through time, distance and shielding) during the performance of the Nuclear Medicine procedure.

A short "orientation" program will be conducted annually for the non-occupational personnel such as security, clerical, housekeeping, etc., who may be involved in Nuclear Medicine Department functions where radioactive materials are stored or used. The orientation will include:

(a) Tour of the Department to indicate the radioactive material storage space(s), location of the 10 CFR Parts 19, 20, 30, 31 and 35, location of the survey meter, etc.

(b) Concepts of radiation safety - distance, time, shielding.

(c) Names and phone numbers of person(s) to contact in case of a radiation emergency.

If a new, non-occupational employee is involved in Nuclear Medicine Department functions, the employee will be given a short orientation program before the employee begins duties in the Nuclear Medicine Department.

(d) The radioactive material, if used (injected) in our Cardiac Stress Lab for Tl-101 stress studies, the access to the stress unit will be limited to the physician, the stress lab technologist(s) and the patient during the use of Tl-201. The stress lab technologists will be given a copy of "Emergency Procedures for Minor Spills" for posting in the stress unit room.

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

ORDERING

Radiopharmaceuticals will be ordered from suppliers licensed by the NRC or State according to 10 CFR 32 or Agreement State Regulations. Ordering will be initiated by the Nuclear Medicine Technologist who will ensure the inventory is adequate for planned and anticipated procedures, but not in excess of possession limits where applicable.

RECEIVING

Instructions will be issued to the carrier delivering radiopharmaceuticals to effect delivery directly to the Nuclear Medicine Department. Radiopharmaceutical packages are not to be left unattended in the unrestricted areas.

In the event that the radiopharmaceuticals arrive during off duty hours, the security staff member on duty will escort the carrier to the Nuclear Medicine section, unlock the door, direct the carrier to place the shipment on the designated counter and resecure the area against unauthorized removal of the shipment.

If the radioactive package appears damaged or damp, the carrier will be requested to remain on the premises until the Radiation Safety Officer can determine that neither he nor the delivery vehicle is contaminated.

Policy No: 40-8466
Subject: After hour materials
Effective: 7/16/80
Revised: 8/20/82
Reviewed: 9/10/84

St. Mary's Hospital

Streator, Illinois 61364

August 20, 1982

TO: DEPARTMENT HEADS OF:

(a) Security
(b) Purchasing
(c) Receiving
(d) Switchboard
(e) Emergency Room
(f) Radiology
(g) Nuclear Medicine

FROM: Terence Schuessler, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIALS BEARING WHITE I, YELLOW II, OR III HAZARDOUS MATERIALS.

1. During hours in which the Nuclear Medicine Department is open, all couriers or common carriers requesting assistance in delivering packages containing radioactive materials are to be directed to the Nuclear Medicine Department. Personnel, excepting those in the Nuclear Medicine Department, are not to accept the package personally.

2. If couriers or common carriers attempt delivery of packages containing radioactive materials when the Nuclear Medicine Department is closed the Security Office is to be contacted.

   The Security Guard will inspect the package and sign for it. If it is wet or appears damaged, he is to immediately contact the hospital Radiation Safety Officer. The carrier is to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

3. If the package is not damaged or wet, the Security Guard will take it to the Hot Lab, unlock the door, place it inside the Hot Lab, close and lock the door.

4. If the package has Radioactive Yellow Label II or III, the package will be transported on a wheelchair so maximum possible distance can be maintained during transportation. (Radiation levels decrease with increase in distance.)

RADIATION SAFETY OFFICER IS T.W. Wagenknecht, M.D.
673-2311 Ex 326

Item # 13

PROCEDURE FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIAL

1. Wear gloves during package inspection and opening to prevent contamination.

2. Inspect and open all packages IMMEDIATELY upon receipt. Should package arrive when the Nuclear Medicine Department is closed, this procedure will receive top priority as soon as the Nuclear Medicine personnel returns. If visual inspection shows any signs of damage (if wet or crushed, etc.) stop procedure and notify the Radiation Safety Officer.

3. All radioactive packages will be surveyed at surface and at three feet to verify that the radiation levels on the surface of the package are not in excess of 200 millirems per hour, or at three feet from the external surface of the package in excess of 10 millirems per hour. If the levels are in excess of the ones indicated above, the NRC Region III will be notified by telephone.

4. Open package, remove packing slip and verify that the contents agree in name and quantity with the packing slip. Check also that shipment does not exceed possession limits.

5. If a wipe test of the package is required to be done as specified in 10 CFR 20.205, the wipe will be performed and analyzed as instructed in "Wipe Test Procedure" which follows.

6. Check for possible breakage of seals or container's loss of liquid or change in color of absorbing material. Wipe test the final source container to rule out contamination. (For wipe test procedure, refer to next page.)

7. Place the radioactive source in its shield and store in the Isotope Storage Area.

8. Monitor the shipment packing material for contamination after removal of the sources. Deface labels and discard.

9. Record type of activity, quantity present, date of receipt and invoice number on the radiopharmaceutical inventory form (attached).

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10. If material was packaged in dry ice, refrigerate immediately.

11. If excessive radiation levels, contamination, leakage or shortages are observed, notify the final delivering carrier and by telephone and telegraph contact the Regional Office of the Nuclear Regulatory Commission. Also notify the Radiation Safety Officer of any damage or leakage resulting in contamination.

WIPE TEST PROCEDURE

1. To be performed on all shipments, SPECIFIED IN PART 10 CFR 20.205, and on final containers of all radioactive sources.

2. To be performed as soon as practicable after receipt. If received during normal working hours, wipe test must be performed within three (3) hours; if received at some other time, within eighteen (18) hours after receipt.

