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

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

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

Mercy Hospital
2500 7th Avenue
Altoona, PA 16603

TELEPHONE NO.: AREA CODE (814) 944 - 1681

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

Same as 1.a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Charles A. Sutton, M.D.

TELEPHONE NO.: AREA CODE (814) 949 - 4478

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 37-03387-02

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

See Attached

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.)*

Charles A. Sutton, 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	3 (each)
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	2000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	30
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30
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	X	600
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	400

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
Americium 241	Sealed Source	14	Searle analytic model SS-10244 anatomical marker
Uranium (depleted U-235)	Cadmium plated metal	159 kilograms	Shielding in linear accerator

"OFFICIAL RECORD COPY" 03175

8506170659 850603
REG1 LIC30
37-03387-02 PDR

License Fee Information on Next Page ML10

NOV 30 1984

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
X	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or see attached
	Supplements A & B Attached for Each Individual User; and see attached		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*		X	Appendix I Procedures Followed; or see attached
	Appendix C Form Attached; or		Equivalent Procedures Attached
X	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 see attached *(Check One)*		Equivalent Information Attached
	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		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	
		N/A	Detailed Information Attached
X	Appendix F Procedures Followed; or see attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached	X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Siemens and/or Landauer	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens and/or Landauer	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

As needed bicassay (Item 19).

RECEIVED BY LEGD
Date 12/10/84
Log Dec 31
By Brown
Orig To
Action Compl 12/12/84

Applicant 00460/1580/1K
Check No.
Amount Fee Category
Type of Fee
Copy Check Rec'd
Log No. Renewal 12/10/84 Brown

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL.

NAME OF HOSPITAL

MAILING ADDRESS
N/A

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: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Sister Anne Trzeciak CSFN

(1) NAME *(Type of Print)*
Sister Anne Trzeciak, C.S.F.N.

(2) TITLE
Executive Director

c. DATE
November 21, 1984

PRIVACY ACT STATEMENT

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

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

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

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

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

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

AUTHORIZED USERS

User	Materials/Procedures
Charles A. Sutton, M.D.	Groups I, II, III, IV In-Vitro studies Americium 241 Xenon 133
Paul F. Webster, M.D.	Groups I, II, III Iodine 131 as iodide for treatment of hyperthyroidism and cardiac dysfunction Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases Americium 241 Xenon 133
Jack D. Schocker, M.D.	Groups IV, V, VI Depleted uranium for shielding
William J. Kirsch, M.D.	Groups I, II, III, IV, V Xenon 133
David Schatanoff, M.D.	Group VI Depleted uranium for shielding
Rudraraju P. Raju, M.D.	Group IV, V, VI Depleted uranium for shielding

RADIATION SAFETY COMMITTEE

1. Members (with specialties) of the Radiation Safety Committee will be as follows:

C.A. Sutton, M.D.	Radiation Safety Officer, Chairman
W.J. Kirsch, M.D.	Pathologist
C.M. Haas, Jr., M.D.	Pathologist
P.F. Webster, M.D.	Radiologist
J.D. Schocker, M.D.	Radiotherapist
D. Schatanoff, M.D.	Radiotherapist
G. McNerney	Radiation Physicist
T. Dillon	Radiation Physicist
R. Roberts	Nursing Service
P. Goven	Assistant Administrator
M.C. Tsai, M.D.	Internal Medicine

2. The Radiation Safety Committee will meet at least quarterly, or more often as necessary to conduct its business, and the duties and responsibilities will be in accordance with those listed in Appendix B to NRC Guide 10.8 (as revised October, 1980).

TRAINING AND EXPERIENCE

Training and Experience

Training and experience for authorized users can be found in previously submitted materials.

1. Charles A. Sutton, M.D. : Dr. Sutton's documentation has been previously submitted.

2. Paul F. Webster, M.D. : Dr. Webster's documentation has been previously submitted.

3. Jack D. Schocker, M.D. : Dr. Schocker's documentation has been previously submitted.

4. William J. Kirsch, M.D. : Dr. Kirsch's documentation has been previously submitted.

5. David Schatanoff, M.D. : Dr. Schatanoff's documentation has been previously submitted.

6. Rudraraju P. Raju, M.D. : Dr. Raju's documentation has been Previously submitted.

Instrumentation

Instrument	No. Available	Range
Keithly X-Gamma Survey Meter Ion Chamber Type	Model 36100	0-20 R/H
Atomic Products Model 069-701 GM Survey Meters	2	0-50 mR/hr
Victoreen Model 471A Ionization Survey Meter	1	0-1000 mR/hr
Victoreen Panaramic Survey Meter	Model 470	0-1000 R/H
Victoreen Thin End Window Survey Meter	Model 493-489-39 Probe	0-10mR/H
Texas Nuclear Survey Meter	Model 2652	0-100mR/H
Capintec Model CRC-8 Dose Calibrator	1	--
Capintec Model CRC-5R Dose Calibrator	1	--
Searle LFOV Gamma Camera	1	--
General Electric Gamma Camera	1	--
(1) Picker Spectroscaler/Well Counter	Model 3161	
(1) Abbott Scintillation Counter	Model 221	
(1) NMC Gas Proportional Counter		
(1) Victoreen TLD reader	Model 2800	
(1) Victoreen Radicon III Dosimetry System		
(1) Victoreen Condenser R-Meter	Model 570	
(1) Keithley Digital Posimeter System	Model 35614	

Instrument Calibration

1. Survey instruments will be calibrated in accordance with the provisions of Appendix D to NRC Guide 10.8 (as revised October, 1980) by the following service organization:

   Mid-Atlantic Radiation Physics, Inc.
   10408 Truxton Road
   Adelphi, Maryland

   Calibration procedures are in accordance with those in Appendix D to NRC 10.8 (as revised October, 1980) and are on-file under Maryland radioactive materials license MD-33-023-01.

   Alternatively, survey instruments will be calibrated in-house by therapy staff physicists in accordance with the provisions of Appendix D and the procedures entitled "Calibration of Survey Instruments" (copy attached).

2. The dose calibrator in the Nuclear Medicine Lab will be calibrated in accordance with the procedures in Appendix D to NRC Guide 10.8 (as revised October, 1980). For linearity testing of the dose calibrator, if generator usage is discontinued and unit doses of radiopharmaceuticals are purchased, then linearity testing will be accomplished with an initial Tc-99m activity sufficient to test linearity over the clinically useful range of activities. As an alternative means of linearity testing (instead of the decay method described in Appendix D) the Calcorp's Calcheck system may be used. This system consists of a set of lead-lined sleeves that allows the simulation of several source strengths with a single source. Should the tolerance of 5% be exceeded on subsequent testing, the corrective procedures of Appendix D will be followed.

DOSE CALIBRATOR

Activity Linearity Testing the easy way

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.

Accurate and Reliable

The new Calicheck kit is designed to attenuate ^{99m}Tc 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, 20, 30, 40 and 50 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 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 Cost

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 $375.00 shipping included.

Just call (216) 641-6841 or write: Calcorp, Inc., P.O. Box 25589, Cleveland, Ohio 44125–0589.

Just four minutes

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

May require approval of the Agency issuing your radioactive materials license.

Calicheck™

• DOSE CALIBRATOR ACTIVITY LINEARITY TEST KIT •

Patent No. 4333010

CALIBRATION OF SURVEY INSTRUMENTS

Sources

The sources to be used will be encapsulated Cs-137 brachytherapy sources (tubes) from Nuclear Associates, Inc., Model 67-800 series. These have been intercompared with NBS traceable sources using a 4 π well ionization chamber by the manufacturer, and are accurate to $\pm$ 2% at the 95% confidence level. There are 9 sources with a net nominal activity of 125 milligrams-radium-equivalency. Physical dimensions are 0.3 cm in diameter x 1.5 cm active length. This means that there is sufficient activity to produce 1 R/hr exposure rate at a distance such that point source behavior is assured, being greater than 10 times the maximum source extent.

Frequency

- before each use, a reference source will be read
- annual calibration, as a minimum, and following repair/battery change

Procedure

Sources will be removed from storage safe into linac room or transported to an x-ray suite in standard lead-lined carrier. Using long forceps as needed, sources will be arranged in a minimum-scatter, close-packed geometry. Each meter will be placed in the field and calibrated at two points (one-third and two-thirds) on each scale, either by internal adjustment or by generating a graph or calibration factors to be attached to the meter. The RSO shall designate the individual (a physicist) to perform these calibrations, and the individual will be film-badge monitored. Exposure to other individuals will be avoided. Additionally, G-M type meters used for low energy measurements will be intercompared on the lower ranges against a more energy-independent ionization-type meter (such as a Victoreen Model 440) for Tc-99m or Co-57. Following calibration, the reference source will be read and recorded for future daily checks.

Facilities and Equipment

1. Floor plans: see previously submitted materials.

2. Equipment available: see previously submitted materials.

Personnel Training Program

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all ancillary personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in items A and B below, and that radiation workers (i.e., technologists) receive instruction in all items below.

A. Areas where radioactive materials are used or stored.

B. Potential hazards associated with radioactive material.

C. Radiological safety procedures appropriate to their respective duties.

D. Pertinent NRC regulations.

E. Pertinent terms of the license.

F. Their obligation to report unsafe conditions.

G. Appropriate response to emergencies or unsafe conditions.

H. Their right to be informed of their radiation exposure and bioassay results.

I. Locations where the licensee has posted or made available notices, copies of pertinent licenses, and license conditions (including applications and applicable correspondence), as required by NRC regulations.

Personnel will be properly instructed as follows:

A. Before assuming duties with or in the vicinity of radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms of the license.

Procedures for Ordering and Receiving Radioactivew Materials

1. Orders for radioactive material will be placed by the radiotherapist, chief of Nuclear Medicine, or individuals designated by them. These persons shall insure that the materials and quantities requested are authorized by the license.

2. During normal working hours, carriers will deliver radioactive packages directly to the respective departments, where receipt procedures will be carried out.

3. During after-duty hours*, all radioactive material will be brought to the Nuclear Medicine Lab by the carrier. X-ray or security personnel will unlock the door, the package will be placed in the center of the floor, and the room re-locked. The next time the department is opened, the technician will perform a cursory survey of the materials. If an irregularity is noted, a complete survey will be performed then. If there is no problem, materials will be sent to the other departments via persons that are monitored (film-badged) for complete receipt procedures.

* No after-hours shipments are anticipated.

DATE: November 1984

TO: Security Personnel, Radiology Technologists

FROM: Sr. Anne Trzeciak, Executive Director Sr. Anne

SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive at the hospital after receiving departments have been closed i.e. in the PM, early AM or on Sundays shall be taken immediately to the Nuclear Medicine Department. The door will be unlocked and the package will be placed in the center of the floor and the room relocked. The Security guard on duty and/or the Radiology technologist will then sign for the package.

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

RADIATION SAFETY OFFICER - Charles A. Sutton, M.D.

OFFICE PHONE - 814-949-4478

HOME PHONE - 814-695-9406

Alternate: RSO Gerald McNerney, Physicist
Office: 814-949-4280
Home: 814-696-9406

Terrence Dillon, Physicist
Office: 814-949-4280
Home: 814-946-8852

Procedures for Safely Opening Packages Containing Radioactive Materials

The procedures of Appendix F of NRC Guide 10.8 (as revised October,1980) will be followed with the following addendum:

For in-Vivo and in-Vitro RIA materials where quantities are 20 uCi or less per package, these kits will be logged in by date, condition of package, and description (including type and amount of radioisotope) provided that these kits are not received in the same box with higher-activity materials. If the potential of cross-contamination from other materials should be present, a complete survey will be performed.

General Rules for Safe Use of Radioactive Material

The provisions of Appendix G to NRC Guide 10.8 (as revised October, 1980) will be followed.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

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

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

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

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

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

Major Spills

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

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

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

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

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

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

RADIATION SAFETY OFFICER: _____*
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____
_____
_____

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

RSO: Charles A. Sutton, M.D. Office: 814-949-4478
Home : 814-695-9406

Alternate: RSO Gerald McNerney, Physicist Office: 814-949-4280
Home: 814-696-3902

Terrence Dillon, Physicist Office: 814-949-4280
Home: 814-946-8852

Mercy Hospital, Altoona, PA
NRC 37-03387-02

Item 16
November, 1984
p. 1 of 1

Area Survey Procedures

Area surveys will be conducted in accordance with the procedures described in Appendix I to NRC Regulatory Guide 10.8 (as revised October, 1980) with the following addendum:

The waste storage areas and all other laboratory areas of the Department of Radiation Oncology will be surveyed after each use.

APPENDIX J

WASTE DISPOSAL

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

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

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

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

____ Other (specify): _____

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

X Returned to the manufacturer for disposal.

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

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

____ Other (specify): _____

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

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

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

____ Other (specify): _____

4. The commercial waste disposal service used will be

Radiac Research Corp., Brooklyn, NY*

(Name) (City, State)

NRC/Agreement State License No. _____

* or equivalent vendor such as Radiation Services Organization of Laurel, Maryland

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

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

RADIATION SAFETY PROCEDURES FOR

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected.

2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 of 1- 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 a tthe patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Physicist will then determine how long a person may remain at these positions and will post these times on the patient's chart and in his room. The results of daily surveys will be used to recalculate permitted times which will be posted on the patient's chart and in his room.

4. The form, Special Instructions for Systemic Radioisotope Therapy, will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's room.

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

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

7. 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 daily by the Physics Staff, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. 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 Physics Staff. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

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

PART 11 NURSING INSTRUCTIONS

ADMINISTRATION OF THERAPEUTIC DOSES OF UNSEALED RADIOISOTOPES

(Isotopes in liquid form such as I-131-Iodine, 32-Phosphorus, and 198 Gold given intrapleurally, intraperitoneally, or orally.)

1. Order isolation cart for protective care from Central Service.

2. Follow all general directions. (See Item 20: Nursing Care of the Patient Receiving Internal Radiation Therapy) In addition:

   a. Patient shall be in a private room, with private bath, and if possible, at the end of the hall on an outside wall.

   b. Use plastic matress covers and pillow covers to lessen danger of contaminating the bed and pillows.

   c. Disposable gloves shall be worn by nursing personnel while caring for the patient.

   d. Dressings and linen must be monitored before being discarded.

      1. Handle carefully with gloves to decrease possibility of transferring radioactive contamination (try to prevent articles from touching clothing).

      2. Place linens and dressings in separate plastic bags.

      3. Store bags in patient's room until they are monitored and declared free of contamination by a radiation physicist.

   e. If the patient's skin becomes contaminated by leakage through dressings, urine, feces, perspiration, or emesis, remove bedclothes, wash skin area with soap and water. Wear disposable gloves. Save clothing, etc. for monitoring.

   f. After disposing of gloves, wash hands thoroughly.

   g. Special precautions for patients receiving oral 131-Iodine in therapeutic doses (administered activity greater than 50 millicuries).

      1. Disposable gloves must be worn by all individuals entering the patient's room (NO EXCEPTIONS). The use of aprons or other clothing protection is optional.

      2. The use of disposable items (e.g., food trays, utensils) is strongly recommended for the patient. Both nondisposable and disposable items must be collected separately in special plastic-lined containers and must be monitored for radioactivity. These containers will remain in the patient's room until transfer or disposal by Radiation Oncology personnel according to results of radiation monitoring.

      3. Urine may be saved in (polyethylene) containers and monitored for radioactivity. These containers will remain in the patient's room until transfer or disposal by Radiation Oncology personnel.

4) Bedpans should be washed thoroughly with soap and water after each use. The water from this washing and rinsing may be flushed down the toilet in the patient's room. Gloves used for this procedure should be washed before disposal.

5) Linens must be monitored before being cycled.

6) Handle all items in room carefully.

7) If the patient vomits within 24 hours of receiving the dose, notify Radiation Oncology. DO NOT dispose of vomitus or soiled clothes until monitoring is done. Keep these articles in plastic bags.

8) If the patient is incontinent or otherwise spills some urine, the radiation physicist must be called. Put absorbent pads on the area of the spill, but do not attempt to clean-up the spill until radiation monitoring is done.

9) The patient's bed and clothing should be changed, if necessary, and these items saved for monitoring.

3. Patient shall not be discharged from private accommodations until clearance is given by Radiation Physicis.

4. When patient is discharged, close room and do not remove any items from the room until clearance is given by Radiation Physics.

Mercy Hospital

2500 SEVENTH AVENUE -::- ALTOONA, PENNSYLVANIA 16603
(814) 944-1681

RADIATION ONCOLOGY DEPARTMENT

Patient Name _____ Room Number _____

Radionuclide _____ _____ mCi/mg Ra eq.

Administered/Inserted - Date _____ Time _____

Administered By Doctor _____

Route of Administration

Intracavitary _____ Interstitial _____ Systemic _____

_____ M.D.
Physician's Signature

INITIAL EXPOSURE RATES

Measured by _____

Exposure rate at 1 meter _____ mR/hr

At door _____ mR/hr

Behind shield at 1 meter _____ mR/hr (if used)

INSTRUCTIONS

Patient Must Remain In Hospital

_____ until implant is removed

_____ until (date) _____

At such time, "Precautions" tag may also be removed.

The Radiation Oncology Department must be notified before discharge or transfer of patient, unless radioactive material has been removed.

