3/4-Reg III
DCS

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

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

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

St. Joseph's Hospital
700 Broadway
Ft. Wayne, Indiana 46804

TELEPHONE NO.: AREA CODE (219) 423 2614

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Sandy Siebert

TELEPHONE NO.: AREA CODE (219) 423 2614

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 13-00418-02

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

See Attachment 1

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.)*

John Pasalich, M.D. 2/29/80 7B

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
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	3000
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	1000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	500

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

Applicant
Check No. 13803
Amount/Fee Category H 150 (7D)
Type of Fee Renewal
Date Check Rec'd FEB 4 1980
Received By Thorn

RECEIVED BY LFMB
Date FEB 4 1980
Log FEB PG 1 Renewal
By TDRoun
Orig. To
Action Compl. 2/4/80

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: Jan 1979

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and See Attached
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or Also See attached
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
x	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
X	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Searle	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	same	monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ $150

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)* Sr.M.Kathleen Quinn

Sister M. Kathleen Quinn

(2) TITLE

Administrator

c. DATE

Jan. 29, 1980

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.

FORM NRC-313M
(8-78)

Individual Users	Materials and Uses Authorized
Fouad Halaby, M.D.	All
Steve C. Cuff, M.D.	All
Richard Bauman, M.D.	For Diagnosis
John Pasalich, M.D.	For Diagnosis
David Sorg, M.D.	For use of I-131 for treatment of hyperthyroidism

Attachment 1
1/28/80

MEDICAL ISOTOPES COMMITTEE

Fouad Halaby, M.D. Radiologist

Steve C. Cuff, M.D. Radiologist

Richard L. Bauman, M.D. Radiologist

John N. Pasalich, M.D. Radiologist

David Sorg, M.D. Internal Medicine

Sisira Ranasinghe, M.D. Pathologist

Sashi Ahuja, M.D. Cardiologist

John M. Hoog, M.D. Urologist

William Wissman, Associate Administrator

Melvin J. Powell, M.D., Radiologist

John Daughdrille, M.D., Radiologist

ITEM 7
1/28/80

TRAINING AND EXPERIENCE

Training and experience documentation for all Individual Users except Dr. Steve Cuff is currently on file with license # 13-00418-02.

Training and experience documentation for Dr. Cuff except for Group VI is on file with license # 13-00418-02.

Form 313M Supplement B on Dr. Cuff is enclosed in support of our request to authorize Dr. Cuff for the materials and uses listed in Group VI.

Item 8
1/28/80

FORM NRC-313M-SUPPLEMENT B
(8-78)

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

STEVE C. CUFF. MD

STREET ADDRESS

700 BROADWAY

CITY	STATE	ZIP CODE
FORT WAYNE	IN	46802

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	144	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	180	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES	—	
	KIDNEY FUNCTION STUDIES	36	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	157	
P-32	EYE TUMOR LOCALIZATION	—	
Se-75	PANCREAS IMAGING	—	
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	47	
OTHER			
Tc-99m	BRAIN IMAGING	250	
	CARDIAC IMAGING	17	
	THYROID IMAGING Tc99m	250	
	SALIVARY GLAND IMAGING	—	
	BLOOD POOL IMAGING	—	
	PLACENTA LOCALIZATION	17	
	LIVER AND SPLEEN IMAGING	70	
	LUNG IMAGING	75	
	BONE IMAGING	52	
OTHER			

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	13	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	7	
I-131	TREATMENT OF THYROID CARCINOMA	2	
	TREATMENT OF HYPERTHYROIDISM	10	
Au-198	INTRACAVITARY TREATMENT	2	
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT	12	
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT	1300	
Sr-90	TREATMENT OF EYE DISEASE	—	
	RADIOPHARMACEUTICAL PREPARATION	—	
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

6-1963 through 6-1966 Illinois Masonic Hospital, Chicago, Ill. (Wm. T. Morgans, MD)
7-1966 Through present time, St. Joseph's Hospital, Fort Wayne, Ind