3. Procedure:

   a) Wipe the surface of the container over its entirety with an alcohol swab.

   b) Check the wipe using a low level GM survey meter probe with window open. The wipe should be placed in a small plastic or paper cup and the base of the cup should then be centered on the open window of the probe and held in place, in contact with the probe, for approximately 10 to 15 seconds. Record the reading in mR/hr.

      If the radiation level is higher than the natural background levels in an unrestricted area, a scintillation camera detector without collimator will be used to determine the level of contamination.

ITEM 14

[9/84]

RADIOPHARMACEUTICAL INVENTORY

DATE RECEIVED __/__/__ RADIATION LEVELS (mR/hr): SURFACE_____ 3 FT_____ EMPTY_____ INITIALS____

WIPE: mR/hr

PLACE LABEL HERE ACT. ADM_____mCi TIME _____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME _____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME _____ INITIALS_____
PLACE LABEL HERE ACT. ADM._____mCiTIME_____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME_____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME_____ INITIALS_____

All used syringes, needles, & unused doses above, returned to supplier. DATE INITIALS [9/84]

RADIOPHARMACEUTICAL INVENTORY

HOSPITAL:

DATE RECEIVED:	RADIATION LEVEL mR/hr Wipe	Empty	3 Ft.	Surface	Date or Time	Patient Name	Patient #	Concentration mCi/ml	Activity administered mCi	Volume administered ml	Volume remaining ml	Activity remaining mCi
RADIOPHARM												
MANUFACTURER:												
LOT #												
DATE RECEIVED:	RADIATION LEVEL mR/hr Wipe	Empty	3Ft.	Surface								
RADIOPHARM:												
MANUFACTURER:												
LOT #:												
DATE RECEIVED:	ADIATION LEVEL mR/hr Wipe.	Empty	3Ft.	rface								
RADIOPHARM:												
MANUFACTURER:												
LOT #:												

HOSPIT

IML INVENTORY FORM

Mo99/Tc99m Generator

1. No more than 1 uCi Mo99/ 1 mCi Tc99m, or
2. No more than 5 uCi per dose

	RADIATION LEVEL mR/hr				DATE	TIME	Tc99m Pertechnetate QUANTITY (mCi)	Volume (ml)	Concentration mCi/ml	Net Mo99 Activity	uCi Mo99 / mCi Tc99m	Date Generator Disposed	GM reading mR/Hr
DATE RECEIVED:	Surface	3 Ft.	Empty	Wipe									
RADIOPHARM:													
MANUFACTURER:													
LOT #:													
DATE RECEIVED:	Surface	3Ft.	Empty	Wipe									
RADIOPHARM:													
MANUFACTURER:													
LOT #:													
DATE RECEIVED:	Surface	3Ft.	Empty	Wipe									
RADIOPHARM:													
MANUFACTURER:													
LOT #:													

USE OF Mo99/Tc99m GENERATOR

The Mo99/Tc99m generator will be eluted according to the instructions described in the package insert from the radiopharmaceutical company. This will provide an eluent of pharmaceutical quality.

99mTc and 99Mo assay of the eluted material from the generator will be performed after each elution according to the instructions described in the package insert from the radiopharmaceutical company. The assay, along with the assay of compounds synthesized from technetium eluates, will be accomplished through the use of a dose calibrator device. When the dose calibrator is sent away for repairs, a "loaner" will be obtained.

The purity of the eluted material will be determined by the above assay. The eluted sources containing more than 1.0 uCi of 99Mo per millicurie of 99mTc or final patient dose containing more than 5.0 uCi of 99Mo, will not be used directly or in compounding.

Compounds formulated using kits and technetium from the above generator will be prepared by following the kit manufacturer's directions, exactly as outlined in the package insert. No alterations or substitutions will be permitted. In this way a product or pharmaceutical quality will be insured. Syringe shields and lead containers for vials will be used during formulation of these compounds.

All patient doses will be assayed with a dose calibrator to assure that the dose is within $\pm$10% of the prescribed dose.

GENERAL RULES AND SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coat or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves while handling radioactive materials.

3. Monitor hands and clothing if contamination is suspected after handling radioactivity.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g. through use of a butterfly valve).

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

   Do not store food, drink or personal effects with radioactive material.

6. 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%.

   For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated, low background area.

8. Wear TLD finger badges during elution of generator and preparation assay and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly sheilded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination at the end of the day. Decontaminate if necessary.

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[9/84]

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

14. Mo99/Tc99m generator eluent will be assayed to determine Mo99 concentration and the eluent will not be used if Mo99 concentration is equal to or exceeds 1 uCi Mo99 per 1 mCi of Tc99m; or if a dose contains more than 5 uCi of Mo99.

ITEM #15

[9/84]

EMERGENCY PROCEDURES FOR RADIOACTIVE SPILLS

Unsealed radioactive liquids are handled routinely in the Nuclear Medicine Department. The potential for spillage is always present. It is imperative that individuals handling radioactive materials respond properly to these spills so as to limit their radiation exposure and prevent the spread of contamination.

MINOR SPILLS: (tracer activities)

1. Notify persons in the immediate area that a spill has occurred.
2. Cover the spill with absorbent paper.
3. Limit access to area to only those persons dealing with the spill.
4. Survey (GM survey meter) potentially contaminated personnel before they disperse; and decontaminate as necessary.
5. Notify the Radiation Safety Officer of the incident.