In case of an Emergency, notify the Radiation Oncology Department, the attending physician and the Radiation Physicist. The telephone operator has a call list for use when these sections are not open.

OTHER INSTRUCTIONS

- - No pregnant or potentially pregnant visitors permitted.
- - No children under 18 years of age permitted.
- - Other visitors may stay _____ minutes per day.

SPECIAL NURSING INSTRUCTIONS

- - No pregnant or potentially pregnant nurses permitted.
- - Keep hamper in room for used linen.

Date _____

Signature/Title _____

Item No. 19
Date: May 30, 1979

FORM A

GENERAL NURSING INSTRUCTIONS FOR PATIENTS

RECEIVING UNSEALED RADIOISOTOPE THERAPY

Unsealed Radioisotope therapy indicates the patient has been administered a liquid Radioactive substance, or has ingested a radioactive substance that subsequently enters all the fluid systems of the patient's body. Any one or anything coming in contact with the liquid or possibly any body fluids of this patient may become contaminated with the Radioisotope. The Radiation Safety concern is two fold: (1) The possible Radiation exposure; and (2) the possible contamination and absorption of the Radioisotope into the body of visitors and hospital personnel coming in contact with the patient. In order to minimize this exposure and the possibility of contamination, the following instruction are to be followed.

1). Patient may not leave this room under any circumstances without immediate notification and/or permission of the Department of Radiation Oncology.

2). Do not remove from this room any linens, dressings, or pads without authorization (Save in room).

3). Disposable gloves must be worn by anyone coming in contact with the patient or handling any dressings, linens, or pads in contact with the patient. (Save used gloves in room until monitored)

4). No pregnant or potentially pregnant nurses, hospital personnel, or visitors are permitted to enter this room.

5). No visitors under the age of 18.

6). Nurses should rotate duties to provide comprehensive care to this patient while observing individual exposure limits.

7). Contact Department of Radiation Oncology immediately if:

   a). There is a leakage of a large quantity of Radioactive (or suspected radioactive) fluid. (Do not remove from room)

   b). Patient exhibits signs of a marked change in state of health (serious illness, extreme discomfort, etc. not present at time Radioisotope was administered).

8). For a further discussion on General Nursing Procedures refer to the Nursing Manual under "Nursing Care of the Patient Receiving Internal Radiation Therapy."

Department of Radiation Oncology
Extension 4280 (8:00 AM - 4:30 PM: Monday Thru Friday)
During non-working hours please contact the telephone operator for home phone number or paging.

SPECIAL NURSING INSTRCTIONS FOR SYSTEMIC RADIOISOTOPE THERAPY

Name _____ ROOM# _____

Isotope _____ Activity _____ mCi

	DATE	TIME	ACTIVITY	EXPOSURE RATE @ 1 METER	ESTIMATED RETENTION	COMMENTS
Initial Survey						
24 Hrs.						
Dismissal Survey						

Placement of Shield _____

Initial Exposure Rate: @ 1 meter_____mR/Hr; @ 1 meter behind shield_____mR/Hr

VISITORS

_____may stay up to _____minutes per day.

_____must remain behind shield.

_____must remain at least 6 feet from patient.

This patient has a Radioisotope throughout all body fluid systems. The risk of comtamination is from any and all body fluids. (Urine, perspiration, blood, saliva, vomitus, etc.)

1). Anyone entering the room must wear disposable gloves.

2). Disposable items should be used whenever possible (food trays, thermometers, etc.)

3). All disposable and non-disposable items must be kept in seperate containers until monitored by Radiation Physics Personnel.

4). No item may be removed from this room without authorization - <u>This includes blood and urine samples.</u>

5). Patient should drink plenty of fluids and shower several times daily. Toilet should be flushed several times after each use.

6). After patient discharge, close door to room and restrict entry. Do not remove anything from room or start clean up until room is monitored by Radiation Physics Personnel.

7). SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT.

Item 19
Date: November 1984

SPECIAL NURSING INSTRUCTIONS FOR RADIOISOTOPE INSTILLATIONS

NAME _____ ROOM# _____

ISOTOPE _____ ACTIVITY _____ mCi

TYPE OF INSTILLATION _____ DATE _____ TIME _____ AM/PM

Discharge/Radiation Precautions Discontinued DATE _____ TIME _____ AM/PM

Initial Survey		Dismissal Survey	
Patient @ 1 meter	_____ mR/Hr	Patient @ 1 meter	_____ mR/Hr
Patient - contact	_____ mR/Hr	Patient - contact	_____ mR/Hr
		Trash	_____ mR/Hr
		Linens	_____ mR/Hr
		Room - (max.)	_____ mR/Hr

Placement of shield _____

VISITORS

_____ may stay up to _____ minutes per day.

_____ must remain behind shield.

_____ must remain at least 6 feet from patient.

This patient has had a Radioisotope instilled into a body cavity. The isotope is principally confined to the cavity and the risk of contamination is from seepage of fluid from the cavity.

1). Patient may/may not have normal food tray.

2). Gloves should be worn when changing dressings or pads that may have been contaminated with seepage from the site of instillation. Bag and save dresssings, pads, and gloves separately from other disposable items.

3). Linen must be saved in room until monitored by Radiation Phyiscs Personnel.

4). Notify the Department of Radiation Oncology immediately should anyone desire to remove fluid accumulation.

5). SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT.

Item 19
November 1984

12. WASTE DISPOSAL

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

Bioassay Procedures

Bioassay studies of occupationally exposed personnel will be performed when there is believed to be a risk of significant internal exposure. Commensurate with the relative infrequency of handling millicurie quantities of Iodine-125 or Iodine-131, the following bioassay procedures will be followed:

1. Any individual who handles (1). more than 200 mCi of nonvolatile, high-specific activity compounds of I-125 or I-131, or (2). more than 1 mCi of these isotope compounds in volatile form, at any one time shall be bioassayed.

2. Between 6 and 72 hours after exposure, the person above will be bioassayed for I-125/I-131 by urinalysis and/or thyroid counting by gamma camera. This shall be performed under the supervision of the Chief of Nuclear Medicine.

3. If bioassay indicates that the thyroid burden is greater than 0.12 uCi of I-125 or 0.04 uCi of I-131:

   a) an investigation of the causes of the exposure will be undertaken to determine causes of the exposure and to evaluate the potential of recurrence;

   b) a repeat bioassay will be made within 14 days of the first measurement to aid in calculating dose committment;

   c) notification, as stipulated by Section 20, 10 CFR will be carried out if needed.

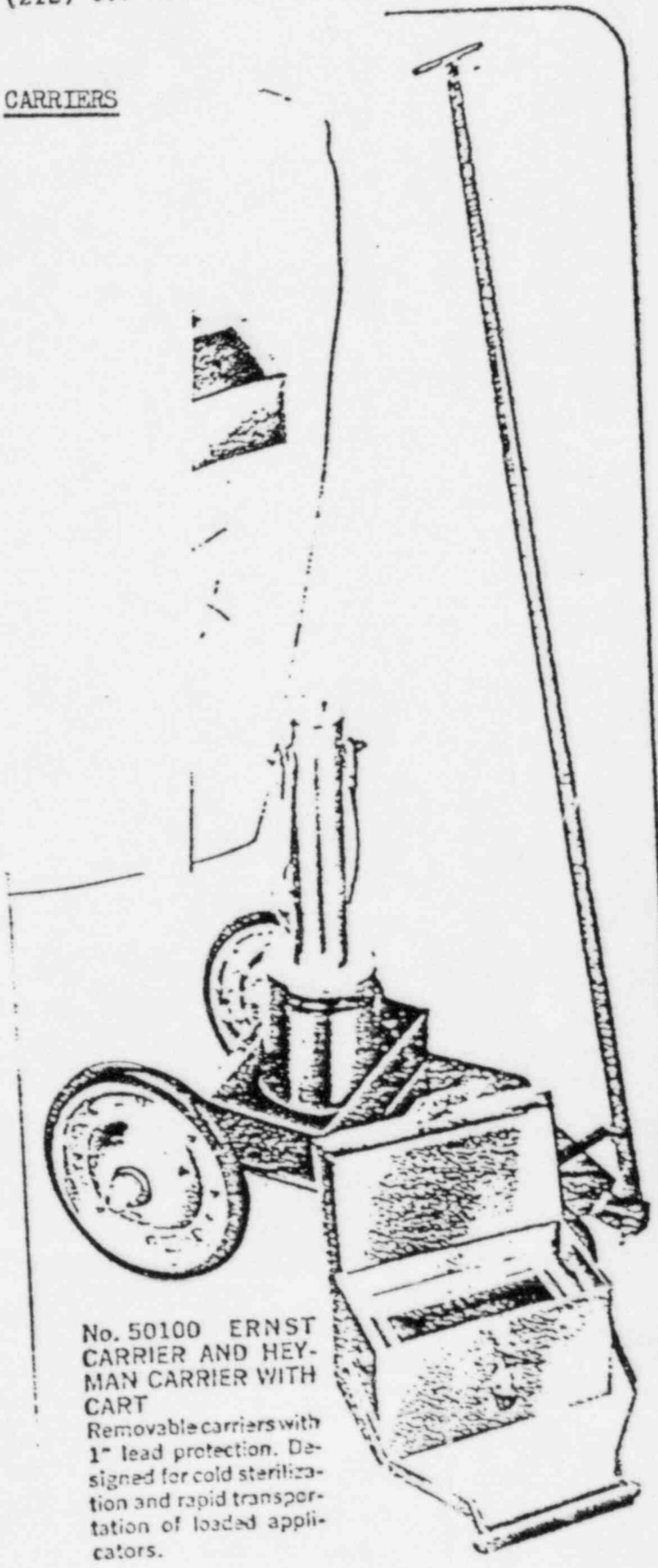
4. If bioassay indicates burdens in excess of 4 times those listed above, procedures will be implemented to accelerate removal of radioactive Iodine from the body. Additionally, repeat bioassays will be performed weekly until levels are below those listed above.

5. Results of all bioassays will be maintained for inspection.

ADIUM CHEMICAL COMPANY INC.
161 EAST 42ND STREET
NEW YORK, N.Y. 10017

(212) 687-2180

DESCRIPTION OF CESIUM SOURCE CARRIERS



No. 50100 ERNST CARRIER AND HEYMAN CARRIER WITH CART
Removable carriers with 1" lead protection. Designed for cold sterilization and rapid transportation of loaded applicators.

Item 20
Date: October, 1979

Storage of Sealed Sources

The sources will be storded in a leaded storage safe when not in use. The same contains four inches (10.2 cm.) of lead on all sides as shielding materials.

The storage safe will be located in the medical linear accelerator room, which was designed to house a Varian Associates, Inc., Model Clinac-IV accelerator.

The treatment room is located on the basement floor of a new addition to the hospital. The outside walls of the treatment room contain a minimum of thirty (30) inches of standard density (147 lbs/ft^3 or 2.35 g/cm^3) concrete. With the exception of a maze wall, any inner walls contain a minimum of twenty-four (24) inches of concrete as shielding. The ceiling contains at least thirty six (36) inches of concrete in addition to flooring and/or roofing materials. The space below the treatment room is inaccessible.

Using date from Report #49 of the National Council on Radiation Protection and Measurements, the 10.2 cm of lead in the safe provides an exposure reduction factor of approximately 2E-5, based on a tenth value thickness of 21.6 mm of lead for ^{137}Cs. The lead storage safe provides adequate protection to reduce exposure levels from the stored sealed sources to levels on the order of natural background rates (i.e., in micro-rem per hour), far below the acceptable levels of Section 20.101 of 10 CFR Part 20.

For the concrete support and barrier walls, the tenth value thickness for ^{137}Cesium is 15.7 cm, and exposure reduction factors of 1.3E-4, 1.4E-5 and 1.5E-6 are afforded by the concrete thickness of 24, 30 and 36 inches, respectively.

Based on the exposure reduction factor of 1.4E-5 for the outside walls, exposure rates and radiation levels to unrestricted areas (the area beyond the outside wall is accessible) would be for the levels of Section 20.105 (a) of 10 CFR Part 20. The concrete alone would reduce radiation levels far below the limits of Section 20.105, and in conjunction with the shielding afforded by the storage safe, radiation levels at the outside wall due to the presence of the ^{137}Cs sources would be virtually unmeasureable.

Handling of Sealed Sources

The use of afterloading applicators is intended to minimize the radiation hazard to personnel from the sealed sources.

For the tube-type sources (Nuclear Associates Model 67-800 series ^{137}Cs sources), loading of the applicators will be performed using forceps, tongs or other manipulative devices to reduce the radiation exposure to the extermities. Personnel involved with the loading and unloading of the applicators will utilize a lead L-block to shield the headed body. The L-block contains approximately two inches (5 cm) of lead as shielding and also has a leaded glass window. The 5 cm lead thickness reduces exposure to 0.5% (0.005 relative transmission) while the lead glass window (5 cm thick, 6.2 g/cm^3 density) reduces exposure to 5.4% of the initial intensity.

For the MICRAD™ Sources (Nuclear Associates Model 67-600 series) the separation of the active length from the handler affords a great extremity exposure reduction. No intermediate applicators are necessary, so loading and unloading of the sealed sources involves even less radiation exposure to attending personnel.

Personnel involved with the loading, unloading or other handling of the sealed sources will wear and use ring monitors containing thermoluminescent dosimeters to measure extremity exposure. These will be in addition to the whole body film badges worn by departmental personnel.

A copy of the instructions for the "Sealed Source Curator" follows.

INSTRUCTIONS FOR SEALED SOURCE CURATOR

Mercy Hospital, Altoona, PA

1. Keep storage safe locked except when removing/returning sources.

2. All cesium sources must be accounted for everytime the storage safe is opened. This involves counting the sources and checking all the sources not in the safe against current cesium insertions. Record this information in the Brachytherapy log book. If any discrepancy is noted, notify the Radiation Therapist immediately.

3. Wear ring badges whenever handling the sealed sources.

4. Applicators (but no radioactive material) wil be sterilized by Central Supply.

5. Insertion and removal of the radioactive materials will be performed in the Radiation Oncology Department or the patient's room.

6. Immediately after every insertion into the applicators, return all unused cesium to the safe. Count and record results in the usage log book. If incorrect, notify Radiation Oncology physicians immediately.

7. A nursing instruction form (Form A) must be completed and inserted as the first page of the patient's chart following insertion.

8. See that the cover of the patient's chart is labeled with a "Caution, Radioactive Material" tag. Radiological safety instructions are to be included.

9. Check to see that all surveys of and concerning the patient are done and properly recorded in the log book.

11. After the radioactive sources have been removed, the proper source counts and dismissal surveys should be done according to the usage book form. The applicators themselves (not containing the sources) should be removed from the patient by a physician.

12. Following removal, applicators should be cleaned and sent to Central Supply for resterilization.

13. If sources must be transported, use proper shielded mobile containers.

Item No. 20
Date: November 1984

INVENTORY CONTROL AND SOURCE ACCOUNTABILITY

A log of the use of the sources for Brachytherapy treatments will be kept by the personnel who use and handle these sources (primarily the Radiation Therapy Physicists).

The entries in this log will include:

a) the name and location (room number) of the patient.
b) the applicator (s) and activities used in the implant.
c) the initials or signature of the individual who prepared the applicators.
d) strengths used
e) date and time of source insertion.
f) date and time of removal of sources from the patient, with the signature of the individual who removed the sources.
g) date and time of the return of the sources to the storage safe, with initials or signature of the individual doing this.
h) results of patient/room survey after sources removed.

A count of the number of sources present in the storage safe will be made both prior to applicator loading and following the return of the sources to the storage safe after removal of the sources from the patient. The count will be made to assure that the number of sources of any given activity agrees with the inventory number (the storage will be segregated by strength in the drawers of the storage safe). The results of the counts will be recorded in the Brachytherapy log book, along with the initials or signature(s) of the individuals who performed the counts.

Also recorded in the log book will be the results of the survey of the patient's room and adjacent areas (a sketch or drawing of the patient's room and other areas surveyed, with the measured exposure rates due to the implanted sealed sources, constitutes the initial survey) as well as the results of the follow-up survey. This follow-up survey will consist of meter measurements of the patient and his room to confirm that no sources remain.

The described method of inventory will be followed whenever the sealed sources are used for treatment. A more detailed, complete inventory of the sealed sources received, possessed and used will be performed on a quarterly basis following the requirements of Section 35.14 (b) (5) (4) of 10 CFR Part 35.

BRACHYTHERAPY ROOM SURVEY PROCEDURE

The purpose of the Brachytherapy Room Survey is to assure that no licensed material is used "in such a manner as to create in any unrestricted area...:

"(1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour, or

"(2) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days." (10 CFR Part 20.105)

In order to assure compliance with the above regulations, the following procedure is adhered to:

ROOM SELECTION AND PREPARATION

All brachytherapy patients are assigned to a private room on Pavilion I. All nursing personnel on Pavilion I are assigned film badges. When the patient containing radioactive material is present in the room:

(1) a portable shield is placed at the patient's bedside between the patient and the hallway and centered about the sources for all patients with exposure rate greater than 2 mR/Hr at 1 meter.

(2) the door to the room is posted as a restricted area.

(3) a wristband is placed on the patient with a "Radioactive Materials" caution.

(4) the patient's chart (front cover) is posted with a radiation caution label.