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Fouad A. Halaby, M.D.

b. NAME OF INSTITUTION
St. Joseph's Hospital

c. MAILING ADDRESS
700 Broadway

d. CITY
Fort Wayne, Indiana

5. MATERIALS LICENSE NUMBER(S)
13-00418-02, 13-00418-04

6. PRECEPTOR'S SIGNATURE
Fouad A Halaby MD

7. PRECEPTOR'S NAME *(Please type or print)*
Fouad A. Halaby, M.D.

8. DATE
January 28, 1980

FORM NRC-313M-SUPPLEMENT B
(8-78)

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Picker

      Manufacturer's model number: 655-186

      Number of instruments available: 1

      Minimum range: 0 mr/hr to .2 mr/hr

      Maximum range: 0 mr/hr to 2000 mr/hr

   b. Manufacturer's name: _____

      Manufacturer's model number: _____

      Number of instruments available: _____

      Minimum range _____ mr/hr to _____ mr/hr

      Maximum range _____ mr/hr to _____ mr/hr

2. Dose calibrator

   Manufacturer's name: General Electric

   Manufacturer's model number: CRC-8

   Number of instruments available: _____

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	Pho-Gamma III HP

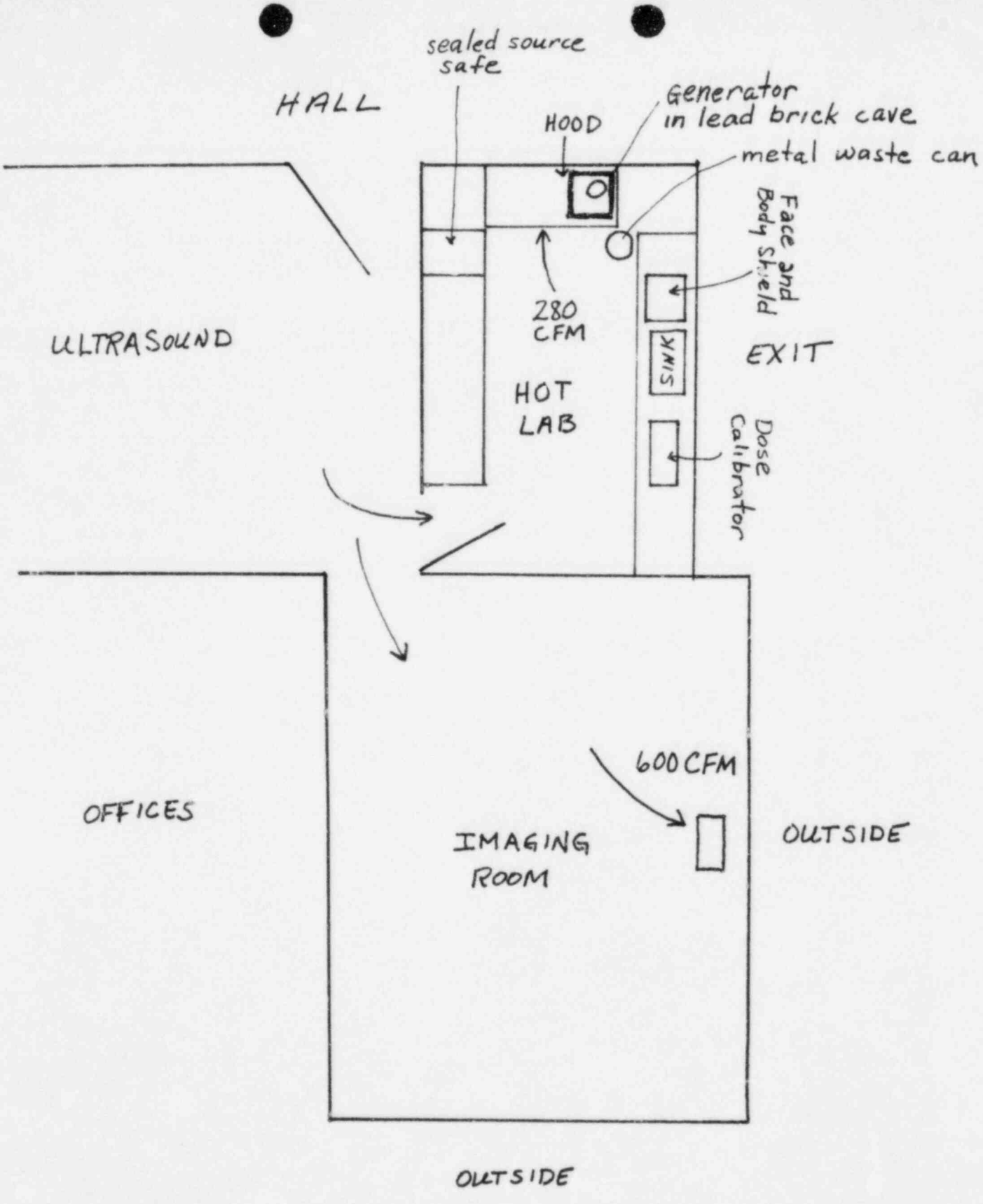
4. Other

   General Electric Model INS-15 (serial no. 44053308)
   spectrometer with well crystal and thyroid uptake probe

FACILITIES AND EQUIPMENT

A sketch of the areas in which radioactive materials are used is attached. All work benches and the hood work area have impervious surfaces which are routinely covered with absorbent paper (changed weekly or more often if necessary). Remote handling tongs are used for handling and preparing "hot" materials. The Mo-99/Tc-99m generator is set up in the hood behind lead bricks. All other radioactive sources (except the sealed therapy sources) are kept in an appropriate lead pig (original shipping container when possible) in the hood and lead bricks are used as supplemental shielding. All individuals working with radioactive materials wear lab coats and gloves. All patient dose preparations are done behind the leaded face-and-body shield.