MAJOR SPILLS: (therapy activities)

1. Notify all persons not involved in the spill to vacate the room at once. Limit the movement of displaced persons to confine the spread of contamination.
2. Cover spill with absorbent paper.
3. Switch off all fans. Close windows.
4. Vacate room.
5. Close the door to the room. Prevent entry into the room.
6. If the spill is on the skin, flush thoroughly.
7. If the spill is on the clothing, discard outer or protective clothing at once.
8. Notify the Radiation Safety Officer immediately.
9. Survey (GM survey meter) personnel involved. Immediately initiate decontamination of personnel as necessary, using mild soap and luke warm water.

FIRE AND / OR EXPLOSIONS

1. In the event of fire, explosion or similar catastrophy, the emergency within the hospital must be given attention first. Patients must be immediately cared for.

2. Should the catastrophe occur within the Department of Nuclear Medicine, vacate the area and all surrounding areas immediately.

   HOWEVER, DO NOT LET THE LOCATION OF OCCURRANCE PREVENT ADEQUATE AND IMMEDIATE PATIENT PROTECTION.

3. Block off the area with ropes, chairs or whatever is available until such time as fire or other emergency personnel arrive.

4. Notify the Radiation Safety Officer immediately.

5. Monitor area to determine extent of contamination.

6. Take necessary steps to decontaminate the area according to instructions of the Radiation Safety Officer.

LOSS OR THEFT OF RADIOACTIVE MATERIALS
OR
DAMAGE TO A RADIOACTIVE SOURCE

If the radioactive source is damaged, the precaution to prevent the spread of the contamination will be taken. The area concerned will be decontaminated and the damaged source will be stored in adequate shielding.

If a source is lost or stolen, the Radiation Safety Officer and the U.S. Nuclear Regulatory Commission or the appropriate State authorities will be notified.

If a source is involved in a fire and/or explosion and if a source is damaged, the appropriate State authorities will be notified.

Illinois Department of Nuclear Safety	**(217) 782 - 7860**
U.S. Nuclear Regulatory Commission	**(312) 790 - 5500**

ITEM #16

[9/84]

AREA SURVEY PROCEDURES

1. All elution, preparation and injection areas will be surveyed daily with a GM survey meter and decontaminated if necessary. Results will be recorded on the form attached: "DAILY RADIATION SAFETY RECORD".

2. Laboratory areas where only small quantities of radioactive material are used will be wipe tested and surveyed weekly. Results will be recorded.

3. All the areas in the Nuclear Medicine Department will be surveyed once a week using a low-level GM survey meter. Results will be recorded. The areas surveyed are:

   A. Dose Preparation Area
   B. Generator
   C. Radioactive Material Storage
   D. Radioactive Material Waste Storage
   E. Floor Near the Dose Prep Area
   F. Tl-201 Stress Unit (if Tl-201 is used during the week)
   G. Injection Area

4. Wipe tests of areas (listed above) A-E, and F if used during the week, and injection areas will be taken once a week. The wipe will be checked in an unrestricted area (natural background radiation levels) using a low level GM survey meter with the window on the probe open. The wipe will be held for approximately 20 seconds as close to the probe as possible, without actually touching the probe.

   If the wipe indicates radiation levels above those of natural background in unrestricted areas (0.1 mR/hr or less), the area will either be secured and/or decontaminated until a wipe indicates natural background radiation levels.

   We have found in our experience that a wipe test of an area is essential when attempting to detect contamination near a radioactive container such as near an Mo99/Tc99m generator. If a GM survey is done, it would be impossible to differentiate between the radiation levels from the source and the radiation levels from contamination in the proximity of the source. But a wipe of the area can be analyzed in an unrestricted area, away from any source of radiation (other than natural background). Hence, the generator area and the dose preparation area (where sources emitting radiation, easily detectable by a GM survey meter, may be stored) would be wipe tested once a week. Any contamination in the other areas in the department would be easily detected by a low level GM survey meter and hence, a wipe test would not be necessary.

WEEKLY AREA SURVEYS

ALL LEVELS IN MR/HR UNLESS STATED OTHERWISE

HOSPITAL______________________________ YEAR__________

SURVEY INSTRUMENT MAKE:__________MODEL__________DUE FOR CALIBR_____

NATURAL BACKGROUND IN UNRESTRICTED AREA IS ________MR/HR

DATE	DOSE PREP	RADIOPHARM STORAGE	RADIO.WASTE STORAGE	REFRIGERATOR	SINK & TRAP	INJECTION AREA	GEN.WIPE WIPE/BKG	DOSE PREP WIPE/BKG	STRESS LAB	CAMERA RM 1	CAMERA RM 2	SURVEY INSTR CHECK	INITIALS

DAILY RADIATION SAFETY RECORD

YEAR_____ HOSPITAL_____

Monitor your clothing and shoes, dose preparation, injection and elution areas prior to leaving the department for the day. Use a low level GM survey meter and record and initial the survey meter readings below. If radiation contamination is detected in any of the surveys, remonitor after decontamination. Record levels in mR/hr.