(5) general and specific nursing instructions are placed in the patient's room.

ROOM SURVEY:

(1) a diagram of the patient's room is entered in the Brachytherapy log book. This diagram shows the position of the patient, the sources, and any shields.

(2) Direct readings of the exposure rate at a minimum of the five following points are taken and recorded on the diagram (see figure 1):

(1) side of bed at 1 meter -- this gives the maximum exposure rate at 1 meter and is on the side of the room which is the outside wall of the room.

(2) head of bed -- this will yield the exposure rate to the adjacent room, which is an unrestricted area.

(3) foot of bed -- this will yield the exposure rate to the adjacent room, which is an unrestricted area.

(4) behind shield at 1 meter -- this gives the pelvis and thorax exposure rate to personnel behind the shield.

(5) doorway -- this is the exposure rate to the unrestricted hallway area.

Point (2) -head of bed- may be augmented or replaced by a direct reading of the exposure rate in the adjacent room at the discretion of the surveying personnel.

POINT SELECTION AND DATA ANALYSIS:

It is the intent of this department to protect the health and welfare of the hospital staff and the public - as well as comply with all applicable regulations - but with an absolute minimum of disruption and attention. It should be noted that the sight of a white coated technician or physicist, survey meter in hand, monitoring the room of a patient adjacent to, but otherwise uninvolved with, radiation sources can cause a high level of anxiety which can and should be avoided when possible.

From the readings measured above, the following information can be obtained:

(1) side of bed at 1 meter: this is the maximum exposure rate at 1 meter. The outer wall is an unrestricted area but is three stories above ground level and so is of no concern. The floors and ceilings are of a composite structure consisting of at least four and three quarters inches of concrete plus some steel (greater than one quarter inch). This is a little more than two and one half HVL of shielding. Additionally, the floors are over 3 meters in height. It can be estimated, then, that the maximum permissible exposure rate at 1 meter to restrict the exposure rate on floors above and below the patient's is 2 mR/Hr X 6 X 9 = 102 mR/Hr. For our purposes a base exposure rate of 100 mR/Hr is used.

(2) head of bed: This measurement is taken at the forehead or crown of the patient's head. Obviously the greatest distance from the sources to this point is for endocavitary insertions. In this "worst case" it is estimated the measurement is made three feet from the sources (we have not had an endocavitary implant on a patient greater than 6 feet in height. Measurements on one individual , 5 feet 10 inches in height, yielded a measurement from mid pelvis to crown of head of 30 inches). It is estimated that this measurement is taken 12 inches from the wall. It is estimated the wall is 6 inches thick and it is estimated the lens of the eye of the patient in the adjoining room is 18 inches from the wall. It can be estimated, then, that the maximum permissible exposure rate at this point to restrict the exposure rate to the lens of the eye of a patient in an adjoining room is 2 mR/Hr X 4 = 8 mR/Hr. If the term "dose" is interpreted to mean "whole body dose" this limit could be considered to be a factor of 2 higher. For our purposes a base exposure rate of 8 mR/Hr is used.

(3) foot of bed: This measurement is taken at the foot of the patient's bed (generally within the footboard). In general the distance from the sources to the adjoining room is more than

three times the distance from the sources to the point of measurement. This estimate can be adjusted at the discretion of the surveying personnel for specific cases. In general, then, it can be estimated that the maximum permissible exposure rate at this point to restrict the exposure rate in an adjoining room is 2 mR/Hr X 9 = 18 mR/Hr, unless otherwise indicated.

(4) behind shield at 1 meter: This measurement is used to estimate exposures to visitors and staff. It also dramatically illustrates for nursing personnel the reduction in exposure when the shield is utilized.

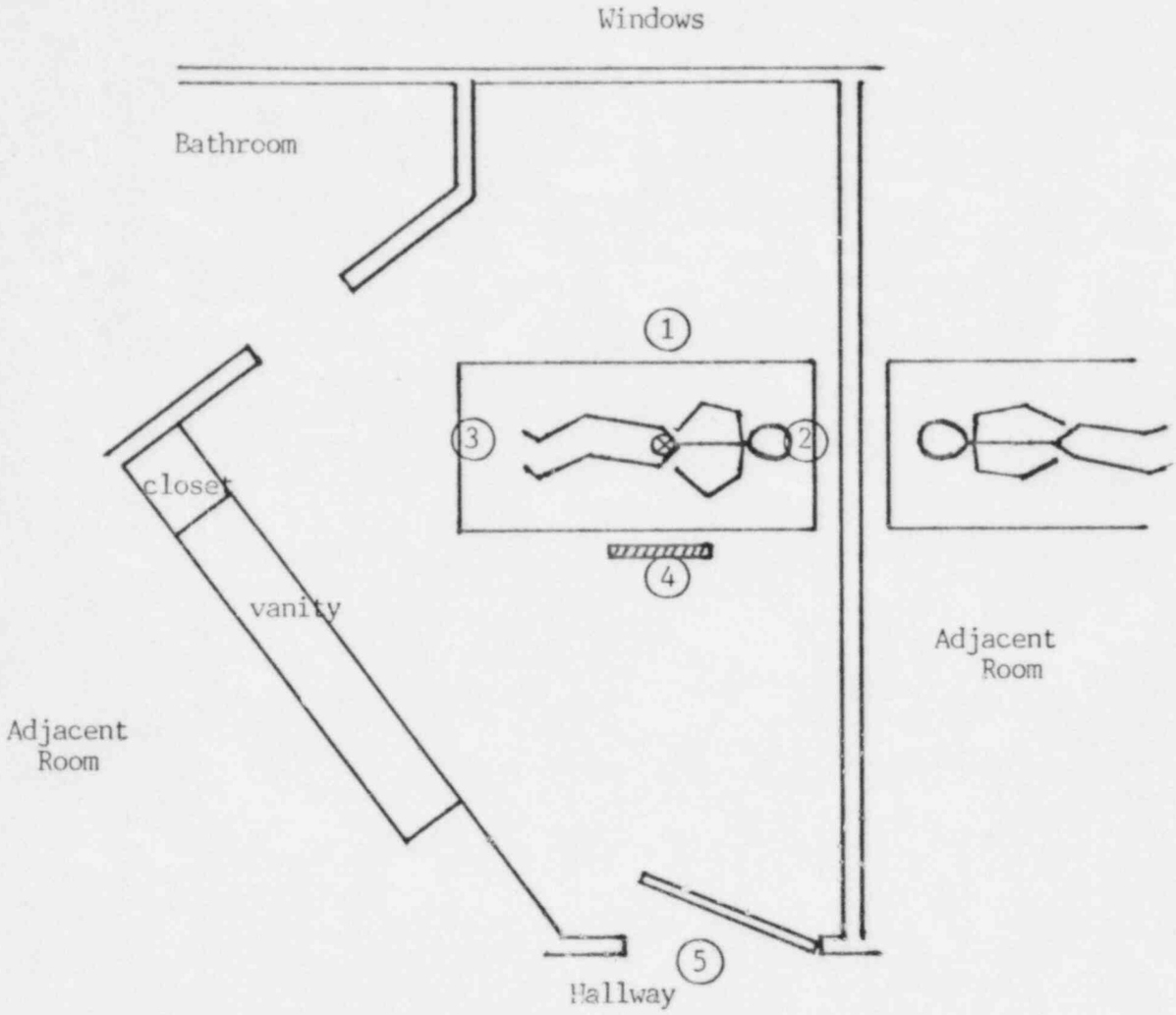
(5) doorway: This point is taken at the doorway to the patient's room. It is often oblique to the patient and may or may not reflect the effect of shielding. It is representative of the maximum exposure rate in the hallway and is taken at the most likely point that visitors or staff may stop or wait. This point must not exceed the specified exposure limit.

Should any exposure measurement exceed the base limits outlined above, a portable shield is interposed between the patient and the unrestricted area affected by the measurement. A second measurement is then taken and recorded to verify that the exposure rate in the unrestricted area is below the specified limit. Additionally should the projected elapsed time of the implant exceed 50 hours, the base limits are recalculated to meet part (2) of 10 CFR 20.105.

EXCEPTIONS:

Iodine-125: Due to the extremely low energy and permanent nature of Iodine-125 implants, the patient's room is not posted and is considered to be unrestricted. The exposure rates at 1 meter and 10 centimeters from the sources are measured and recorded to assure that they do not exceed the applicable limits (100 mR/Hr ÷ 7 ÷ 24 = 0.6 mR/Hr at 1 meter).

ROOM SURVEY ROOM # 168



(1) Side of bed at 1 meter ____mR/Hr
(2) Head of bed ____mR/Hr
(3) Foot of bed ____mR/Hr
(4) Behind shield at 1 meter ____mR/Hr
(5) Doorway ____mR/Hr

FIGURE 1

Item 20
Date: November 1984

NURSING INSTRUCTIONS

MERCY HOSPITAL

Altoona, Pennsylvania

Nursing Care of the Patient Receiving Internal Radiation Therapy

Definition:

The administration (implantation, insertion, oral dosage) of radioactive materials (Isotopes) into the body or specific body areas for a specified period of time (usually 48 hours or longer).

Objectives:

1. To destroy malignant cells in a specific area of the body.
2. To prevent growth and metastasis of malignancies.
3. To provide palliative relief in patients whose malignancy is in advanced stages.

General Directions:

1. Preparation of the patient.
   a. The physician will write specific orders for nursing care measures. These may include an enema, a vaginal douche, insertion of a Foley Catheter, or other specific care.
   b. The physician will write specific orders for preoperative surgical preparation.
   c. The nurse should be available to the patient to give psychological support, answer questions, and assess the patient's individual needs.
2. Room selection.
   a. Location of the patient
      1) The patient shall be placed in a private room with toilet on Pav. I. This room will be assigned by the Admitting Office.
      2) The bedside stand and other bedside equipment should be placed as to minimize time and exposure of personnel to radiation, whenever possible.
      3) The radiation area should be marked with appropriate signs, e.g., Radiation precautions tag, and visitor limitations. See b. 4.

Item No.20
Date: November 1984

4) The patient is to remain in the room at all times. The door may be kept open.

b. Time - Distance - Shielding

1) All nursing care should be pre-planned to provide maximum care for the patient in a minimum of time.

2) Confirmed or potentially pregnant nursing personnel shall not be assigned to care for patients receiving internal radiation therapy.

3) Nursing personnel shall be rotated in the care of the patient according to the time limits allowed for specific type of radiation. Additionally, film badges or pocket dosimeters will be assigned to each individual nurse aiding in the care of the patient. These people shall be instructed in the use of these monitors, and records of the readings shall be maintained.

4) Nursing personnel and visitors should follow both the time and distance recommendations determined by the physician or a radiation physicist. These distances and time depend on the type and quantity of the Isotope used. (See form A).

5) A portable lead shield may be used at the patient's bedside.

c. Emotional Support

1) Reassure the patient that he/she will receive adequate nursing care even though the time involved will be minimized.

2) Explain specific limitations regarding movement, care and visitors.

3) If sealed sources of radioactive materials are used, assure the patient that he or she will not be radioactive when the treatment is completed. (If unsealed radioactive materials are used, there is the danger of radioactive contamination.)

4) Advise the patient not to become alarmed if the radioactive material (in implants) become dislodged. Follow instructions under e.

5) Be available to the patient for answering questions and periodically assess individual patient needs.

d. General Observations.

1) Systemic reactions

a) Most patients being irradiated may experience some nausea, vomiting, anorexia, lethargy, constipation or diarrhea, and insomnia.

b) The physician will write specific orders for these systemic reactions as it becomes necessary.

c) Report to the attending physician immediately any significant temperature elevation, unusual pain or distress, and any unusual bleeding or discharge.

d) Patients receiving internal radiation are prone to develop such conditions as mucositis, proctitis, cystitis, and the nurse should observe the patient for symptoms of these conditions.

2) Patient receiving internal radiation may require special mouth and skin care depending on patient positioning, limitations of movement, and placement of the radioactive material in the patient.

e. Dislodging of Radioactive Materials (sealed sources) and Other (radiation) Emergencies.

1) Call the Radiation Oncology Department.

2) Should any radioactive material become dislodged, do not touch it.

3) Immediately notify the Radiation Therapist or therapy technologist who will bring proper handling equipment to the unit for disposition of the radioactive material. On evenings, nights, and weekends, notify the telephone operator who will contact the necessary personnel.

4) In the case of implanted radioactive needles or seeds, capsules or wires, no linen, dressings, or waste materials are to be discarded until it has been monitored by a radiation physicist.

f. Death of a Patient

1) Notify the physician or the Radiation Oncology Department (see Form A).

2) Temporarily implanted sealed sources are to be removed prior to post mortem care or prior to the body being sent to autopsy.

3) If an autopsy is to be performed on a patient that contains unsealed radioactive materials, notify the Pathologist of the presence of unsealed radiation sources. The Radiation Therapist must also be notified.

4) In the case of unsealed sources, place a radiation label on the patient's chest and on the shroud to indicate that the patient contains radioactive materials.

A. Insertion of R[redacted]oactive Materials (e.g., Radi[redacted] Cesium) Into the Endocervical Canal

1. While the radioactive material is in place, all nursing measures are geared to maintaining the location of the inserted material.

2. The physician may order a low residue diet to keep the bowels from moving and possible dislodging of the radioactive material. The bowel may become irritated because of the proximity of the radiation sources.

3. A Foley Catheter is usually inserted before implantation and connected to continuous drainage to prevent distention of the bladder which may alter the distribution of the radiation.

4. Vaginal packing is usually inserted to help keep the radioactive material in place.

5. The physician may order specific position and movement limitations for the patient.

   a) Usually, the patient is to stay in bed for the entire duration of the treatment.

   b) She may turn from side to side in a log-rolling position, with a pillow between the legs for support.

   c) The head of the bed may be raised 15-30°.

   d) The legs should remain extended.

6. Perineal pads and T-binders should not be used unless ordered by the physician. A blue incontinent pad may be used to catch vaginal discharge.

7. Special back and skin care may be necessary for these patients since movement is limited. Complete baths should not be given.

8. Keep linen in room for duration of treatment.

9. The patient should be instructed to use the bedpan for bowel elimination.

   a) The nurse should inspect the excreta for dislodged applicators before discarding.

   b) Bedpans may be emptied and cleaned as usual, if the applicators have not been dislodged.

10. In certain treatments, strings are [redacted]ed to the radioactive sources and taped to the inner leg. [redacted]ve these for placement and possible dislodgement. Count nu[redacted] of strings and record on nurse's notes at end of each shift.

11. Care after removal of the radioactive material.

a) Nursing personnel should be aware of when the treatment is to be discontinued. This information (day and time of removal) is in the patient's chart or is available from Radiation Oncology.

b) Removal of the sources is performed in the Radiation Oncology Department. If removal must be performed elsewhere, personnel from Radiation Oncology will provide the necessary equipment for disposition and monitoring of the radioactive materials.

c) The physician usually writes specific aftercare orders which may include a cleansing enema and a vaginal douche.

d) Unless otherwise ordered, the Foley Catheter is removed.

e) Unless otherwise ordered, the pre-implant diet is resumed.

12. RADIATION PRECAUTION SHALL BE DISCONTINUED ONLY WHEN ALL RADIOACTIVE MATERIALS HAVE BEEN ACCOUNTED FOR:

Linens, dressings, clothing, and utensils can be cycled (disposal or reuse) as usual when all sources have been removed and accounted for. If a source is missing or otherwise not accounted for, monitoring of the room and all its contents must be performed. In this event, nothing is to be taken from the patient's room and entry should be barred.

B. Implantation of Isotopes by Wire, Seeds, Needles and Capsules

1. Follow all general directions caring for patients receiving internal radiation. The techniques are essentially the same as those involving sealed sources. The following exception may be made (consult patient chart for specific exceptions).

a) Patients are usually permitted to be ambulatory, but must remain in their private rooms.

b) If no specific time and distance recommendations are given in the chart, nursing personnel should maintain a distance of six feet from the patient unless giving direct nursing care.

c) No linen is to be discarded until it is monitored by a radiation physicist to detect lost radioactive materials. Keep linen hamper in patient's room.

2. Patients with implantation in the mouth, cheek, or tongue require special mouth care.

a) Observe the placement strings or ribbons to assure that they remain intact.

b) Do not throw dressings away until they are monitored for lost implant materials. Place waste container in patient room.

3. Care after removal of radioactive implantations.

a) If it is a temporary implant, follow instructions as for removal of radioactive material as given under number 11 and 12.

b) If it is a permanent implant, monitoring of the patient shall be performed prior to discharge from the hospital.

c) If permanent implant, monitoring of the room and all its contents shall be performed to assess any radiation hazard.

Mercy Hospital

2500 SEVENTH AVENUE -:::- ALTOONA, PENNSYLVANIA 16603
(814) 944-1681

RADIATION ONCOLOGY DEPARTMENT

Patient Name _____ Room Number _____

Radionuclide _____ _____ mCi/mg Ra eq.

Administered/Inserted - Date _____ Time _____

Administered By Doctor _____

Route of Administration

Intracavitary _____ Interstitial _____ Systemic _____

_____ M.D.
Physician's Signature

INITIAL EXPOSURE RATES

Measured by _____

Exposure rate at 1 meter _____ mR/hr

At door _____ mR/hr

Behind shield at 1 meter _____ mR/hr (if used)

INSTRUCTIONS

Patient Must Remain In Hospital

_____ until implant is removed

_____ until (date) _____

At such time, "Precautions" tag may also be removed.