All radioactive waste is stored for decay until it can be disposed of as nonradioactive waste. All waste is stored either on a short term basis in the hot lab (behind lead bricks in hood) or on a long term basis in a well in the floor of the Co-60 teletherapy room. All waste is surveyed periodically with a GM survey meter and is discarded as nonradioactive only when the survey meter reading is no more than background.



ITEM 11 (cont)
1/28/80

All hospital personnel who work with or in the vicinity of radioactive materials will receive proper instruction in accordance with Section 19.12 of 10CFR Part 19, including:

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) The rules and regulations of the licensee.

f) The 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.

The above instruction will be provided in the form of an approximately one hour lecture to all appropriate personnel, such as nursing, clerical, housekeeping and security personnel. Such instruction will be provided before these personnel assume their duties with or in the vicinity of radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations or in the terms of the license.

INSTRUCTIONS FOR RECEIPT OF

PACKAGES CONTAINING RADIOACTIVE MATERIAL

The following instructions are to be observed for all incoming shipments of radioactive material:

Examine package for evidence of external damage:

1. If there is no evidence of external damage, take the package to the Nuclear Medicine hot laboratory.

2. If there is evidence of external damage, such as crushing, wetness or water stains, put on plastic gloves and place the package in a plastic bag. Seal the bag and take it to the Nuclear Medicine hot laboratory. Notify the Radiation Safety Officer immediately. Do not let carrier leave the facility until he and his vehicle have been checked for contamination by the Radiation Safety Officer.

Note: Radioactive material is to be ordered only by Nuclear Medicine personnel and packages containing radioactive material are to be opened only by Nuclear Medicine personnel.

Radiation Safety Officer: *John Pasalich, M.D.*
Office: 219/423-2614 ex. 2281
Home: 219/432-6394

Item 13
1/28/80

INSTRUCTIONS FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Packages containing radioactive material are to be opened only in the Nuclear Medicine hot lab by authorized individuals.