NATURAL BACKGROUND RADIATION LEVELS ARE: _____mR/hr

DATE	CLOTHING & SHOES	DOSE PREP AREA	INJ. AREA	ELUTION AREA	INITIAL	DATE	CLOTHING & SHOES	DOSE PREP AREA	INJ. AREA	ELUTION AREA	INITIAL

WEEKLY AREA SURVEY

ALL LEVELS IN MR/HR UNLESS STATED OTHERWISE

HOSPITAL_____YEAR_____

SURVEY INSTRUMENT MAKE:_____MODEL_____DUE FOR CALIBR_____

NATURAL BACKGROUND IN UNRESTRICTED AREA IS _____MR/HR

DATE	DOSE PREP Area	RADIOPHARM. STORAGE	RADIO.WASTE STORAGE	REFRIGERATOR	SINK & TRAP	INJECTION AREA	Generator Area	DOSE PREP Floor	STRESS LAB (If used)	CAMERA RM 1	RIA Lab	SURVEY INSTR CHECK	INITIAL

WEEKLY WIPE TESTS

YEAR_____ HOSPITAL.: _____

DATE	RADIOACTIVE STORAGE AREA #_____	RADIOACTIVE WASTE STORAGE #_____	DOSE PREP AREA #_____ L-BLOCK	DOSE PREP AREA #_____ FLOOR	RIA WORK AREA #_____	INJECTION AREA #_____	INJECTION AREA STRESS LAB (If Used)	GENERATOR ELUTION AREA	NATURAL BKG. LEVELS	INITIAL

[Rev. 10/19/83]

Mo99/Tc99m GENERATOR

RADIOACTIVE WASTE, STORAGE AND DISPOSAL

Radioactive waste storage and disposal can be broken down into three categories:

1. Molybdenum-99 Technetium-99m generators
2. Technetium 99m residues
3. "Long-lived" radionuclides: radionuclides with relatively longer (greater than six hours) half-life such as Selenium-75, I-131, etc.

1. Mo99m/Tc99m GENERATOR DISPOSAL

A. The current Mo/Tc99m generator used for daily elution will be stored behind the lead bricks in the hot lab. Generator systems, one week old and older, can be safely stored in their original lead shipping containers for the balance of the decay necessary to reduce levels from the generator core to those of background.

It is estimated that Mo99/Tc99m generators will be decayed for approximately two months from the date of assay; that is, about 25 half-lives. The generator core will be monitored with a low level GM survey meter and, upon reaching background level, will either be incinerated or the labels defaced and discarded.

B. In the event a return program is initiated, the generator may be sent to the supplier intact according to directions received with shipment. The date of the disposal will be recorded on the "RADIOPHARMACEUTICAL INVENTORY FORM". If returned to the supplier, the date will be recorded.

2. Tc99m COMPOUNDS

Ninety percent or more of the radioactivity used in this hospital will be associated with the use of Tc99m in its various chemical forms.

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Tc99m sources and residues, i.e. contaminated syringes, needles, vials of unused Tc99m preparation and Tc99m eluents, will be stored in a plastic bag behind the lead bricks. At the beginning of the following week, the plastic bag containaing the Tc99m contaminated sources will be sealed and held in the Nuclear Medicine Department behind lead shielding. At the end of the week, the contents of the plastic bag containing the decayed compounds (every item in the bag now has been decayed for a minimum of seven days, 24 half-lives) will be brought out from their lead shielding.

The low level survey meter probe will be brought into contact with the unshielded vials and/or syringes. If the meter needle does not deflect above background levels, these formerly contaminated items will be discarded, after defacing or removing the "radioactive" labels . The date of disposal and the survey meter reading indicating background levels will be recorded on the isotope disposition form.

3. UNIT DOSE FROM A RADIOPHARMACY

All used syringes, needles and unused doses will either be stored for decay or will be returned to the radiopharmacy in containers in which the doses were received. A representative from the radiopharmacy will pick up the containers from the hospital. Records of such disposal will be maintained. Applicable Department of Transportation Regulations will be followed.

4. "LONGER HALF-LIFE RADIONUCLIDES

Radionuclides having half-lives up to and including I-131:

Such nuclides and their residues will be stored behind lead bricks. A survey will be conducted with the probe held against the unshielded source. After a period of decay of from one to three months, depending upon the nuclide's half-life, levels as measured with the lowest range on the GM survey meter in excess of background will indicate the need for a continuing period of decay. Finding levels the same as that of background will result in discarding these sources.

Radionuclides having half-lives in excess of I-131 will be diluted via the sewer as early as convenient (in compliance with 10 CFR 20.303).

A measurement of the quantity of radioactivity will be made using the dose calibrator prior to disposing of the radioactivity down the drain. Syringes, needles and vials contaminated with such radionuclides will then be rinsed three or four times and then they will be surveyed unshielded in contact with a low level GM survey meter prior to disposal.

If levels in excess of background are noted, the contaminated articles will be further rinsed until background levels are achieved. In-vitro test wastes in the laboratory will be recorded as 100% sewer-deluted, based on receipt quantity. No measurement with the dose calibrator will be made. The date and quantity of radioactivity sewer-diluterd, will be entered on the isotope disposition form. To comply with 10 CFR 20.303(b), a sample calculation for Se-75 is attached. Similar procedures will be followed for other radionuclides.

To comply with 10 CFR 20.203(d), a separate record of all types of activity sewer-diluted by this institution will also be maintained to ensure that the gross quantity of licensed and other radioactive material released into the sewer system does not exceed one curie per year.

Calculation for the quantity of Se-75 which can be sewer-diluted daily:

As specified in 10 CFR 20.303(b)(1), the average concentration for Se-75 as give in Appendix B, Table 1, Column 2, is 9×10^{-3} uCi/ml.

Quantity of Se-75 which can be sewer-diluted:

= number of beds occupied X 10^6 X Appendix B, Table 1, Column 2, limits for Se-75

= $100 \times 10^6 \times 9 \times 10^{-3}$ uCi/day

= 900×10^3 uCi/day

= 900 mCi/day

The total quantity of all types of radioactivity sewer-diluted is not to exceed 1000 mCi/year.