The Radiation Oncology Department must be notified before discharge or transfer of patient, unless radioactive material has been removed.

In case of an Emergency, notify the Radiation Oncology Department, the attending physician and the Radiation Physicist. The telephone operator has a call list for use when these sections are not open.

OTHER INSTRUCTIONS

- - No pregnant or potentially pregnant visitors permitted.
- - No children under 18 years of age permitted.
- - Other visitors may stay _____ minutes per day.

SPECIAL NURSING INSTRUCTIONS

- - No pregnant or potentially pregnant nurses permitted.
- - Keep hamper in room for used linen.

Date _____

Signature/Title _____

Item No. 20
Date: May 30, 1979

FORM A

GENERAL NURSING INSTRUCTION FOR PATIENTS RECEIVING SEALED SOURCE RADIOTHERAPY

Source Types: Cesium (Cs-137), Gold (Au-198), Iridium (Ir-192)
Iodine (I-125)

Sealed Source Radiotherapy means the patient is being treated with a discrete radiation producing source. This patient cannot become contaminated, nor can the patient contaminate anyone or anything they come in contact with. The only radiation safety concern is possible radiation exposure to visitors and hospital personnel within the patients room due to the presence of the sources. To help minimize this exposure, the following instructions are to be followed:

1). Patient may not leave this room under any circumstances without immediate notification and/or permission of the Department of Radiation Oncology.

2). Do not remove from this room any linens, dressings, or pads without authorization.

3). Check periodically for the possible dislodging of applicators or sources.

4). Pregnant or potentially pregnant nurses, hospital personnel, or visitors are not permitted to enter this room or to remain in the immediate area of this room for extended periods of time.

5). No visitors under the age of 18.

6). Nurses should rotate duties to provide comprehensive care to this patient while observing individual exposure limits. (time/day the same as for visitors)

7). Contact Department of Radiation Oncology Immediately If:

   a. Applicators or suspected sources become dislodged.(DO NOT HANDLE)

   b. Patient exhibits signs of serious illness or extreme discomfort.

8). For a further discussion on general nursing procedures refer to the Nursing Manual under "Nursing Care of the Patient Receiving Internal Radiation Therapy".

Department of Radiation Oncology
Extension 4280(8:00 AM - 4:30 PM; MONDAY THRU FRIDAY)
During non-working hours please contact telephone
operator for home phone number or paging.

SPECIAL NURSING INSTRUCTIONS FOR GYN IMPLANTS

NAME: _____ ROOM# _____

Number of Sources _____ Isotope _____ Activity _____ mCi./mg Ra eq

Time Sources Inserted		Removal Time	
_____ AM/PM	DATE _____	_____ AM/PM	DATE _____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Placement of Sources _____

Placement of Shield _____

Dose Rate @ one meter _____ mR/Hr

Dose Rate @ one meter behind Shield _____ mR/Hr

VISITORS

____ May stay up to _____ minutes per day.

____ Must remain behind Shield

____ Must remain at least 6 feet from patient

1). Patient may not leave bed.

2). Legs should be extended - Head of bed may be raised up to 30^{o} - patient may roll onto side.

3). Blue incontinent pad should be used to catch vaginal discharge.

4). Bed pan should be used if necessary. Bedpan should be checked after use for any dislodged applicators or sources, then emptied and cleaned as usual -- if no sources or applicators were dislodged.

5). Foley catheter (if used) should not be removed until sources are removed or specific orders are written.

6). Do not remove linens or trash or sweep room until cleared by Radiation Physics Personnel after sources have been removed or patient has been discharged.

7). PLEASE SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT

SPECIAL NURSING INSTRUCTION FOR NON-GYN TEMPORARY IMPLANTS

NAME _____ ROOM# _____

Number of Sources _____ Isotope _____ Activity _____mCi./mg Ra eq

Time Sources Inserted		Removal Time	
_____AM/PM	DATE_____	_____AM/PM	DATE_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Placement of Sources _____

Placement of Shield _____

Dose rate @ one meter _____mR/Hr

Dose rate @ one meter behind shield _____mR/Hr

VISITORS

____May stay up to _____minutes per day

____Must remain behind Shield

____Must remain at least 6 feet from patient

1). Patient may/may not be ambulatory.

2). Check dressings over implant carefully- - save in separate plastic bag in room until monitored by the Radiation Physics Personnel.

3). Do not remove linen or trash or sweep room until monitored by Radiation Physics Personnel after sources have been removed.

4). PLEASE SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT.

SPECIAL NURSING INSTRUCITONS FOR NON-GYN PERMANENT IMPLANTS

NAME _____ ROOM # _____

NUMBER OF SOURCES _____ ISOTOPE _____

	DATE	TIME	ACTIVITY	EXPOSURE RATE @ 1 METER	COMMENTS
@ TIME OF IMPLANT					
@ TIME OF DISCHARGE					

Placement of Sources _____

Placement of shield _____

Initial Dose Rate @ 1 meter _____ mR/Hr

Initial Dose Rate @ 1 meter behind shield _____ mR/Hr

VISITORS

_____ May stay up to _____ minutes per day.
_____ Must remain behind shield.
_____ Must remain at least 6 feet from patient.

1). Patient may/ may not be ambulatory.

2). Check dressings over implant carefully - save in seperate plastic bag in room until monitored by the Radiation Physics Personnel.

3). For all implants, but particularly for implants of the oral cavity, any very small unidentified pieces of metal found by patient or hospital personnel should be kept in room until monitored by Radiation Physics Personnel. DO NOT HANDLE - USE FORCEPS, HEMOSTATS, etc.

4). Do not remove linen or trash or sweep room until monitored by Radiation Physics Personnel after patient has been discharged.

5). PLEASE SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT.

Item 20
Date: November 1984

GENERAL NURSING INSTRUCTIONS FOR IODINE-125 IMPLANTS

Iodine-125 is a sealed radiotherapy source. The patient does not pose a contamination hazard. Iodine-125 is also of relatively low energy and is absorbed within the body of the patient. The exposure levels are detectable but pose no radiation safety hazard, therefore, NO RADIATION SHIELD IS NECESSARY. The radiation safety concern is limited to the detection and recovery of dislodged sources. To minimize exposure and aid in the recovery of sources, the following instructions are to be followed:

1. Do not remove from this room, any linen, dressings, or pads until monitored by Radiation Physics Personnel.

2. Pregnant or potentially pregnant nurses, hospital personnel or visitors should not enter this room.

3. No visitors under the age of 18.

4. Check periodically for dislodged sources. Should a suspected source be found, DO NOT HANDLE. The source may be picked up with long handled hemostats or forceps and placed into any metal container. Contact the Department of Radiation Oncology immediately.

5. After discharge, do not remove linens or trash or sweep room until monitored by Radiation Physics Personnel.

6. For a further disccusion on general nursing procedures, refer to the Nursing Manual under "Nursing Care of the Patient Receiving Internal Radiation Therapy".

Department of Radiation Oncology
Extension 4280 (8:00 A.M. - 4:30 P.M.; Monday Through Friday)
During non-working hours, please contact Telephone Operator for home phone number or paging.

SPECIFIC NURSING INSTRUCTIONS FOR IODINE-125 IMPLANTS

Name: _____ Room Number: _____

Number of Sources: _____ Activity: _____ mCi.

Exposure Rate at 1 meter: _____ mR/Hr.

Exposure Rate at 10 centimeters: _____ mR/Hr.

Visitors - Unrestricted Time.

SPECIFIC NURSING INSTRUCTIONS FOR PROSTATE IMPLANTS

1. Catheter bag must be monitored by Radiation Physics Personnel before being emptied or discarded. (Replace with new one if necessary.)

2. Radiation Physics Personnel should be present at removal of catheter to verify no sources become dislodged.

3. After removal of catheter, all urine should be saved and visually inspected for sources. If none are found, it may be discarded. If a source is found, DO NOT HANDLE, use forceps, hemostats, etc., and place into any metal container. Contact the Department of Radiation Oncology immediately.

4. PLEASE SEE PATIENT CHART FOR SPECIFIC ORDERS REGARDING THIS PATIENT.

Item 20
Date: November 1984

Procedures and Precautions for Use of Item 6b Materials

Sealed Source Leak Testing

The procedures for sealed source leak testing will be in accordance with previously submitted materials for this item (May, 1979).

ALARA PROGRAM

The ALARA program at Mercy Hospital will be in accordance with the model ALARA program in Appendix O in NRC Guide 10.8 (as revised October, 1980).

1620

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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
Mercy Hospital 2500 7th Avenue Altoona, PA 1660[illegible] TELEPHONE NO.: AREA CODE (814) 944 - 1681	Same
2. PERSON TO CONTACT REGARDING THIS APPLICATION Charles A. Sutton, M. D. TELEPHONE NO.: AREA CODE (814) 944 - 1681	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. ____ c. ☒ RENEWAL OF LICENSE NO. 37-03387-02
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* Charles A. Sutton, M. D. 1-4 Warren A. Wilkins, M. D. 6	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.)* Charles A. Sutton, M. D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	20	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	30 mCi.
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30 mCi.
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	100 mCi.
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 curies	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	200 mCi.
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	600 mCi.
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	400 mCi.
10 CFR 35.100, SCHEDULE A, GROUP VI	X	2 curies			

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
Important! authorize inst calibration for G VI	See Attached List		

U.S. NUCLEAR REG. COMMISSION MAIL SECTION
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FORM NRC-313M
(8-78)

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944-1681

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: January, 1979

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
X	Duties as in Appendix B; or *(Check One)*	X	Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
X	~~Supplement A & B~~ Attached for Each Individual User; and information		Equivalent Procedures Attached
NA	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	
		NA	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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Searle Diagnostics and Landauer	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Searle Diagnostics and Landauer	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

As needed bioassay (Item 19).

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

N/A

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: 7B

(2) LICENSE FEE ENCLOSED: Paid with previous application.

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

Sister Maristella

(1) NAME *(Type or Print)*

Sister Maristella

(2) TITLE

Acting Administrator

c. DATE

May 30, 1979

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

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

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

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

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

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

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

RADIOACTIVE MATERIAL NOT LISTED IN ITEM 6A

1. Cobalt-57 — in flood sources (Nuclear Associates #67-298 or equivalent), for peaking of gamma camera performance-15 mCi.

2. Cobalt-57 — sealed source (NEN #NES-206 or equivalent), for calibration of dose calibrator-10 mCi.

Note

3. Uranium — (depleted in U-235)--137 kg of cadium-plated metal as collimation for Varian Clinac-4 accelerator.

4. Cesium 137 — sealed sources (Nuclear Associates #67-800 and 67-600), for brachytherapy-600 mCi.

Note

5. Americium-241 — as anatomical and motion correction marker for Searle camera. Sealed source-5 mCi.-Searle model AMC 24. Searle Analytic model SS-10244.

Item 6b
Date: May 30, 1979

ISOTOPE & SCANNING COMMITTE - 1979

Charles A. Sutton, M. D., Chairman
A. E. Fraire, M. D.
Charles M. Haas, Jr., M. D.
Paul F. Webster, M. D.
Warren M. Wilkins, M. D.
Lawrence F. Hans
Gil DeLaura

Biographical Sketch of Committee Members

Charles A. Sutton, M. D. - Medical Education - University of Tennessee, Memphis, Tennessee - M. D. Degree - 1963

Internship - U. S. A. Tripler General Hospital, Honolulu, Hawaii

Residencies - Fitzsimmons General Hospital, Denver, Colorado (Radiology)

Certification by the Specialty Board of Radiology (December 1969)
Certification by the Specialty Board of Nuclear Medicine (May 18, 1973)

A. E. Fraire, M. D. - Medical Education - Faculty of Medicine, Monterrey, Mexico

Internship - University Hospital, Monterrey, Mexico

Residencies - Altoona Hospital, Altoona, PA (First Year - Pathology)

- Baylor College of Medicine, Houston, Texas (Second, Third and Fourth Year Pathology Residency)

Certification by the Specialty Board of Pathology (Anatomical and Clincial Pathology) (May 19, 1972)

Charles M. Haas, Jr., M. D. - Medical Education - University of Pittsburgh, Pittsburgh, PA - M. D. Degree - 1972

Internship - York Hospital, York, PA

Residencies - York Hospital, York, PA (Pathology)

Certification by the Specialty Board of Pathology (Anatomical and Clinical Pathology) (December, 1977)

Item 7
Date: May 30, 1979

Paul F. Webster, M. D. - Medical Education - University of Pittsburgh, Pittsburgh, PA - M. D. Degree - 1950

Internship - Allegheny General Hospital, Pittsburgh, PA

Residencies - Washington County Hospital, Hagerstown, Maryland. (Radiology)

Warren M. Wilkins, M. D. - Medical Education - University of Pittsburgh, Pittsburgh, PA - M. D. Degree - 1973

Internship - Conemaugh Valley Memorial Hospital, Johnstown, PA

Residencies - University of Pittsburgh, Pittsburgh, PA (Radiation Oncology)

- Allegheny General Hospital, Pittsburgh, PA (Radiation Oncology)

Certification by the Specialty Board of Radiology in Therapeutic Radiology (June 8, 1978)

Lawrence F. Hans - Education - University of Pittsburgh, Graduate School of Public Health - 30 post-graduate credits toward a Master's Degree in Health Physics

Fellowship in Radiologic Physics at Allegheny General Hospital, Division of Radiation Physics

California State College, California, PA
BA in Physics

Pennsylvania State Certification to teach Civil Defense

Eligible to become certified by the American Board of Health Physics

Gil DeLaura - Assistant Administrator

Education - Master of Hospital Administration - 1970, Department of Hospital and Health Care, Adminstration, St. Louis University, St. Louis, Missouri

Professional affiliations - Nominee, American College of Hospital Administrators

Member, American Society of Law and Medicine

Member, Pittsburgh Institute of Legal Medicine

MEDICAL ISOTOPES COMMITTEE

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 to enable them to perform their duties safely and in accordance with NRC regulations and the 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, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, 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 §19.12 of 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 review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system.

ITEM 7
Date: May 30, 1979

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.

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

ITEM 7
Date: May 30, 1979

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Charles A. Sutton, M.D.	Pennsylvania

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Radiology	December 1969
American Board of Nuclear Medicine	Nuclear Medicine	May 1973

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours)
	Fitzsimmons Gen. Hosp.	400 hrs.	
a. RADIATION PHYSICS AND INSTRUMENTATION	" "	"	"
b. RADIATION PROTECTION	" "	"	"
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	" "	"	"
d. RADIATION BIOLOGY	" "	"	"
e. RADIOPHARMACEUTICAL CHEMISTRY	" "	"	"

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	100 mc	Fitzsimmons Gen. Hosp.	400 hrs.	Dx & Rx
Au-198	150 uc	" "	"	Dx
Cr-51	200 uc	" "	"	"
Co-57	0.5 uc	" "	"	"
Hg-197	150 uc	" "	"	"
Tc-99m	10 uc	" "	"	"
Sr-85	100 uc	" "	"	"
I-125	0.5 mc	" "	"	"
Se-75	250 uc	" "	"	"
All		U.S. Army	1967- 1971	Dx & Rx
		Mercy Hosp. Altoona, PA	1971- 1979	Dx & Rx

Form AEC-313a (11/63) Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code.)

Charles A. Sutton, M.D. - 2601 8TH AVE., ALTOONA, PENNA 16603

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function	220	(a) (b) (c)
	~~Clinical studies~~ Placentograms	7	(a) (b) (c)
	~~Excretion studies~~ (24 take)	119	(a) (b) (c)
	~~Urinary excretion~~ Renograms	15	(a) (b) (c)
	Scanning studies (lung) (heart) (thyroid)	(22) (0) (54)	(a) (b) (c)
	Treatment of hyperthyroidism		
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma	1	(a) (b) (c)
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases		
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies (Liver)	11	(a) (b) (c)
Cr-51	Blood determinations (bld. Vol.) (RBC survival)	(4) (1)	(a) (b) (c)
	Scanning studies spleen	1	(a) (b) (c)
Co-58 or Co-60	Diagnosis of pernicious anemia (schilling)	11	(a) (b) (c)
Co-60	Interstitial treatment		
I-192	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment		
Sr-90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page	Hg-197 kidney scans	18	(a) (b) (c)
	Tc-99m brain scans	72	(a) (b) (c)
	Sr-85 bone scans	5	(a) (b) (c)
	I-125 (T_3)	128	(a) (b) (c)

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING April 8, 1968 through June 28, 1968 (400 hours)

IF TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF NORMAN HELLMAN, M.D.

AT FITZSIMONS GENERAL HOSP. (Name of Hospital or Laboratory) USAEC (Byproduct Material License Number)

Norman Hellman, M.D. (Signature of Preceptor)

Form AEC-313a
(11/63)
Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9. NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code)

Charles A. Sutton, M.D. 2601 8th Ave. Altoona, Pa. 16603

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function		
	Dilution studies		
	Excretion studies		
	Brain tumor localization		
	Scanning studies		
	Treatment of hyperthyroidism		
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma		
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases		
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies		
Cr-51	Blood determinations		
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia		
Co-60	Interstitial treatment		
I-192	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment		
Sr-90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page	Se-75 Pancreas Scanning	4	4 a, b, c
	Parathyroid	1	1 a, b, c

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and planning of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 8 Aug '72 - 24 Apr. '73 (8 months)

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF W. E. McKenney, M.D.