2. Individual opening package will wear protective clothing and gloves.

3. Note external condition of package and record. If package is wet or stained, immediately wipe test the package surface with filter paper or alcohol prep and forceps. Place wipe in a test tube and count in the well spectrometer. If counts are above 22,000 dpm, notify the Radiation Safety Officer.

4. All packages must be surveyed with a GM survey meter prior to opening. Record results.

   A. Measure exposure rate at 3 feet from package surface with thin-window GM detector. If this reading is >10 mR/h, proceed with caution and immediately notify the Radiation Safety Officer.

   B. Measure the exposure rate at the package surface. If this reading is >200 mR/h, proceed as in step A (above).

5. Carefully open outer shipping container and remove the radionuclide. Measure the exposure rate at the surface of the empty shipping container and record result. If this reading is greater than twice background, the final container must be wipe tested and the results recorded.

   A. Wipe test with filter paper or alcohol prep and forceps. Place wipe in a test tube and count in the well spectrometer. If counts are above 22,000 dpm, notify the Radiation Safety Officer immediately.

6. After package has been surveyed, complete the remaining sections on the package receipt form.

7. If package and/or packing material are contaminated, treat as radioactive waste. If not, obliterate radiation warning labels and discard as normal waste.

RADIATION SAFETY OFFICER: John Pasalich, M.D.
Office phone:219/423-2614 ex. 2281
Home phone:219/432-6394

ITEM 14
1/28/80

PACKAGE RECEIPT LOG

DATE	ISOTOPE	FORM	MANUFACTURER	PACKAGE CONDITION	LABEL T.I.	MR/HR @CONTACT	MR/HR @ 3 FEET	MR/HR EMPTY CONTAINER	WIPE TEST RESULTS	TECH

AREA SURVEY PROCEDURES

Appendix I procedures are followed except that 1000 CPM per 100 cm^2 is the action level requiring decontamination. Wipe samples are counted in a well counter using a wide PHA window.

ITEM 17
1/28/80

APPENDIX J

WASTE DISPOSAL

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

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

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

X Other (specify): Held for decay

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

_____ Returned to the manufacturer for disposal.

X Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

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

_____ Other (specify): _____

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

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

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

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

ITEM 18
1/28/80

PRECAUTIONS FOR
HANDLING SEALED RADIOACTIVE SOURCES
CONTAINING THERAPEUTIC QUANTITIES
OF RADIOACTIVE MATERIAL

Special precautions to be used when handling sealed sources for therapy are as follows:

1. Sealed sources should be handled only by a Radiation Therapist or by the Therapy technologist.

2. Sealed sources shall always be handled with remote handling devices, never with the fingers.

3. Sealed sources shall be handled behind a face-and-body shield whenever possible.

4. In addition to the whole body badge, a TLD finger ring shall be worn whenever handling sealed sources.

5. Transportation of sealed sources within the hospital shall always utilize an appropriate shielding apparatus. Only occupationally exposed individuals shall be allowed on an elevator when sources are taken to one of the other floors of the hospital.

6. When not in use, the sealed sources shall be stored in lead pigs inside the leaded safe in the Nuclear Medicine hot laboratory. This safe shall remain locked at all times when the Nuclear Medicine laboratory is unattended.

7. Any time a sealed source is removed from storage an entry shall be made in the log book. Such entry shall indicate the date, the number and type of sources removed, the patient's name, and the name of the individual removing the sources. When the sources are returned to storage, an entry shall be made indicating the date, the number and type of sources returned, and the name of the individual returning the sources to the safe.

8. Whenever new sources and/or new procedures are utilized, "dry" runs with dummy sources shall be performed in order to evaluate shielding design and to perfect the handling techniques.

John Pasalich, M.D.
Radiation Safety Officer

ITEM 20
1/28/80

12.0 PRECAUTIONS IN THE MANAGEMENT OF PATIENTS RECEIVING RADIOACTIVE MATERIALS FOR THERAPEUTIC PROCEDURES

12.1 General

1. Patients containing therapeutic quantities of gamma emitting radioactive nuclides with half-lives greater than 125 days must be hospitalized for the duration of the treatment. The sources must be removed before discharge of the patient.