RADIOACTIVE WASTE DISPOSAL RECORDS

ATE SPOSED	RADIONUCLIDES IN WASTE	DATES DURING WHICH THE WASTE WAS PUT IN THIS CONTAINER		GM READING (mR/hr)	NATURAL BACKGRD (mR/hr)	COMMENTS	INITI
		FROM	TO				

PROCEDURES FOR USE OF GROUPS IV AND V RADIOPHARMACEUTICALS

FOR TREATMENT OF PATIENTS (I-131 THERAPY)

1. Ordering and Handling I-131 Therapy Dose

   A. Ordering:

      The I-131 therapy dose will be ordered when possible, in capsule form, and will be delivered on the morning of the day the therapy is scheduled.

   B. Upon receipt of the therapy dose package, it will be monitored in accordance with conditions of the NRC license.

   C. The source will then be stored, in its lead shielding, in the radiopharmaceutical storage area until the time of administrating therapy.

   D. If the I-131 is obtained in a liquid form:

      (i) The stopper of the vial containing the therapy dose will be opened in the fume hood with the fume hood blower operating.

      (ii) The liquid dose will be administered orally, directly from the shielded vial, using a straw and the vial will be rinsed several times, each time the patient drinking the contents.

      (iii) The "empty" vial will be decayed in storage in accordance with conditions of our license.

      (iv) 24 hour thyroid uptake will be performed on the technologist involved in handling the liquid therapeutic dose.

2. Patients requiring hospitalization and treated with 8 mCi or more of I-131 will be placed in a private room with a toilet, or a semi-private room without another patient.

3. The patient's room will be properly posted in accordance with section 20.203, 10 CFR Part 20.

4. 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, three feet away, and the entrance to the room.

The Radiation Safety Officer or his designate, will then determine how long a person may remain at these positions and will post these items in the patient's chart and on the 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.

5. The form, "NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH I-131", will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

6. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR Part 20.

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

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

9. Non-disposable items used for these patients will be held in plastic bags in the patient's room and checked for contamination by the Radiation Safety Officer (or his designate). Items may be returned for normal use, held for decay, or decontaminated as appropriate.

10. The patient's urine will not be collected. The patient will be instructed to use the toilet and flush the toilet at least three times after each use.

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

ITEM #19

[9/84]

NURSING INSTRUCTIONS

1. 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 care. Nurses should read these instructions before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

2. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.

3. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes, approved by the Nuclear Medicine Department.

4. No nurse, visitor or attendant who is pregnant or under the age of 18 years, 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.

5. Attending personnel must 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 them and then wash hands. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

6. 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 Nuclear Medicine Department for proper disposal of the contents of the designatd waste container.

7. All clothing and bed linens used by the patient should be placed in the laundry bag provided and left in the patient's room to be checked by a member of the Nuclear Medicine Department.

8. All non-disposable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.

ITEM #19

[9/84]

9. The patient will be instructed to void in the toilet and flush the toilet at least three times after use. If the patient is bedridden, a separate urinal or bedpan should be provided. The urinal or bedpan should be flushed several times with hot soapy water after use.

10. If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards, she should wash her hands 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 Nuclear Medicine Department.

11. Disposable plates, cups, and eating utensils will be used by patients who are treated with Iodine-131.

12. Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situations, or if radioactive urine and/or feces is spilled during collection, call the Nuclear Medicine Department. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

13. All vomitus must also be kept in the patient's room for disposal by the Nuclear Medicine Department. 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.

14. 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 Nuclear Medicine Department.

15. If a nurse, attendant, or anyone else knows or suspects that his skin or clothing (including shoes) is contaminated, notify the Nuclear Medicine Department immediately. The person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.

16. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately.

17. When the patient is discharged, call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

ITEM #19

[9/84]

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH I-131

PATIENT'S NAME_____

ROOM #_____PHYSICIAN'S NAME_____

RADIOISOTOPE ADMINISTERERD_____

DATE AND TIME OF ADMINISTRATION_____

EXPOSURE RATES IN MR/HR

DATE	3 FEET FROM BED	10 FEET FROM BED
_____	_____	_____
_____	_____	_____
_____	_____	_____

COMPLY WITH ALL CHECKED ITEMS

_____1. Visiting Time Permitted_____
_____2. Visitors must remain_____from patient.
_____3. Patient may NOT leave room.
_____4. Visitors under 18 NOT permitted.
_____5. Pregnant vistors NOT permitted.
_____6. Dosimeter Badges must be worn.
_____7. Use and complete the follwoing tags:

_____door
_____bed
_____chart
_____wrist

_____8. Gloves must be worn while attending patients.
_____9. Patient must use disposable utensils.
_____10. All items must remain in room until ok'd by RSO
_____11. Smoking is NOT permited.
_____12. Do not release room to admitting until ok'd by RSO.
_____13. Other instructions:

IN CASE OF EMERGENCY CONTACT THE RADIATION SAFETY OFFICER

_____RSO PHONE #_____

ITEM #19

[9/84]

Cs-137 BRACHYTHERAPY SOURCES

(Storage, Inventory and Wipe Tests)

1. The brachytherapy sources, upon receipt, will be assayed in a dose calibrator to ensure that each source has the activity certified by the supplier.

2. The sources will be stored in a secured room with sufficient lead shielding to ensure that the radiation levels from the sources will be as far below 2mR/hr as possible in the unrestricted area.

3. The sources will be inventoried at quarterly intervals.

4. The sources will be wipe tested at intervals required by NRC Rules and Regulations. The sealed sources will be wipe tested as specified in the application for license No. 12-09160-01 issued to Health Physics Associates, Ltd., Northbrook, Illinois.