AT Altoona, Pa
Mercy Hospital (Preceptor's Name and Address)

37-03397-02 (Byproduct Material License Number)

W. E. McKenney M.D. (Signature of Preceptor)

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION PROTECTION OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION PROTECTION OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Warren M. Wilkins, M.D.	Pennsylvania

3. CERTIFICATION

SPECIALITY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiology	June 1978

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. of Pittsburgh 7/74-6/75 Allegheny General Hosp. 7/75-6/78	200	35
b. RADIATION PROTECTION	Univ. of Pittsburgh 7/74-6/75 Allegheny General Hosp. 7/75-6/78	25	15
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. of Pittsburgh 7/74-6/75 Allegheny General Hosp. 7/75-6/78	25	0
d. RADIATION BIOLOGY	Univ. of Pittsburgh 7/74-6/75 Allegheny General Hosp. 7/75-6/78	50	15
e. RADIOPHARMACEUTICAL CHEMISTRY	Univ. of Pittsburgh 7/74-6/75 Allegheny GEneral Hosp. 7/75-6/78	10	0

Item 8
Date: May 30, 1979

FORM NRC-313M-SUPPLEMENT B
(7-77)
10 CFR 35

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Warren M. Wilkins, M.D.

STREET ADDRESS

2500 Seventh Avenue

CITY | STATE | ZIP CODE

Altoona PA 16603

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheet.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	250	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	3	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	0	
	IN VITRO STUDIES	0	
OTHER			
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	250	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	75	
Yb-169	OSTEROGRAPHY	0	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	125	
OTHER			
Tc-99m	BRAIN IMAGING	400	
	CARDIAC IMAGING	20	
	THYROID IMAGING	200	
	SALIVARY GLAND IMAGING	1	
	BLOOD POOL IMAGING	15	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	300	
	LUNG IMAGING	125	
	BONE IMAGING	250	
OTHER			

Item 8
Date May 30, 1979

FORM NRC-313M-SUPPLEMENT B
(7-77)
10 CFR 35

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Warren M. Wilkins, M.D.

STREET ADDRESS

2500 Seventh Avenue

CITY | STATE | ZIP CODE

Altoona PA 16603

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	250	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	3	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	0	
	IN VITRO STUDIES	0	
OTHER			
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	250	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	75	
Yb-169	CISTERNOGRAPHY	0	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	125	
OTHER			
Tc-99m	BRAIN IMAGING	400	
	CARDIAC IMAGING	20	
	THYROID IMAGING	200	
	SALIVARY GLAND IMAGING	1	
	BLOOD POOL IMAGING	15	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	300	
	LUNG IMAGING	125	
	BONE IMAGING	250	
OTHER			

Item 8
Date

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	3	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	6	
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM AND CARDIAC CONDITION	10	
Au-198	INTRACAVITARY TREATMENT	3	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	N/A	
	INTRACAVITARY TREATMENT	N/A	
I-125 or Ir-192	INTERSTITIAL TREATMENT	N/A	N/A--Not applicable --board certified therapeutic radiology
Co-60 or Cs-137	TELETHERAPY TREATMENT	N/A	
Sr-90	TREATMENT OF EYE DISEASE	N/A	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/Tc-99m	GENERATOR	1,300	
Sn-113/In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	0	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

July 1, 1975 to June 30, [illegible] -- [illegible] hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:	5. PRECEPTOR'S SIGNATURE
a. NAME OF SUPERVISOR Mustafa H. Adatepe, M.D.	Mustafa H. Adatepe
NAME OF INSTITUTION Allegheny General Hospital	7. PRECEPTOR'S NAME *(Please type or print)* Mustafa H. Adatepe, M.D.
MAILING ADDRESS [illegible] East North Avenue	8. DATE
CITY [illegible]	
MATERIALS LICENSE NUMBER(S) [illegible]-01717-01	

ITEM 8

DATE: May 30, 1979

INSTRUMENTATION

I. Survey Meters

A. Victoreen "Panoramic" Ionization Chamber--Model 470
Low Range: 0-3 mR/hr High Range: 0-1000 MR/hr

B. Victoreen G-M Survey Meter--Model 493
Low range: 0-0.5 mR/hr High Range: 0-50 mR/hr

C. Picker G-M Survey Meter--Model CDV-700
Low range: 0-0.5 mR/hr High Range: 0-50 mR/hr

D. Victoreen Ionization Meter--Model 740F
Low Range: 0-25 mR/hr High Range: 0-25 R/hr

E. Texas Nuclear Survey Meter--Model 2652
Low Range: 0-0.1 mR/hr High Range: 0-100 mR/hr

II. Dose Calibrators

A. Capintec Model CRC-8

B. Capintec, Victoreen, or equivalent (to be acquired)

III. Diagnostic Instruments

A. Picker Nuclear Magna-Scanner Model 2806

B. General Electric Radicamera II

C. Another gamma camera to be acquired of at least the quality and capabilities of the Radicamera II.

IV. Other

A. Picker Spectroscaler IIIA/Well Counter # 1361

B. Abbott Scintillation Counter, Model #221

C. NMC Gas Proportional Counter (Ordered)

D. Victoreen TLD Reader Model 2800

E. Victoreen Radicon III Dosimetry System

F. Victoreen R-Meter, Model 570, plus chambers

Item 9

Date: May 30, 1979

CALIBRATION OF SURVEY INSTRUMENTS

Sources

The sources to be used will be encapsulated Cs-137 brachytherapy sources (tubes) from Nuclear Associates, Inc., Model 67-800 series. These have been intercompared with NBS traceable sources using a 4 π well ionization chamber by the manufacturer, and are accurate to $\pm$ 2% at the 95% confidence level. There are 9 sources with a net nominal activity of 125 milligrams-radium-equivalency. Physical dimensions are 0.3 cm in diameter x 1.5 cm active length. This means that there is sufficient activity to produce 1 R/hr exposure rate at a distance such that point source behavior is assured, being greater than 10 times the maximum source extent.

Frequency

- before each use, a reference source will be read
- annual calibration, as a minimum, and following repair/battery change

Procedure

Sources will be removed from storage safe into linac room or transported to an x-ray suite in standard lead-lined carrier. Using long forceps as needed, sources will be arranged in a minimum-scatter, close-packed geometry. Each meter will be placed in the field and calibrated at two points (one-third and two-thirds) on each scale, either by internal adjustment or by generating a graph or calibration factors to be attached to the meter. The RSO shall designate the individual (a physicist) to perform these calibrations, and the individual will be film-badge monitored. Exposure to other individuals will be avoided. Additionally, G-M type meters used for low energy measurements will be intercompared on the lower ranges against a more energy-independent ionization-type meter (such as a Victoreen Model 440) for Tc-99m or Co-57. Following calibration, the reference source will be read and recorded for future daily checks.

CALIBRATION OF DOSE CALIBRATOR

Sources

The activities or these sources shall be known to $\pm$ 5%, traceable to the NBS:

A. Cobalt-57—NEN #NES-206, or equivalent - up to 10 mCi.*

B. Cesium-137--ICN Catalog #NES-356, or equivalent - up to 0.2 mCi.

C. Barium-133, ICN Catalog #NES-358, or equivalent - up to 0.2 mCi.

D. Additionally, a Tc-99m vial source obtained directly from NBS may be used.

*calibrated as Tc-99m equivalent

Frequency

Full calibration will be performed annually as a minimum; linearity will be checked semi-annually. Both will be performed after repair. These will be supplemented by daily checks described below.

Calibration Procedures

1. Set the calibrator dial setting for Tc-99m. Obtain a background level for that setting.

2. Assay the Co-57 standard in the calibrator at each activity range setting for both Co-57 and Tc-99m (if appropriate) and subtract the background level to obtain net activity. If variable dial settings are available, assay at the number recommended by the manufacturer. If necessary, vary the number until the true activity of the source is registered.

3. Repeat the assay for a total of 3 determinations and average the results. The average activity measured should agree with the activity of the standard within 5% variation after decay corrections.

4. Repeat the above steps with the other standards, with the dial settings appropriate for these isotopes.

5. Insert a Cs-137 constancy source. Assay at all routinely used radioisotope settings for use in daily comparisons.

6. Document these results and maintain for reference.

ITEM 10
Date: May 30, 1979

Linearity Check Procedures

1. On the first day the generator is used it should be eluted using the normal method.
2. The eluant should be assayed in the calibrator and the results and time documented.
3. Fifty percent of the eluant* should be aspirated from the original vial and placed into another identical vial. Add one equal volume of water.

*this diluted activity cannot be used for patient studies.

4. Assay the technetium and water and record the results and time.
5. Six hours later, again assay the diluted technetium; record the time and the results.
6. Repeat this procedure at 24 and 30 hours after elution; repeat a final time at 48 hours after elution.
7. Using the 30-hour measurement, calculate the predicted activities using the following multiplicative factors:

ASSAY TIME (hours)	0	6	24	30	48
FACTOR	32	16	2	1	0.125

8. Plot results on log-log graph paper, and if variation from predicted values exceeds $\pm$ 5%, the instrument will be repaired.
9. Keep results of these tests on file.

Daily Checks

Either daily or before each use, the background readings will be checked for abnormalities and investigated if need be. Then the previously mentioned Cs-137 constancy source will be read at each setting for radioisotopes used. Results will be recorded and compared to readings taken at the time of calibration (decay-corrected). Variation outside $\pm$ 5% will be cause for investigation which may include repair and/or re-calibration.

RADIATION HANDLING EQUIPMENT

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine laboratory will have on hand the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the radioisotope labs.

Shielding Equipment

Lead bricks (e.g., 2 inch x 4 inch x 6 inch)
Lead syringe holders for transporting syringes containing radioactivity
Lead syringe shields for reducing exposure during injection of radiopharmaceuticals
Lead vial and container shields (pigs) for reducing exposure during transport and storage of vials, etc., that contain radioactive material.

Contamination Control

Disposable gloves
Laboratory coats or uniforms
Absorbent pads (absorbent layer backed by non-absorbent plastic material) for covering work surfaces
Trays (e.g., 14 inch x 18 inch x 7/8 inch deep) used with absorbent pads for covering work surfaces
Decontaminating agents. Special agents are commercially available for decontaminating hands, utensils, work areas, etc.
Signs and labels indicating the presence of radioactive materials in areas or rooms where they are being used or stored. Labels on containers indicating radionuclide, activity, and date.

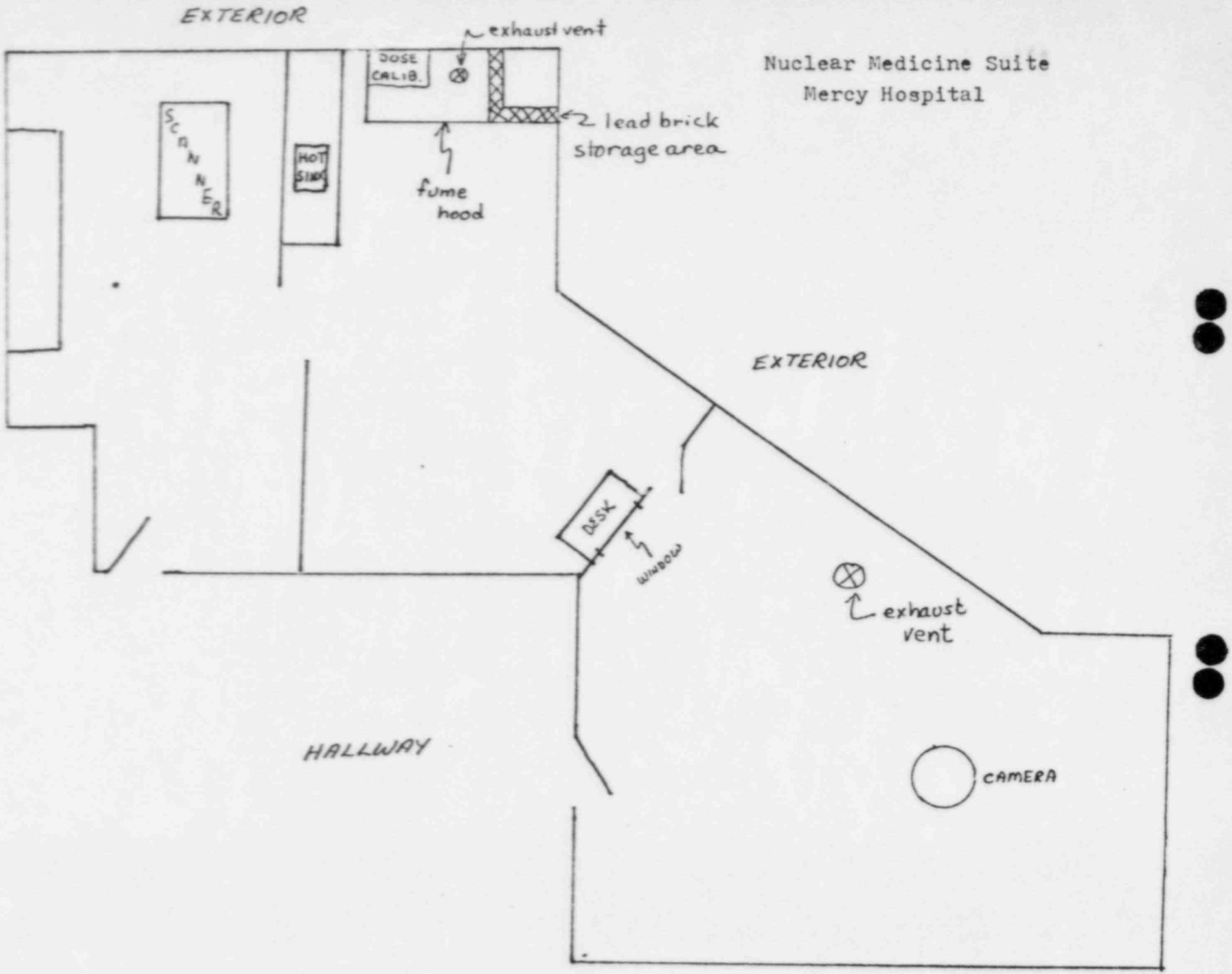
FACILITIES AND EQUIPMENT

I. Nuclear Medicine Suite/Radiation Oncology Lab/Pathology Lab

See Attachments 11-A, 11-B, 11-C, 11-D

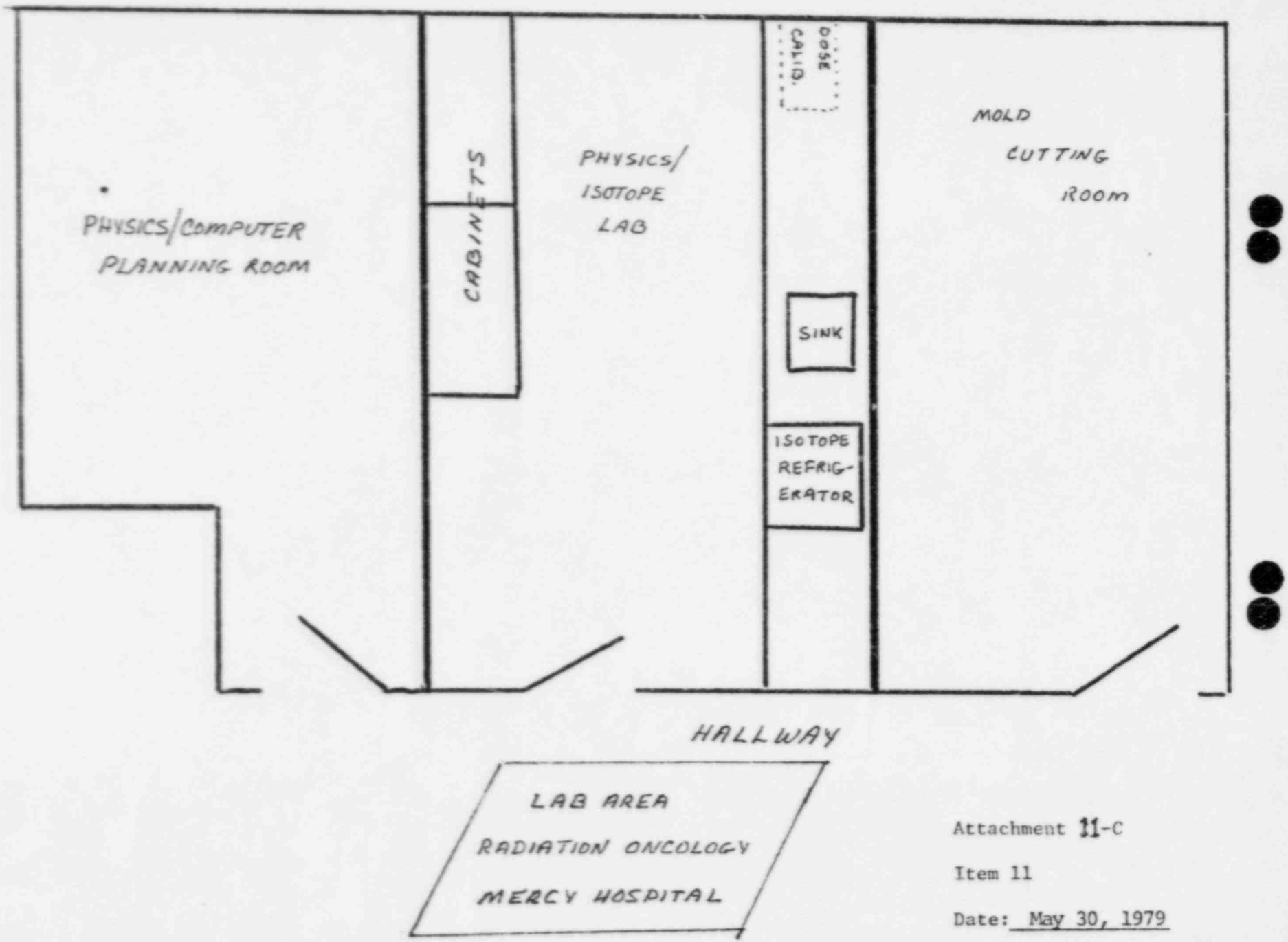
II. Waste Storage Room

This room, located in the X-ray Department, provides locked storage for radioactive waste generated by Nuclear Medicine. Receptacles are provided for holding material for decay to background. The room diagram and environs are shown in Attachment 11-E.