2. Patients containing therapeutic quantities of gamma emitting radionuclides with half-lives less than 125 days may be released from the hospital when their radioactivity content does not exceed 30 millicuries (except in the case of intraperitoneal or intrapleural administration of colloidal gold-198, where the patient should remain hospitalized for 48 hours for observation of the insertion site).

12.2 Instructions for Care of Patients Containing Sealed Source Implants

1. Radium or cesium as sealed sources may be used in three (3) ways:

   a) Plaque, for superficial lesions of skin, mouth, eye.

   b) Intracavitary, for lesions within any accessible body cavity.

   c) Interstitial implants, as needles or seeds, within body tissues.

2. The radioactive sources are in solid sealed containers and present no danger of contamination of excreta, bed clothing, bandages or other dressings. However, all linen, waste baskets, etc., leaving the room during treatment should be surveyed for sources that may have become dislodged. No radioactivity remains in the patient after the sources are removed.

3. Radioactive sealed sources must always be applied and removed by the Radiotherapist.

4. Intracavitary and interstitial therapy will usually be done in surgery under general anesthesia. Plaque therapy and some intracavitary therapy may be done in the patient's room or in the Radiation Therapy Department. Transportation of the patient after the radioactive sources are in place will be kept to a minimum and will be supervised by personnel trained in radiation safety. Whenever possible, afterloading devices will be employed in order to minimize unnecessary personnel exposure, (e.g., when radiographs are required to document applicator positioning).

5. Implant patients will be confined in a private room during the time that the radioactive sources are in place and the room will be posted with a "CAUTION: RADIATION AREA" sign, a "CAUTION: RADIOACTIVE MATERIALS" sign, and the [illegible] Temporary Implant Radiation Safety Report form (Appendix 1). The same room(s) should be used for all implant patients, thus eliminating the need for detailed exposure rate surveys of adjacent areas for each implant procedure (see Item 7 below), and also insuring that properly informed paramedical personnel are attending the patient.

6. Time and distance are important factors in assuring minimal personnel exposures. Radiation exposure is directly proportional to the time spent at a given distance from the patient, while increasing the working distance from the patient decreases the radiation exposure by the square of the change in distance (e.g., doubling the distance decreases the radiation exposure by a factor of 4, tripling the distance decreases the radiation exposure by a factor of 9, etc.).

7. The Radiation Safety Officer is responsible for insuring that the radiation exposure of nurses and other paramedical personnel, visitors and adjacent patients is limited to less than 2 mR in any one hour and 100 mR per admission. The Radiation Safety Officer will perform, or cause to be performed, exposure rate surveys sufficient to document that these exposure levels will not be exceeded. If the same room(s) is(are) used for all implant patients, detailed exposure rate surveys of adjacent areas need only be performed once for each type of treatment procedure. When temporary implants are removed, the patient and all areas occupied by the patient will be surveyed to be sure that all sources have been removed.

8. All hospital personnel attending a patient containing radioactive sealed sources must wear a personnel monitoring device (usually a pocket ionization chamber).

9. In cases involving the uterus, cervic or other pelvic organs, the patient may be permitted to use a bedpan. It should be remembered, however, that the sources can be expelled during defecation and the bedpan must be carefully checked after use to be sure the applicator or a source has not been expelled.

10. Should one of the radiation sources be found outside the patient (on floor, in bed linen, in bedpan, etc.) notify the Radiation Therapist and/or Radiation Safety Officer immediately. Do not pick up the source with your fingers. Prevent entry into the room until the arrival of one of the above individuals.

11. Visitors should consist of adults only (over age 18) and should be instructed to remain at least six (6) feet from the patient. Visiting time should be limited to 20-30 minutes, although longer visits may be permitted by the Radiation Therapist and/or Radiation Safety Officer if necessary. Pregnant visitors are not allowed in the room.