5. The inventory of the sources when removed from storage for therapy and returned to the storage at the completion of the therapy will be maintained. ("Please see the attached Cs-137 Brachytherapy Sources Inventory Form").

Cs-137 BRACHYTHERAPY SOURCES INVENTORY FORM

SOURCES IN STORAGE:

DATE OF INVENTORY	SOURCE ACTIVITY MILLIGRAM RADIUM EQUILAVENT	NO. OF SOURCES IN STORAGE	SOURCES INVENTORIED BY:
	5		NAME:
	10		SIGNATURE:
	15		
	20		
	30		

SOURCES REMOVED FROM STORAGE FOR THERAPHY:

DATE	TIME	SOURCE ACTIVITY MILLIGRAM RADIUM EQUIVALENT	No.OF SOURCES REMOVED FROM STORAGE	SOURCES LEFT IN STORAGE	SOURCES REMOVED **FROM** STORAGE BY:
		5			NAME:
		10			SIGN:
		15			
		20			
		30			

SOURCES RETURNED TO STORAGE AT THE COMPLETION OF THERAPY:

DATE	TIME	SOURCE ACTIVITY MILLIGRAM RADIUM EQUIVALENT	No.OF SOURCES RETURNED TO STORAGE	TOTAL No.OF SOURCES IN STORAGE	SOURCES RETURNED **TO** STORAGE BY:
		5			NAME:
		10			SIGN:
		15			
		20			
		30			

ARE <u>ALL</u> SOURCES ACCOUNTED FOR ?

yes [ ] **no [ ]** **INITIALS:** _____

RADIATION SAFETY PROCEDURE

FOR

THERAPEUTIC USE OF Cs-137 BRACHYTHERAPY SOURCES

IMPLANT PROCEDURE:

The licensed physician will perform the implants.

A record will be maintained of the number of sources implanted and the number of sources not used.

All personnel involved will be provided with pocket dosimeters or film badges.

Upon completion of the implant procedure, and after the patient has been transferred from the operating room, the room and any containers used (such as containers used in the suction, irrigation, etc.) will be carefully surveyed with a low-level G.M. survey meter.

ITEM #20

[9/84]

Control No. 77478

OPERATING ROOM SURVEYS

Cs-137 BRACHYTHERAPY SOURCES

NAME OF PATIENT: _____

DATE: _____ TIME: _____

SURVEY METER USED: _____ CALIBRATION DATE: _____

Cs-137 SOURCES IMPLANTED:

SOURCE ACTIVITY (mg.Ra.eq.)	No. OF SOURCES IMPLANTED

TOTAL ACTIVITY USED FOR THERAPY = _____ mgm radium equivalent.

1. Are all personnel involved provided with pocket dosimeters or film badges?

   yes[ ] no[ ]

2. Survey of containers, etc. _____ mR/hr

3. Survey of surgical room _____ mR/hr

REMARKS: _____

SIGNED BY _____ DATE _____ TIME _____ A.M. / P.M.

RADIATION SAFETY PROCEDURES

FOR

THERAPEUTIC USE OF Cs-137 BRACHYTHERAPY SOURCES

1. Patient with brachytherapy implants will be placed in a private room that has a toilet.

2. The patient's room will be posted with "CAUTION - RADIATION AREA" sign.

3. Survey of patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Radiation levels will be measured at 3 feet from patient with brachytherapy sources, at the patient's bedside, at 3 feet from the bed and at the entrance of the room.

   The Radiation Oncologist, or his designee, will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet from the patient on the patient's chart. (See the attached form)

4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and attached to the patient's chart.

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

6. Nurses caring for patient will be assigned pocket dosimeters. A record of exposure of each nurse involved will be kept.

7. The implant patient's room will not be released for reassignment until the room has been surveyed to rule out radiation levels above those of natural background levels. The record of these surveys will be maintained.

ITEM #20

[9/84]

PATIENT ROOM SURVEYS

FOR

PATIENTS WITH IMPLANTS OF Cs-137 BRACHYTHERAPY SOURCES

NAME OF PATIENT: _____

ROOM NO. _____ DATE: _____

SURVEY METER MODEL NO. _____ CALIBRATION DATE _____

		YES
1.	Room posted with "CAUTION RADIATION AREA" sign	[ ]
2.	Nursing Staff given "Nursing Care Instructions"	[ ]
3.	Nursing Staff provided with pocket dosimeters	[ ]

4. Radiation Levels:

DO NOT REMAIN LONGER THAN THE TIME INDICATED IN ANY GIVEN HOUR

A.	Bedside	_____ mR/hr	_____ minutes
B.	3 feet from bed	_____ mR/hr	_____ minutes
C.	6 feet from bed	_____ mR/hr	_____ minutes
D.	At door	_____ mR/hr	_____ minutes
E.	Adjoining room	_____ mR/hr	_____ minutes

5. Patient's used gowns, linens, etc.

_____ mR/hr Date _____ Signature _____

_____ mR/hr Date _____ Signature _____

_____ mR/hr Date _____ Signature _____

6. Patient discharged on _____

7. The entire room surveyed? [ ] Yes

8. Natural background radiation levels _____ mR/hr

If any area or article in the patient's room is above natural background radiation levels, give the particulars below:

_____

_____

_____

NURSING INSTRUCTIONS

FOR

PATIENTS WITH IMPLANTS OF Cs-137 BRACHYTHERAPY SOURCES

PATIENT:_____

ACTIVITY:_____mCi of Cs-137 has been implanted

On_____ at_____ A.M. / P.M.

BASIC RULES TO FOLLOW:

TIME: Every effort should be made to spend the least possible time in the patinet's room

DISTANCE: When not giving direct care, keep a distance of at least three feet from the patient.