Attachment 11-B
Item No. 11
Date: May 30, 1979

EARTH FILL



Attachment 11-C

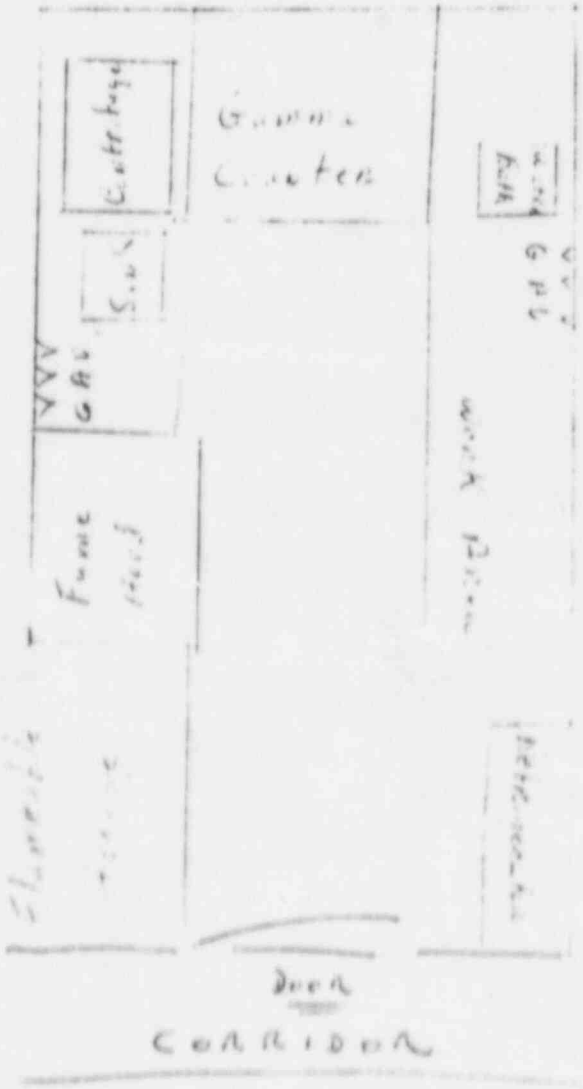
Item 11

Date: May 30, 1979

LABORATORY

Mercy Hospital

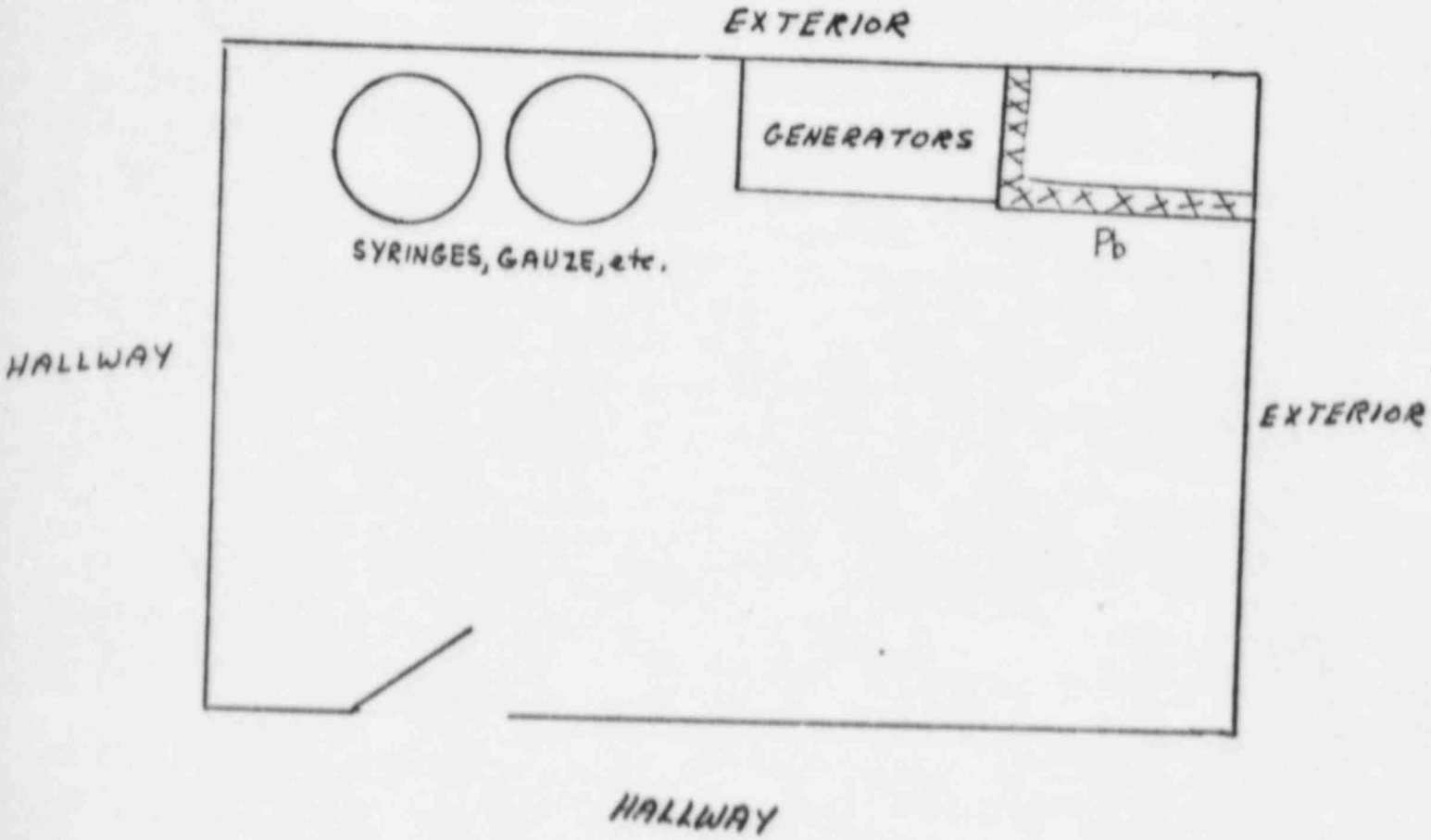
MERCY HOSPITAL
ITEM 11-D
RADIOISOTOPE LAB
IN VITRO PROCEDURES ONLY



Attachment 11 D
Item No. 11
Date: May 30, 1979

RADIOACTIVE WASTE STORAGE AREA

Mercy Hospital



Attachment 11-B
Item 11
Date: May 30, 1979

RADIATION SAFETY TRAINING FOR RADIATION WORKERS

1. The principal user of radiation sources is responsible for insuring that all such sources under his jurisdiction are used only by individuals who have been properly trained to use them safely.

2. Radiation workers shall participate in continuing education programs such as on-the-job training, in-service educational programs, technical workshops, and professional society meetings. Such training shall be documented.

3. In addition to on-the-job training provided initially by supervisory personnel, all individuals who work with radiation sources (including security, nursing, and housekeeping personnel) shall receive radiation safety training at least annually, or whenever there is a significant change in duties, regulations, or license status. The radiation safety officer or his designated representative will conduct this training. Items discussed shall include: (a) areas where radioactive material is used or stored, (b) potential hazards associated with radioactive material, (c) radiological safety procedures appropriate to their respective duties, (d) pertinent NRC regulations, (e) rules and regulations of the license, (f) pertinent terms of the license, (g) their obligation to report unsafe conditions, (h) appropriate response to emergencies or unsafe conditions, (i) their right to be informed of their radiation exposure and bioassay results, (j) locations where the licensee has posted or made available copies of the license and supporting material. The depth of discussion will be based upon the extent of applicability to the employees involved. This training will be documented by participant and topic list.

Item 12
Date: May 30, 1979

1620

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. Oriers for radioactive material will be placed by the radiotherapist, chief of Nuclear Medicine, or individuals designated by them. These persons shall insure that the materials and quantities requested are authori ed by the license.

2. During normal working hours, carriers will deliver radioactive packages directly to the respective departments, where receipt procedures will be carried out.

3. During after-duty hours*, all radioactive material will be brought to the Nuclear Medicine Lab by the carrier. X-ray or security personnel will unlock the door, the package will be placed in the center of the floor and the room re-locked. The next time the department is opened, the technicial will perform a cursory survey of the materials. If an irregularity is noted, a complete survey will be performed then. If there is no problem, materials will be sent to the other departments via persons that are film-badged for complete receipt procedures.

* No after-hours shipments are anticipated.

Item 13
Date: May 30, 1979

PROCEDURES FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIAL

I. General Procedures

1. Visually inspect package for any sign of damage (e.g., wetness, or crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR/hr. stop and notify RSO.
3. Measure surface exposure rate and record. If greater than 200 mR/hr., stop and notify RSO.
4. Put on gloves.
5. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents and check integrity of final source container. Check also that shipment does not exceed possession limits.
6. Wipe external surface of final source container with moistened cotton swab or paper. Assay and record. If greater than 0.01 uCi is detected, notify RSO. Use either a thin-end-window G-M survey meter or well counter for this assay, taking precautions to avoid the spread of possible contamination.
7. Monitor the packing material and packages for contamination before discarding: (a) if contaminated, treat as radioactive waste; (b) if not contaminated, obliterate radiation labels and discard in regular trash. A reading above background is considered to define contamination here.

II. Records

A receipt log will be maintained with the following information as a minimum: date, surveyor, package condition, description including type and amount of radioisotope, exposure and wipe test results as above.

Item 14
Date: May 30, 1979

III. In-vitro Test Materials (20 uCi or less per package)

These kits, unless received in the same box with higher-activity materials, will be logged in by date, condition of package, and description (including type and amount of radioisotope). If the potential of cross-contamination from other materials should be present, a complete survey will be performed.

Item 14
Date: May 30, 1979

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Only those people specifically designated by the users listed on the license shall use radioactive material. All uses of radioactive material shall be approved by the Medical Isotopes Committee.
2. Wear lab coats or other protective clothing at all times in areas where radioactive materials are used.
3. When handling <u>in vivo</u> diagnostic or therapeutic quantities of radioactive material, wear disposable gloves.
4. Handle quantities of liquid, high specific-activity I-125 or I-131 under a fume hood.
5. Remote handling equipment and lead shielding should be used whenever possible.
6. Use syringe shields for 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.
7. 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%.
8. Transport radioactive materials in shielded containers.
9. Store radioactive materials with sufficient shielding to keep exposure rates as low as reasonably achievable. When not in use, make sure materials are returned to designated storage areas. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level, if applicable.
10. Wear personnel monitoring devices at all times in areas where greater than microcurie amounts of radioactive material are used or stored. Wear at chest or waist level. Wear ring or wrist badges when eluting generators, and during preparation, assay and injection of radiopharmaceuticals. Turn in these devices promptly when due to be collected for reading.
11. Be completely familiar with designated, marked radioactive waste receptacles and procedures and dispose of wastes accordingly.
12. Do not eat, drink, smoke, or apply cosmetics or store these items,

in any area where radioactive material is stored or used.

13. Never pipette by mouth.

14. Survey hands, clothing, and work areas after each use of radioactive material or at the end of the day. Decontaminate if necessary.

Item 15
Date: May 30, 1979

EMERGENCY PROCEDURES*

Minor Spills

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

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

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

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

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

Major Spills

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

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

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

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

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

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

RADIATION SAFETY OFFICER: Dr. Charles Sutton
OFFICE PHONE: 944-1681 Ext. 391
HOME PHONE: 695-9406

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

1. Dr. Wilkins — Contact Hospital Telephone
2. Mr. Larry Hans
3. Ms Marianne Pelton — Operator for No. 1,2,3 & 4
4. Sr. Rose Mary

*Appendix H. NRC Regulatory Guide 10.8, January 1979

Item 16
Date: May 30, 1979

ARFA SURVEY PROCEDURES

1. All elution, preparation, and injection 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 at any one time) will be surveyed monthly.

3. Nuclear Medicine will be surveyed weekly. The Radiation Oncology Lab will be surveyed after each use of unsealed radioactive materials, and weekly while these materials are stored there.

4. The weekly and monthly survey will consist of:
   (a) A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr, and

   (b) a series of wipe tests to measure contamination levels. 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 records will include:
   (a) location, date, and type of equipment used
   (b) name of surveyor
   (c) drawing of area surveyed which shall include relevant features such as work areas, waste areas, etc.
   (d) measured exposure rates, keyed to drawing
   (e) detected contamination levels, with locations keyed to drawing
   (f) clear indication of unusual results, and details of corrective action. Re-survey area following correction, and record these results.

6. Action levels for exposure readings will be established by the RSO, based on occupancy factors and on keeping these levels as low as reasonably achievable. The action level for decontamination will be 100 dpm per 100 cm^2.

7. For daily surveys where no abnormal exposures are found, only the date, name of surveyor, and survey report will be recorded.

Item 17
Date: May 30, 1979

WASTE DISPOSAL

Liquid Wastes

Liquid wastes from in vitro tests will be disposed of via sanitary sewer system. Compliance with Section 20.303 of 10 CFR will be assured by an initial test of each test kit type, which shall consist of counting each test tube before and after the liquid is poured off. Averaged over several trials, this will determine, on a per test basis, the percentage amount of disposed activity in liquid form. From this, monthly and yearly disposed quantities can be determined. There will be no other routine waste disposal via the sanitary sewer system. Other liquid wastes will be held for decay.

Mo-99/Tc-99m Generators

These generators will be returned to the manufacturer for disposal.

Solid Wastes

Short-lived solid wastes will be held for decay until radiation levels (as measured with a low-range 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.

Long-lived wastes will be either held for decay as above or transferred to a licensed commercial vendor, such as Radiac Research Corp., of Brooklyn, New York, or equivalent.

Records

Records of these disposals will be maintained for review as necessary by the Radiation Safety Officer.

Item 18

Date: May 30, 1979

MERCY HOSPITAL

Altoona, Pennsylvania

Nursing Care of the Patient Receiving Internal Radiation Therapy

Definition:

The administration (implantation, insertion, oral dosage) of radioactive materials (Isotopes) into the body or specific body areas for a specified period of time (usually 48 hours or longer).

Objectives:

1. To destroy malignant cells in a specific area of the body.
2. To prevent growth and metastasis of malignancies.
3. To provide palliative relief in patients whose malignancy is in advanced stages.

General Directions:

1. Preparation of the patient.
    a. The physician will write specific orders for nursing care measures. These may include an enema, a vaginal douche, insertion of a Foley Catheter, or other specific care.
    b. The physician will write specific orders for preoperative surgical preparation.
    c. The nurse should be available to the patient to give psychological support, answer questions, and assess the patient's individual needs.
2. Room selection.
    a. Location of the patient
        1) The patient shall be placed in a private room with toilet. This room will be assigned by the Admitting Office.
        2) The bedside stand and other bedside equipment should be placed as to minimize time and exposure of personnel to radiation, whenever possible.
        3) The radiation area should be marked with appropriate signs, e.g., Radiation precautions tag, and visitor limitations. See b. 4.

4) The patient is to remain in the room at all times. The door may be kept open.

b. Time - Distance - Shielding

1) All nursing care should be pre-planned to provide maximum care for the patient in a minimum of time.

2) Confirmed or potentially pregnant nursing personnel shall not be assigned to care for patients receiving internal radiation therapy.

3) Nursing personnel shall be rotated in the care of the patient according to the time limits allowed for specific type of radiation. Additionally, film badges or pocket dosimeters will be assigned to each individual nurse aiding in the care of the patient. These people shall be instructed in the use of these monitors, and records of the readings shall be maintained.

4) Nursing personnel and visitors should follow both the time and distance recommendations determined by the physician or a radiation physicist. These distances and time depend on the type and quantity of the Isotope used. (See form A).

5) A portable lead shield may be used at the patient's bedside.

c. Emotional Support

1) Reassure the patient that he/she will receive adequate nursing care even though the time involved will be minimized.

2) Explain specific limitations regarding movement, care and visitors.

3) If sealed sources of radioactive materials are used, assure the patient that he or she will not be radioactive when the treatment is completed. (If unsealed radioactive materials are used, there is the danger of radioactive contamination.)