12. Pregnant nurses or other paramedical personnel who are pregnant must not be assigned to a patient containing radioactive sealed sources.

13. Should the patient expire during the therapy procedure, the Radiation Therapist must be notified immediately.

12.2 Instructions for Care of Patients Receiving Iodine-131 and Requiring Hospitalization

1. Patients hospitalized for treatment with iodine-131 present special handling problems since there is potential for internal contamination as well as the expected external hazard. A substantial fraction of the administered radioiodine is excreted in the urine and may also be present in saliva and perspiration.

2. The patient shall be placed in a private room with a toilet.

3. The patient's room shall be posted with a "CAUTION: RADIOACTIVE MATERIALS" and a "CAUTION: RADIATION AREA" sign, and the Iodine-131 Radiation Safety Report form (Appendix 2).

4. Surveys of the patient's room and surrounding areas shall be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times in the patient's chart and on his door (see Appendix 2). The results of daily surveys will be used to recalculate permitted times which will be posted in the patient's chart and on his door.

5. The Radiation Safety Officer is responsible for insuring that the radiation exposure of nurses and other paramedical personnel, visitors, and adjacent patients is limited to less than 2 mR in any one hour and 100 mR per admission.

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

7. Disposable plates, cups, eating utensils, tissue, surgical dressings and other similar waste items shall be placed in a specially designated container. This material will be collected daily by the Radiation Safety Officer or his designee, 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 checked for contamination by the Radiation Safety Officer or his designee. Items will be returned for normal use, held for decay, or decontaminated, as appropriate.

9. The patient shall be confined to the room until the retained activity is less than 30 millicuries.

10. Hospital personnel entering the room must wear a radiation monitoring device (film badge or pocket dosimeter) and gloves.

11. Pregnant nurses shall not be permitted in the room.

12. There will be no visitors during the first 24 hours.

13. There shall be no visitors who are pregnant or under 18 years of age. Other visitors should be limited to 30 minutes per day and should stay at least 6 feet from the patient.

14. Since NRC regulations do not apply to excreta from patients containing radioactive material, the patient can use the regular toilet facilities. If the patient is not ambulatory and must use a urinal or bedpan, he should be instructed to collect his own urine. If an attendant must help, he should wear protective gloves and wash his hands thoroughly before and after removing the gloves. A separate, preferably disposable, bedpan or urinal should be kept for the patient until he is

discharged. The urinal or bedpan should be flushed several times with hot soapy water after each use.

15. Vomiting, urinary incontinence, or excessive sweating in the first 48 hours after administration of the Iodine-131 may result in significant contamination of linen and/or floor. Contact Nuclear Radiology and/or the Radiation Safety Officer immediately. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading the contamination.

16. If the patient dies or needs emergency surgery during the confinement period, contact the Radiation Safety Officer and/or Nuclear Radiology immediately.

17. Before the room is reassigned to another patient, it shall be surveyed for contamination (and decontaminated, if necessary) by the Radiation Safety Officer or his designee.

HOSPITAL AND NURSING INSTRUCTIONS FOR PATIENTS RECEIVING PHOSPHORUS-32

1. Colloidal radioactive chromic phosphate (P-32) therapy for palliation of serous effusions of the pleural or peritoneal cavities:

   a. The only significant hazard is leakage from the puncture wound made during injection.

   b. The dressing over the injection site should be inspected visually several times each day. If there is evidence of drainage, notify the attending physician and Nuclear Medicine immediately. The dressing should be changed only under the direction of the attending physician.

   c. In the event of drainage, the dressing and linen must be considered contaminated until monitored by Nuclear Medicine personnel. Rubber gloves must be worn when contamination is suspected and all linens, dressings and gloves must be placed in a plastic bag.

   d. Excreta from these patients will not contain radioactivity and no special handling procedures are necessary.

   e. Usual nursing care can be performed for these patients without special precautions.