SPECIFIC INSTRUCTIONS:

1. Patient must remain in his room at all times. The entrance to the room must have a "CAUTION - RADIATION AREA" sign posted in such a manner that anyone entering the room would immediately notice the caution sign.

2. Pregnant employees should not be assigned to the personal care of these patients.

3. Nurses must wear a pocket dosimeter while in the room. One dosimeter will be assigned to each nurse in the shift who will be responsible for the patient care. The nurses will not interchange the dosimeters.

4. If the source becomes dislodged, use long forcepts and put it in a container in the corner of the room. Contact the physician or the Radiation Therapy Department.

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

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

7. All gowns and linens used by the patient should be kept in a plastic bag or container in the patient's room until it has been checked with a radiation survey meter to ensure that no dislodged sources are inadvertently removed.

continued

NURSING INSTRUCTIONS FOR PATIENTS WITH IMPLANTS OF Cs-137 BRACHYTHERAPY SOURCES (continued)

8. Floor and trash cannot be cleaned by housekeeping until patient is discharged or approved by the Radiation Therapist.

9. Surgical dressings and bandages used to cover the area of implant may not be discarded until they have been surveyed with a survey meter. Similarily, all utensils and other such items should be checked with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.

10. Visitors will be limited to those 18 years of age and over, unless other instructions are noted on the patient's chart.

11. Visitors should sit at least three feet from the patient.

12. No nurse, visitor or attendant who is pregnant should be permitted in the room of implant patient.

13. **Emergency Procedure:**

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

    b) If the patient dies, or

    c) If the patient requires emergency surgery,

    Immediately call Dr._____or the Radiation Oncology Department

    TELEPHONE NUMBER - DAYS:_____

    NIGHTS:_____

    RADIATION ONCOLOGY DEPARTMENT EXTENSION:_____

14. Discharge of Patient:

    Before the implant patient's room is assigned to another patient, Dr._____or designate must survey the room thoroughly and maintain a log of the survey levels.

ITEM #20

[9/84]

POCKET DOSIMETER READINGS RECORD

DATE OF USE	TIME INTERVAL OF USE FROM	TO	NAME OF EMPLOYEE	POCKET DOSIMETER NO.	INITIAL READING MREM	FINAL READING MREM	TOTAL EXPOSURE	CHECKED BY DATE	TIME	INITIALS

REMARKS: _____

_____

_____

_____

ITEM #20

[9/84]

ITEM 21

Please refer to our letter dated April 1982, regarding the use and storage of Xenon-133.

This letter was accepted by the NRC and is Amendment No. 19 to our current NRC license. A copy is attached here for completeness.

APPLICATION FOR USE OF XENON-133 GAS

NRC LICENSE AMENDMENT

A. QUANTITIES TO BE USED:

1. It is estimated that approximately 200 patients will be studied per year for Xe-133 pulmonary ventilation. This averages out to be four patients per week. Approximately 20 mCi of Xe-133 will be used per patient; hence, the total quantity of Xe-133 used will be approximately 80 mCi per week.

2. A possession limit of 200 mCi is requested.

B. USE AND STORAGE AREAS:

1. Xe-133 sources used for pulmonary ventilation studies will be received in precalibrated, single dose form. The sources will be stored in the storage container attached to window mounted exhaust fans in the imaging room, in their lead shipping containers. If the radiation level at the face of the storage container exeeds 2mR/hr, additional lead barrier will be used to bring level down to 2 mR/hr or less at the face of the storage container.

2. The exhaust fan in the window will be switched on when:

   (a) Xe-133 sources are stored in the room.

   (b) Xe-133 is in use.

   (c) There is an accidental release of Xe-133 gas.

C. PROCEDURE FOR ROUTINE USE:

1. Close the door between the nuclear medicine room and the corridor.

2. Explain the procedure to the patient.

3. Xe-133 lung function unit, Model 36-002 (without kymograph) from Nuclear Associates will be used. Automatic sequential functions on this unit provide for a single breath (inhalation), equilibrium and washout modes of the Xe-133 ventilation procedure.

   At the end of the procedure, a discharge hose is attached to the external gas port of the lung function unit and the Xe-133 gas is vented through a gas trap (Model #36-023, Nuclear Associates).

continued

Please see attached diagram. The imaging room is supplied fresh air by two floor mounted supply units at the rate of 60 cfm each or a total of 120 cfm. The air supply to each unit is ducted from a central fresh air supply unit.

The open doors of the imaging room act as the exhaust ports, hence, all the room air is exhausted into the corridor.

We have installed a dual speed exhaust fan in the window in the imaging room. The exhaust fan is rated at 300/350 cfm. The exhaust point through the window is approximately ten feet above ground level and there are no fresh air intakes, doors or windows (that may be kept open). There is a sidewalk within approximately 30 feet of the exhaust point.

A small storage unit is attached to the window exhaust fan for storage of Xe-133 sources prior to their use.

The exhaust rate from the fan will be verified semi-annually and a report of verification will be available.

The fresh air supply to the imaging room is 120 cfm. Hence, when the window mounted exhaust fan is switched on, a negative pressure is created in the imaging room When the doors to the corridor are closed, 100% of the room air is vented to the outside.

The window mounted exhaust fan will be installed so that there will be no obstruction to the air flow through the fan.

4. A visual inspection of all tubings, bags, connectors, valves and accessories will be made prior to each study to avoid leakage.

5. In order to avert a patient associated release of gaseous Xe-133, a trial run will be performed with each patient with the face mask and the tubing.