4) Advise the patient not to become alarmed if the radioactive material (in implants) become dislodged. Follow instructions under e.

5) Be available to the patient for answering questions and periodically assess individual patient needs.

d. General Observations.

1) Systemic reactions

a) Most patients being irradiated may experience some nausea, vomiting, anorexia, lethargy, constipation or diarrhea, and insomnia.

b) The physician will write specific orders for these systemic reactions as it becomes necessary.

c) Report to the attending physician immediately any significant temperature elevation, unusual pain or distress, and any unusual bleeding or discharge.

d) Patients receiving internal radiation are prone to develop such conditions as mucositis, proctitis, cystitis, and the nurse should observe the patient for symptoms of these conditions.

2) Patient receiving internal radiation may require special mouth and skin care depending on patient positioning, limitations of movement, and placement of the radioactive material in the patient.

e. Dislodging of Radioactive Materials (sealed sources) and Other (radiation) Emergencies.

1) Call the Radiation Oncology Department.

2) Should any radioactive material become dislodged, do not touch it.

3) Immediately notify the Radiation Therapist or therapy technologist who will bring proper handling equipment to the unit for disposition of the radioactive material. On evenings, nights, and weekends, notify the telephone operator who will contact the necessary personnel.

4) In the case of implanted radioactive needles or seeds, capsules or wires, no linen, dressings, or waste materials are to be discarded until it has been monitored by a radiation physicist.

f. Death of a Patient

1) Notify the physician or the Radiation Oncology Department (see Form A).

2) Temporarily implanted sealed sources are to be removed to post mortem care or prior to the body being sent to autopsy.

3) If an autopsy is to be performed on a patient that contains unsealed radioactive materials, notify the Pathologist of the presence of unsealed radiation sources. The Radiation Therapist must also be notified.

4) In the case of unsealed sources, place a radiation label on the patient's chest and on the shroud to indicate that the patient contains radioactive materials.

Administration of Therapeutic Doses of Unsealed Radioisotopes

(Isotopes in liquid form such as 131-Iodine, 32-Phosphorus, and 198-Gold given intrapleurally, intraperitoneally, or orally.)

1. Order isolation cart for protective care from Central Service.

2. Follow all general directions. In addition:

   a. Patient shall be in a private room, and if possible, at the end of the hall on an outside wall.

   b. Use plastic matress covers and pillow covers to lessen danger of contaminating the bed and pillows.

   c. Disposable gloves shall be worn by nursing personnel while caring for the patient.

   d. Dressings and linen must be monitored before being discarded.

      1) Handle carefully with gloves to decrease possibility of transferring radioactive contamination (try to prevent articles from touching clothing).

      2) Place linens and dressings in separate plastic bags.

      3) Store bags in patient's room until they are monitored and declared free of contamination by a radiation physicist.

   e. If the patient's skin becomes contaminated by leakage through dressings, urine, feces, perspiration, or emesis, remove bedclothes, wash skin area with soap and water. Wear disposable gloves. Save clothing, etc., for monitoring.

   f. After disposing of gloves, wash hands thoroughly.

   g. Special precautions for patients receiving oral 131-Iodine in therapeutic doses (administered activity greater than 50 millicuries).

      1) Disposable gloves and shoe coverings must be worn by all individuals entering the patient's room (NO EXCEPTIONS). The use of aprons or other clothing protection is optional.

      2) The use of disposable items (e.g., food trays, utensils) is strongly recommended for the patient. All nondisposable items must be monitored for radioactivity. These containers will remain in the patient's room until transfer or disposal by Radiation Oncology personnel.

      3) Urine may be saved in (polyethylene) containers and monitored for radioactivity. These containers will remain in the patient's room until transfer or disposal by Radiation Oncology personnel.

Item No. 19
Date: May 30, 1979

4) Bedpans should be washed thoroughly with soap and water after each use. The water from this washing and rinsing may be flushed down the toilet in the patient's room. Gloves used for this procedure should be washed before disposal.

5) Linens must be monitored before being cycled.

6) Handle all items in room carefully.

7) If the patient vomits within 24 hours of receiving the dose, notify Radiation Oncology. DO NOT dispose of vomitus or soiled clothes until monitoring is done. Keep these articles in plastic bags.

8) If the patient is incontinent or otherwise spills some urine, the radiation physicist must be called. Put absorbent pads on the area of the spill, but do not attempt to clean-up the spill until radiation monitoring is done.

9) The patient's bed and clothing should be changed, if necessary, and these items saved for monitoring.

3. Patient shall not be discharged from private accommodations until clearance is given by Radiation Physicis.

4. When patient is discharged, close room and do not remove any items from the room until clearance is given by Radiation Physics.

A. Insertion of Radioactive Materials (e.g., Radium, Cesium) Into the Endocervical Canal

1. While the radioactive material is in place, all nursing measures are geared to maintaining the location of the inserted material.

2. The physician may order a low residue diet to keep the bowels from moving and possible dislodging of the radioactive material. The bowel may become irritated because of the proximity of the radiation sources.

3. A Foley Catheter is usually inserted before implantation and connected to continuous drainage to prevent distention of the bladder which may alter the distribution of the radiation.

4. Vaginal packing is usually inserted to help keep the radioactive material in place.

5. The physician may order specific position and movement limitations for the patient.

   a) Usually, the patient is to stay in bed for the entire duration of the treatment.

   b) She may turn from side to side in a log-rolling position, with a pillow between the legs for support.

   c) The head of the bed may be raised 15-30°.

   d) The legs should remain extended.

6. Perineal pads and T-binders should not be used unless ordered by the physician. A blue incontinent pad may be used to catch vaginal discharge.

7. Special back and skin care may be necessary for these patients since movement is limited. Complete baths should not be given.

8. Keep linen in room for duration of treatment.

9. The patient should be instructed to use the bedpan for bowel elimination.

   a) The nurse should inspect the excreta for dislodged applicators before discarding.

   b) Bedpans may be emptied and cleaned as usual, if the applicators have not been dislodged.

10. In certain treatments, strings are attached to the radioactive sources and taped to the inner leg. Observe these for placement and possible dislodgement. Count number of strings and record on nurse's notes at end of each shift.

11. Care after removal of the radioactive material.

a) Nursing personnel should be aware of when the treatment is to be discontinued. This information (day and time of removal) is in the patient's chart or is available from Radiation Oncology.

b) Removal of the sources is performed in the Radiation Oncology Department. If removal must be performed elsewhere, personnel from Radiation Oncology will provide the necessary equipment for disposition and monitoring of the radioactive materials.

c) The physician usually writes specific aftercare orders which may include a cleansing enema and a vaginal douche.

d) Unless otherwise ordered, the Foley Catheter is removed.

e) Unless otherwise ordered, the pre-implant diet is resumed.

12. RADIATION PRECAUTION SHALL BE DISCONTINUED ONLY WHEN ALL RADIOACTIVE MATERIALS HAVE BEEN ACCOUNTED FOR:

Linens, dressings, clothing, and utensils can be cycled (disposal or reuse) as usual when all sources have been removed and accounted for. If a source is missing or otherwise not accounted for, monitoring of the room and all its contents must be performed. In this event, nothing is to be taken from the patient's room and entry should be barred.

B. Implantation of Isotopes by Wire, Seeds, Needles and Capsules

1. Follow all general directions caring for patients receiving internal radiation. The techniques are essentially the same as those involving sealed sources. The following exception may be made (consult patient chart for specific exceptions).

a) Patients are usually permitted to be ambulatory, but must remain in their private rooms.

b) If no specific time and distance recommendations are given in the chart, nursing personnel should maintain a distance of six feet from the patient unless giving direct nursing care.

c) No linen is to be discarded until it is monitored by a radiation physicist to detect lost radioactive materials. Keep linen hamper in patient's room.

2. Patients with implantation in the mouth, cheek, or tongue require special mouth care.

a) Observe the placement strings or ribbons to assure that they remain intact.

b) Do not throw dressings away until they are monitored for lost implant materials. Place waste container in patient room.

3. Care after removal of radioactive implantations.

a) If it is a temporary implant, follow instructions as for removal of radioactive material as given under number 11 and 12.

b) If it is a permanent implant, monitoring of the patient shall be performed prior to discharge from the hospital.

c) If permanent implant, monitoring of the room and all its contents shall be performed to assess any radiation hazard.

Item No. 19
Date: May 30, 1979

FORM 333-019-0
3-1-79

Mercy Hospital

2500 SEVENTH AVENUE -:::- ALTOONA, PENNSYLVANIA 16603
(814) 944-1681

RADIATION ONCOLOGY DEPARTMENT

Patient Name _____ Room Number _____

Radionuclide _____ _____ mCi/mg Ra eq.

Administered/Inserted - Date _____ Time _____

Administered By Doctor _____

Route of Administration

Intracavitary _____ Interstitial _____ Systemic _____

_____ M.D.
Physician's Signature

INITIAL EXPOSURE RATES

Measured by _____

Exposure rate at 1 meter _____ mR/hr

At door _____ mR/hr

Behind shield at 1 meter _____ mR/hr (if used)

INSTRUCTIONS

Patient Must Remain In Hospital

_____ until implant is removed

_____ until (date) _____

At such time, "Precautions" tag may also be removed.

The Radiation Oncology Department must be notified before discharge or transfer of patient, unless radioactive material has been removed.

In case of an Emergency, notify the Radiation Oncology Department, the attending physician and the Radiation Physicist. The telephone operator has a call list for use when these sections are not open.

OTHER INSTRUCTIONS

- No pregnant or potentially pregnant visitors permitted.
- No children under 18 years of age permitted.
- Other visitors may stay _____ minutes per day.

SPECIAL NURSING INSTRUCTIONS

- No pregnant or potentially pregnant nurses permitted.
- Keep hamper in room for used linen.

Date _____

Signature/Title _____

Item No. 19
Date: May 30, 1979

FORM A

Patient Surveys

Surveys of the patient's room and surrounding areas will be conducted as soon as practicable following implantation of the sources and the return of the patient to the nursing unit.

Exposure rates will be measured using calibrated ionization or GM survey meters, and the measurements will be made at approximately one meter from the approximate center of the implant, at the entrance of the patient's room and at other locations, as needed and as appropriate. These other locations may include sites inside the patient's room, adjacent hallways or corridors, and rooms or areas on either side of the patient's room.

The results of this survey, of which a diagram of the patient's room with notations of measured exposure rates will suffice as minimum, will be recorded in the log book of sealed source usage.

The Radiation Safety Office, Radiation Therapists or Radiation Physicists (or their designates) will then determine allowable times individuals may spend in the patient's room during the course of the implant treatment.

At the time of source removal, when the treatment is discontinued, a survey of the patient will be made with appropriate instrumentation (e.g., a GM survey meter) to assure that all sources have been removed from the patient and that all sources are accounted for (i.e., that no sources are left behind in the patient's room or in other areas occupied by the patient). The results of this (pre)dismissal survey will be entered into the sealed source usage log book.

No posting of the caution signs required by 10 CFR 20.203 will occur for the patient's room (such posting is exempted under the provisions of 10 CFR 20.204(b)), but warning signs more appropriate to the hospital situation will be posted on or near the patient room door alerting personnel and others to the presence of a patient containing radioactive materials.

Bioassay Procedures

Bioassay studies of occupationally exposed personnel will be performed when there is believed to be a risk of significant internal exposure. Commensurate with the relative infrequency of handling miilicurie quantities of Iodine-125 or Iodine-131, the following bioassay procedures will be followed:

1. Any individual who handles (1). more than 200 mCi of nonvolatile, high-specific activity compounds of I-125 or I-131, or (2). more than 1 mCi of these isotope compounds in volatile form, at any one time shall be bioassayed.

2. Between 6 and 72 hours after exposure, the person above will be bioassayed for I-125/I-131 by urinalysis and/or thyroid counting by gamma camera. This shall be performed under the supervision of the Chief of Nuclear Medicine.

3. If bioassay indicates that the thyroid burden is greater than 0.12 uCi or I-125 or 0.04 uCi of I-131:

   a) an investigation of the causes of the exposure will be undertaken to determine causes of the exposure and to evaluate the potential of recurrence;

   b) a repeat bioassay will be made within 14 days of the first measurement to aid in calculating dose committment;

   c) notification, as stipulated by Section 20, 10 CFR will be carried out if needed.

4. If bioassay indicates burdens in excess of 4 times those listed above, procedures will be implemented to accelerate removal of radioactive Iodine from the body. Additionally, repeat bioassays will be performed weekly until levels are below those listed above.

5. Results of all bioassays will be maintained for inspection.

Storage of Sealed Sources

The sources will be storded in a leaded storage safe when not in use. The same contains four inches (10.2 cm.) of lead on all sides as shielding materials.

The storage safe will be located in the medical linear accelerator room, which was designed to house a Varian Associates, Inc., Model Clinac-IV accelerator.

The treatment room is located on the basement floor of a new addition to the hospital. The outside walls of the treatment room contain a minimum of thirty (30) inches of standard density (147 lbs/ft^3 or 2.35 g/cm^3) concrete. With the exception of a maze wall, any inner walls contain a minimum of twenty-four (24) inches of concrete as shielding. The ceiling contains at least thirty six (36) inches of concrete in addition to flooring and/or roofing materials. The space below the treatment room is inaccessible.

Using date from Report #49 of the National Council on Radiation Protection and Measurements, the 10.2 cm of lead in the safe provides an exposure reduction factor of approximately 2E-5, based on a tenth value thickness of 21.6 mm of lead for ^{137}Cs. The lead storage safe provides adequate protection to reduce exposure levels from the stored sealed sources to levels on the order of natural background rates (i.e., in micro-rem per hour), far below the acceptable levels of Section 20.101 of 10 CFR Part 20.

For the concrete support and barrier walls, the tenth value thickness for ^{137}Cesium is 15.7 cm, and exposure reduction factors of 1.3E-4, 1.4E-5 and 1.5E-6 are afforded by the concrete thickness of 24, 30 and 36 inches, respectively.

Based on the exposure reduction factor of 1.4E-5 for the outside walls, exposure rates and radiation levels to unrestricted areas (the area beyond the outside wall is accessible) would be for the levels of Section 20.105 (a) of 10 CFR Part 20. The concrete alone would reduce radiation levels far below the limits of Section 20.105, and in conjunction with the shielding afforded by the storage safe, radiation levels at the outside wall due to the presence of the ^{137}Cs sources would be virtually unmeasureable.

Item No. 20.a.
Date: May 30, 1979

Handling of Sealed Sources

The use of afterloading applicators is intended to minimize the radiation hazard to personnel from the sealed sources.

For the tube-type sources (Nuclear Associates Model 67-800 series ^{137}Cs sources), loading of the applicators will be performed using forceps, tongs or other manipulative devices to reduce the radiation exposure to the extermities. Personnel involved with the loading and unloading of the applicators will utilize a lead L-block to shield the headed body. The L-block contains approximately two inches (5 cm) of lead as shielding and also has a leaded glass window. The 5 cm lead thickness reduces exposure to 0.5% (0.005 relative transmission) while the lead glass window (5 cm thick, 6.2 g/cm^3 density) reduces exposure to 5.4% of the initial intensity.

For the MICRAD™ Sources (Nuclear Associates Model 67-600 series) the separation of the active length from the handler affords a great extremity exposure reduction. No intermediate applicators are necessary, so loading and unloading of the sealed sources involves even less radiation exposure to attending personnel.

Personnel involved with the loading, unloading or other handling of the sealed sources will wear and use ring monitors containing thermoluminescent dosimeters to measure extremity exposure. These will be in addition to the whole body film badges worn by departmental personnel.

A copy of the instructions for the "Cesium Curator" follows.

Item No. 20.b. & d.
Date: May 30, 1979

Instructions for Cesium Curator

Mercy Hospital, Altoona, PA

1. Keep storage safe locked except when removing/returning sources.

2. All cesium sources must be accounted for everytime the storage safe is opened. This involves counting the sources and checking all the sources not in the safe against current cesium insertions. Record this information in the usage log book. If any discrepancy is noted, notify the Radiation Therapist immediately.

3. Wear ring badges whenever handling the sealed sources.

4. Applicators (but no radioactive material) will be stored and sterilized by Operating Room personnel.

5. Insertion and removal of the radioactive materials will be performed in the Radiation Oncology Department.

6. Immediately after every insertion into the applicators, return all unused cesium to the safe. Count and record results in the usage log book. If incorrect, notify Radiation Oncology physicians immediately.

7. A nursing instruction form (Form A) must be completed and inserted as the first page of the patient's chart following insertion.

8. See that the cover of the patient's chart is labeled with a "Caution, Radioactive Material" tag. Radiological safety instructions are to be included.

9. Check to see that all surveys of and concerning the patient are done and properly recorded in the log book.

10. Check date and time of removal of cesium from the patient. Post a notice of this time on the bulletin board.

11. After the radioactive sources have been removed, the proper source counts and dismissal surveys should be done according to the usage book form. The applicators themselves (not containing the cesium) should be removed from the patient by a physician.

12. Following removal, applicators should be cleaned and sent to the Operating Room for resterilization.

13. If sources must be transported, use proper shielded mobile containers.

Item No. 20.b. & e.
Date: May 30, 1979

Inventory Control and Source Accountability

A log of the use of the ^{137}Cs sources for the intracavitary treatments will be kept by the personnel who use and handle these sources (primarily the Radiation Therapy Technologists).