D. EMERGENCY PROCEDURES:

1. Initial concentration =

$$\frac{20{,}000}{2816 \text{ X } 27000 \text{ ml}} = 2.63 \text{ X } 10^{-4} \text{uCi/ml}$$

2. Clearance Rate R =

$$\frac{350 \text{ cfm}}{2816 \text{ cu.ft.}} = 0.1243/\text{min.}$$

3. Desirable concentration level factors in the restricted area =

$$\frac{1 \text{ X } 10^{-5} \text{ uCi/ml}}{2.63 \text{ X } 10^{-4} \text{uCi/ml}} = 0.038$$

4. Time required for the reduction of the concentration to an acceptable level is:

$$\text{Concentration factor} = e^{-Rt}$$
$$0.038 = e^{-0.1243t}$$
$$3.27 = -0.1243t$$
$$t = 26.3 \text{ minutes}$$

In the event that 20 mCi of Xe-133 is released accidentally, the imaging room will be evacuated for a minimum of 27 minutes. The door to the corridor will be kept closed during this time.

Concentration in the unrestricted area:

The calcuations show that if the window fan is kept on for an additional 30 minutes, the concentration of Xe-133 will be reduced to less than $3 \text{ X } 10^{-7}$uCi/ml.

Hence, the window fan will be left in the "ON" position for a total of 57 minutes so that the concentration in the imaging room and the unrestricted area outside of the window fan will be below $3 \text{ X } 10^{-7}$uCi/ml.

E. AIR CONCENTRATION OF XENON-133 IN THE RESTRICTED AREA:

The following calculations indicate that the ventilation rate is adequate to maintain the Xe-133 concentrations below 1 X 10^{-5}uCi/ml.

(a) As mentioned previously, the maximum amount of Xe-133 to be used is estimated at 80 mCi per week. Assuming that a total of 25% of the gas is lost during use and storage, a total of 80 X 0.25 = 20 mCi, will be lost.

(b) The combined volume of the air in the department is 2816 cu.ft. The exhaust rate of the department with the window exahust fan "ON" is 350 cfm.

(c) The total volume of air that the exhaust fan can move in a 40 hour week is:

$$350 \times 6.797 \times 10^{7} = 2.3789 \times 10^{10} \text{ml/40 hr.wk.}$$

(d) The quantity of Xe-133 loss estimation =

$$2.3789 \times 10^{10} \times 10^{-5} = 238 \text{ mCi}$$

Hence, over 238 mCi of Xe-133 can be handled by this exhaust system in a week without exceeding the concentration in 10 CFR 20.103, in the restricted area.

F. METHOD OF XENON-133 DISPOSAL:

When the Xe-133 pulmonary ventilation study is completed, the lung function unit will be connected to the Xenon gas trap and the Xe-133 will be vented into the trap.

The gas trap will be checked for leakage every two hours of use of the trap, as indicated by the "elapsed time meter" on the trap unit. The leak check frequency will be increased to one hour when the "elapsed time meter" indicates 10 hours of usage.

The following method will be used to determine the trap efficiency:

"Balloon Test" method will be used to determine the Xe-133 leakage from the Xe-133 gas trap. Scintillation camera detector without collimator will be used to detect Xe-133 in the balloon.

continued

When the countrate from the balloon exceeds three times the initial countrate (countrate obtained from the first leakage check done on the trap), the trap will be replaced.

The spent cartridge will be stored in the "radioactive waste storage cage" in the subbasement area. As the cartridge will be stored at atmospheric pressure, the chances of Xe-133 "leaking" from the trap unit are essentially nonexistant.

6. RADIATION SAFETY REGULATIONS FOR USE OF XENON-133 GAS:

For the radiation safety of the Nuclear Medicine personnel and patients, the ten precautions listed on the following page will be observed. A copy of radiation safety rules for the use of Xe-133 will be posted in the department for ready reference by the employees.

RADIATION SAFETY FOR THE USE OF XENON-133

During the preparation, administration and performance of this study, all basic procedures of radiation safety, including the proper usage of time, distance and shielding, will be incorporated to reduce the radiation exposure to patient and hospital personnel to an absolute minimum.

1. Store Xenon-133 sources in the storage box so that radiation levels do not exceed 2 mR/hr at face.

2. Visually inspect all tubings, bags, connectors, valves and accessories prior to each and every study to ensure that there are no apparent areas of possible leakage.

3. Absolutely, NO SMOKING, EATING OR DRINKING in the area.

4. The door to the imaging room will be closed for the duration of the study.

5. No personnel other than the patient, physician in charge, and the technologist will be in the immediate area during this study.

6. A background count for Xenon will be performed with the scintillation camera system before and after all Xenon studies to ensure no unobservable release occurred. Should any release occur, any future images will not be initiated until post study background levels are less than twice that of the initial background.

7. In order to avert a patient associated release, the face mask or mouthpiece tubing will be effected with each patient along with an explanation of the operation of the study.

8. Monitoring of the bag, tubing, face mask valves, etc. for residual or absorbed Xe-133 will be accomplished by use of the low level GM survey meter. Contaminated articles will be aired near the vent for release from trapped or absorbed state.

9. In the event of accidental release of a 20 mCi dose of Xe-133, the room in which the discharge occurs will be evacuated and doors locked for 27 minutes. Calcuations are attached. Signs will be posted to this effect.

   Survey the room with a low level GM survey meter with probe "window open" to confirm natural background levels.

10. Exhaust fan will be left on for an additional 30 minutes, bringing concentration down to 3×10^{-7} uCi/ml.

11. Xe-133 trap will be checked at intervals indicated in the application to determine Xe-133 concentration in the exhaust from the trap.