The entries in this log will include:

a) the name and location (room number) of the patient.
b) the applicator(s) and strengths used in the implant. (Strengths (=activities) will be in terms of Radium milligram equivalents.)
c) the initials or signature of the individual who prepared the applicators.
d) strengths used and/or not used.
e) date and time of source insertion.
f) date and time of removal of sources from the patient, with the signature of the individual who removed the sources.
g) date and time of the return of the sources to the storage safe, with initials or signature of the individual doing this.
h) results of patient/room survey after sources removed.

A count of the number of sources present in the storage safe will be made both prior to applicator loading and following the return of the sources to the storage safe after removal of the sources from the patient. This count will be made to assure that the number of sources of any given strength agrees with the inventory number (the storage will be segregated by strength in the drawers of the storage safe). The results of the counts will be recorded also in the usage log book, along with the initials or signature(s) of the individuals who performed the counts.

Also recorded in the log book will be the results of the survey of the patient's room and adjacent areas (a sketch or drawing of the patient's room and other areas surveyed, with the measured exposure rates due to the implanted sealed sources, constitutes the initial survey) as well as the results of the follow-up survey. This follow-up survey will consist of meter measurements of the patient and his room to confirm that no sources remain.

The described method of inventory will be followed whenever the sealed sources are used for treatment. A more detailed, complete inventory of the sealed sources received, possessed and used will be performed on a quarterly basis following the requirements of Section 35.14 (b) (5) (4) of 10 CFR Part 35.

Xenon Handling Procedures
Mercy Hospital, Altoona, PA.

Quantity to be used

1. Approximately 400 patients per year will be studied with an average activity of 10 millicuries per patient.

2. Desired possession limits: 400 millicuries.

Use and Storage Areas

The Xe-133 will be used and stored in the Nuclear Medicine Clinic. Storage of the individual Xe-133 doses will be in a lead container in the isotope storage area surrounded by lead bricks under the fume hood. Patient doses will be administered in the camera room. See Attachment 11-B in Item 11 for diagram.

Description of Ventilation System

The total volume of the camera and adjoining lab area is approximately 4500 cubic feet. The rooms will be under negative pressure with the normal air return system exhausted directly to the outside atmosphere at the measured net flow rate of 800 cfm through ceiling exhaust and fume hood vents, with no recirculated air.

Procedures for Routine Use

1. Xe-133 will be procured in precalibrated doses and delivered directly to the Nuclear Medicine Lab. It will be stored in its shipping container in the isotope storage area until ready for patient administration. Upon receipt, the package will be inspected in accordance with the "Procedures for Opening Packages Containing Radioactive Material" (Item 14).

2. Immediately prior to administration, the dose will be measured in the dose calibrator. A Pulmonex, New England Nuclear, or equivalent Xenon System will be used (see attached descriptions). The patient will be positioned with self-contained breathing bag and/or nose clamp. All valve positions will be checked for proper settings. The dose will then be injected into the mouthpiece and the scan started. After the scan is completed, the exhaled Xe-133 gas will be collected in the integrated gas trap system and allowed to decay to background. No Xe-133 gas will be exhausted into the atmosphere.

Emergency Procedures

1. If during the patient study an accidental release of Xe-133 occurs, the rooms will be evacuated immediately and the doors closed.

2. The room will remain vacated for a minimum of thirty minutes, which will allow for approximately six room air changes.

3. At the end of thirty minutes, the floor will be monitored with a low-range G-M survey meter to check for any residual Xe-133 gas. If the resulting measurements are greater than background, the room will be vacated for another thirty minutes and then monitored again to assure that no Xe-133 is present.

Air Concentrations of Xe-133 in Restricted Areas

I. Camera Room

A. Ventilation rate (V) is 350 cfm.

B. MPC for restricted area for 40 hour week is 1×10^{-5} uCi/ml.

C. Maximum activity used per week (A):

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{8 \text{ patients}}{\text{week}} \times \frac{1 \times 10^3 \text{ uCi}}{\text{mCi}} = 8 \times 10^4 \text{ uCi per week.}$$

D. Assume that as much as 15% of weekly given doses is lost: f=0.15.

E. Volume of air available per week for dilution of Xe-133 (V):

$$V = 350 \text{ ft}^3/\text{min} \times 2.8 \times 10^4 \text{ ml/ft}^3 \times 2.4 \times 10^3 \text{ min/40 hr week} = 2.4 \times 10^9 \text{ ml per week.}$$

F. Volume of air needed to meet the MPC is

$$\frac{A \times f}{1 \times 10^{-5} \text{ uCi/ml}} = \frac{8 \times 10^4 \text{ uCi/week} \times 0.15}{1 \times 10^{-5} \text{ uCi/ml}} = 1.2 \times 10^9 \text{ ml/week}$$

Therefore, the available ventilation rate is more than one order of magnitude above that required to insure compliance with Section 20.103 of 10CFR.

II. Hot Lab

A. Ventilation rate (v) is 450 cfm.

B. MPC is 1×10^{-5} uCi/ml.

C. Maximum activity on hand per week: 400 mCi or 4×10^5 uCi =A.

D. Assume a leakage rate of 15% over a week: f = 0.15.

II. E. Volume of air available per week for dilution of Xe-133:

$$V = 450\ ft^3/min \times 2.8 \times 10^4\ ml/ft^3 \times 2.4 \times 10^3\ min/40\ hr\ wk = 3 \times 10^{10}\ ml/wk.$$

F. Volume of air needed to meet the MPC is

$$\frac{A \times f}{1 \times 10^{-5}\ uCi/ml} = \frac{4 \times 10^5\ uCi/wk \times 0.15}{1 \times 10^{-5}\ uCi/ml} = 6 \times 10^9\ ml/wk.$$

Therefore, the available ventilation rate is five times that needed to insure compliance with Section 20.103 of 10CFR.

Method of Disposal

1. The Xe-133 expired air will be vented through the exit port into the integrated gas trap system. This system will be monitored with a GM survey meter to insure that is performing adequately.
2. If there should be leakage in the gas trap system or storage container, the Xe-133 gas will be exhausted to the outside through the fume hood vent at the rate of 450 cfm.
3. If there is an accidental release of Xe-133 in the camera room, the gas will be exhausted to the outside through the ceiling vent at the rate of 350 cfm.
4. Initially, to insure that collection and ventilation systems are performing satisfactorily, exposure rate measurements will be made at one foot from the breathing bag, prior to venting to the integrated gas trap system. After the bag has been vented, exposure rate measurements will be made at the surface of the bag to assure that no residual radioactivity remains prior to routine disposal (meter reading less than .05mR/hr above background). Results of these measurements and disposals will be recorded and used to periodically check the performance of the system.
5. The air from the outlet port of the trap system will be recollected into the breathing bag, which will be monitored with a G-M survey meter to check on system performance and to determine when the filters approach saturation point.

Item 21
Date: May 30, 1979

Method of Disposal (cont'd.)

6. Saturated filters will be removed from the system and stored in air-tight shielded containers until the X3-133 activity decays to background (meter reading less than 0.05 mR/hr above background), or will be disposed of through a commercial vendor. Records will be maintained of such monitoring and disposal.

7. Flow meter measurements will be used to assure that the ventilation rate is adequate. This has been done and will be repeated annually and after any repairs that may alter the flow rate.

8. Periodic surveys shall be made of the storage areas to insure that radiation levels are within allowable limits and as low as reasonably achievable.

Concentrations in Effluents to "Unrestricted" Areas

The camera room and fume hood vents share a common duct (certified leak-tight) to the roof of a 6 story building, and is 58 feet from the nearest air intake or adjacent building.

A. Maximum amount to be realeased per year (A): $A = A1 + A2$, where
$A1 = 10\ mCi/patient \times 8\ patients/week \times 52\ weeks/year \times 1000uCi/mCi \times 15\%\ assumed\ loss = 6.2 \times 10^{5}\ uCi/year$, and
$A2 = 400\ mCi/week \times 52\ week/year \times 1000uCi/mCi \times 15\%\ loss = 3.1 \times 10^{6} uCi/yr.$
Therefore, A, the sum of patient dose losses and storage losses equals $3.7 \times 10^{6}\ uCi/yr.$

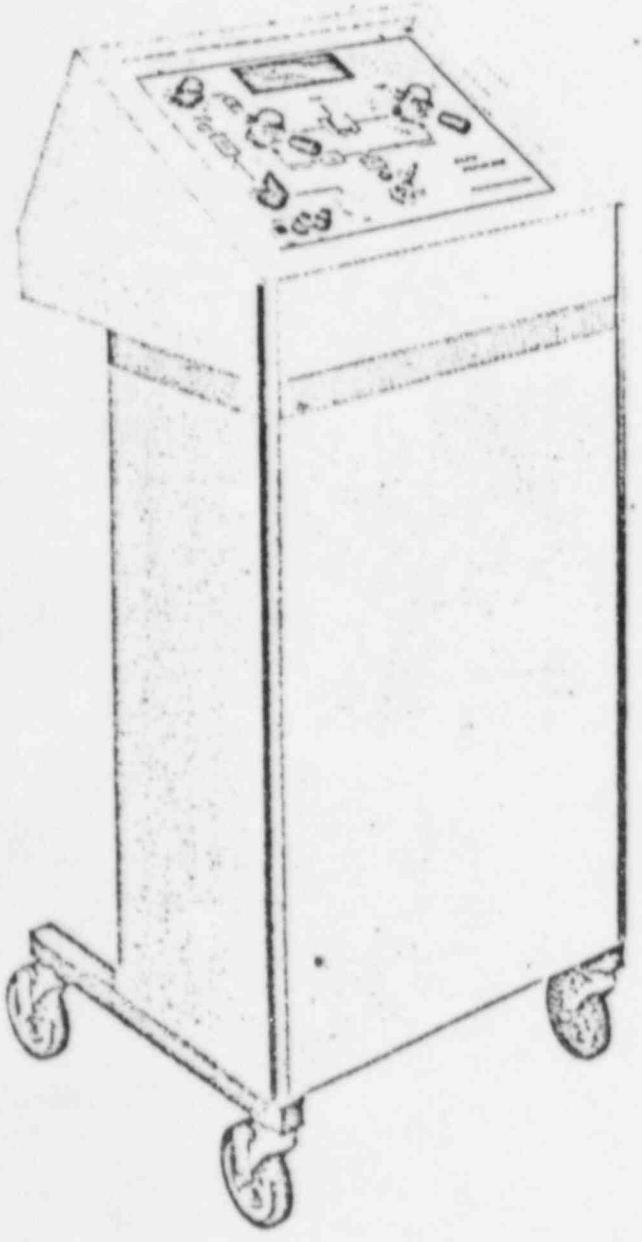
B. Net exhaust rate $= 350 + 450 = 800\ ft^3/min \times 1.49 \times 10^{10}\ ml/yr(ft^3/min)^{-1}$
$= 1.2 \times 10^{13}\ ml/yr.$

6. Concentration, $C = \frac{3.7 \times 10^{6}\ uCi/yr}{1.2 \times 10^{13} ml/yr} = 3 \times 10^{-7}\ uCi/ml$, which is equal to the MPC for unrestricted areas. Given that access to the roof is lock-controlled, that the roof is essentially unoccupied, and that the outlet is as far as it is from possibly "unrestricted" areas, this arrangement is deemed sufficient. Changes in workload or construction changes will warrant re-evaluation.

ATTACHMENT: Xenon System Description

AUTOMATIC

PULMONEX XENON SYSTEM



AUTOMATIC

Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

- Complete easy-to-use system.
- Motor-driven circulator for resistance-free patient breathing.
- Automatically timed washout.
- Adjustable air flow control.
- Accepts any commercial form of xenon.
- Rolls easily on large casters for positioning of supine or seated patients.
- Lead glass window permits observation of patient breathing bag.
- Fully shielded.
- Carbon dioxide and moisture traps included.

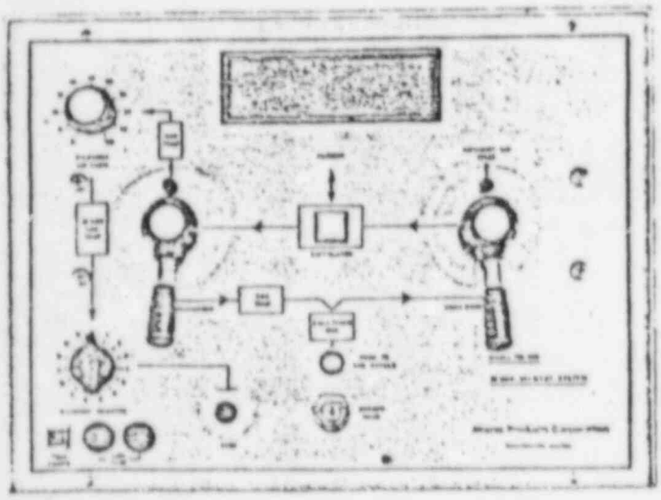
Simple to operate • safe to use

The Pulmonex Xenon System is a simple to use, reliable and complete system for the performance of all regional ventilation studies. A built-in xenon gas trap with disposable charcoal cartridge removes xenon effluent after each study and eliminates the need for expensive venting systems. Motor-controlled air flow assures resistance-free breathing regardless of your patient's pulmonary condition. Practical cabinet design and total mobility permit easy patient positioning in the seated or supine positions.

PULMONEX. .the complete, self-contained xenon system

Pulmonex provides a completely integrated system for performing xenon studies. A series of sensitive valves and synchronized motors permit full-system control of xenon gas flow from initial application to ultimate disposition of the xenon effluent into the gas trap.

All controls are conveniently located on an "up-front" control panel. With the patient on-line, the user can control the system and observe the patient and gamma camera from one position. All controls are clearly marked. A unique procedure flow diagram on the panel provides an indication of each function as the user goes through the study. The 5-liter patient breathing bag can be observed through a lead glass viewing window on the front panel.



The PULMONEX SYSTEM

The Pulmonex Xenon System effectively integrates manual and electronic controls into a simple, sensitive system that provides maximum, reliable test results using minimum effort. System complexities have been eliminated. All internal circuitry, valves and tubing have been designed to afford ease of operation and patient comfort.

Manually operated valves controlled by directional handles direct the flow of gases throughout the system. Oxygen may be added to the system at any time during a study by fingertip button control. A push button operates a circulator blower motor to provide gentle positive system pressure. This, combined with a specially-designed valve and wide diameter, short circuit airways, provides resistance-free patient breathing. There is no dead air space. An injected bolus of xenon reaches your patient exactly when desired. An in-line CO_2 absorber prevents hyperventilation. The system has automatic timer and pressure control dials to accommodate your patient's breathing pattern and to assure complete system washout into the gas trap.

All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter may be used at the mouthpiece to prevent system contamination.

INTEGRATED XENON GAS TRAP

The Pulmonex system has its own built-in gas trap. Exhaled xenon is gently pulled through activated charcoal contained within a "U" shaped cartridge made of 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 clean air leaves the trap exit port. A built-in 30-liter overflow collection bag permits maximum trapping throughout the washout cycle. Under normal usage the charcoal cartridge will last about a year. The gas trap cartridge is easily replaced when expended.

Specifications:

All motors UL approved. 115 VAC, 50/60 Hz.

Size: 18" x 19" x 46"

Weight: 150 lbs.

130 500 Pulmonex Xenon System, complete . . $2350.00

Sealed Source Leak Testing

Following the provisions of 10 CFR 35.14 (b) (5), the sealed sources used for Group VI, human use procedures and other sealed sources listed in Item 6.b. will be inventoried and tested for leakage at intervals not to exceed six months.

The sources (or their active lengths) in the case of the MICRAD™ sources) will be wiped with filter papers or cotton swabs which have been moistened with water, alcohol, or other fluids which would not debrade the sources or their housings. The wipes will be placed into separate, marked test tubes or envelopes until such time as the analysis of leakage were to occur.

The wipes would be counted on equipment such as a gas flow proportional counter or a gamma spectrometer. A reference source of the same isotope or an an isotope with a similar emission decay scheme would be counted with the wipes to determine the detection efficiency. Background count rates would be determined using plain, unusued filter papers or cotton swabs. The net count rate for each wipe, when divided by the detection efficiency, yields the measured leakage. The minumum detectable activity of this method is calculated as (for a 96% confidence level) twice the square root of the background counts divided by the counting time. The minimum detectable activity typically seen by such counting equipment is one nanocurie (0.001 microcurie) or less, enabling the detection of any leakage of 0.005 uCi (5 nCi).

Personnel handling the sources or the performance of the leak test will be film-badge monitored. Such personnel will also utilize protective shielding and manipulative devices to reduce the whole body and extremity dose while handling the sealed sources.

Item No. 23
Date: May 30, 1979

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED

Applicant/Licensee: Mercy Hospital

Application Dated: 11/21/84

Control No.: 03175

License No.: 37-03387-02

2. FEE ATTACHED

Amount: $580.00

Check No.: 004601

3. COMMENTS

Signed Brenda P. Slatcher

Date 12/3/84

12/31/84

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C $580

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal ✓

License _____

Signed Frances Brown

Date 12/10/84

12/17/84

REGION I FORM 213
(MARCH 1983)