2. Therapetuic quantities of injected Phosphorus-32:

   a. If the patient can use the toilet, 2 ounces of Radioactive Phosphorus Protective Solution* should be placed in the bowl before use and then the toilet should be flushed three times.

   b. A separate bedpan should be provided for patients who cannot use the toilet. Add 2 ounces of Radioactive Phosphorus Protective Solution* to the toilet bowl before flushing, then flush the toilet three times. The bedpan should be rinsed with the Protective Solution after each use.

   c. Gloves must be worn when handling bedpans, linen and the patient.

   d. Used gloves and soiled linen should be placed in a bag at the end of the bed for subsequent monitoring by Nuclear Medicine personnel.

   e. These precautions should be followed for one week after each dose of P-32.

*Radioactive Phosphorus Protective Solution = 3 grams NaH_2PO_4 in 1 liter of water.

ITEM 19 (cont)

APPENDIX 1

TEMPORARY IMPLANT RADIATION SAFETY REPORT*

PATIENT'S NAME _____ ROOM NUMBER _____

RADIONUCLIDE _____ TOTAL ACTIVITY _____

DATE AND TIME OF IMPLANT _____

INITIAL SURVEY DATA DATE _____ TIME _____ SURVEYOR _____

LOCATION	EXPOSURE RATE (MR/H)
1. @ 1 METER FROM PATIENT	_____
2. @ 6 FEET FROM PATIENT	_____
3. @ BEDSIDE	_____
4. @ 18" FROM WALL IN ADJACENT ROOMS (A)	_____
(B)	_____
(C)	_____
(D)	_____
5. @ 18" FROM FLOOR ABOVE	_____
6. @ 6' FROM FLOOR BELOW	_____

SPECIAL NURSING INSTRUCTIONS

1. THE PATIENT MUST BE CONFINED TO THIS ROOM.
2. HOSPITAL PERSONNEL ENTERING THE ROOM MUST WEAR A POCKET DOSIMETER.
3. PREGNANT NURSES ARE NOT TO BE ASSIGNED TO THIS PATIENT.
4. THERE ARE TO BE NO VISITORS WHO ARE PREGNANT OR UNDER 18 YEARS OF AGE. OTHER VISITORS ARE LIMITED TO 30 MINUTES PER DAY AND MUST STAY AT LEAST 6 FEET FROM THE PATIENT.
5. SHOULD A RADIOACTIVE SOURCE BE FOUND OUTSIDE THE PATIENT, NOTIFY THE RADIATION SAFETY OFFICER IMMEDIATELY.
6. ALL LINENS, GOWNS, DRESSINGS, ETC. MUST REMAIN IN ROOM AND NO CLEANUP STARTED UNTIL ALL SEALED SOURCES ARE ACCOUNTED FOR BY RADIOTHERAPY.

FINAL SURVEY DATA DATE _____ TIME _____

LOCATION	EXPOSURE RATE (MR/H)
1. @ 1 METER FROM PATIENT	_____

ALL SOURCES ACCOUNTED FOR? YES/NO IF NO, DOCUMENT FOLLOWUP.

* THIS FORM MUST BE POSTED ON THE DOOR TO THE ROOM OF A PATIENT CONTAINING TEMPORARY RADIOACTIVE SEALED SOURCE IMPLANTS.

APPENDIX 2

RADIATION SAFETY REPORT FOR PATIENTS
WHO HAVE RECEIVED THERAPEUTIC (> 30 mCi) AMOUNTS OF RADIOIODINE

PATIENT'S NAME _____ ROOM NO. _____ RADIONUCLIDE _____

TOTAL ACTIVITY ADMINISTERED _____ DATE AND TIME ADMINISTERED _____

EXPOSURE RATE @ ONE METER:

Date	Time	Exposure Rate
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

RECOMMENDED NURSING ATTENDANCE TIMES:

Date	Within 2 feet	Within 6 feet

SPECIAL NURSING INSTRUCTIONS:

1. The patient must be confined to this room.
2. Hospital personnel entering the room must wear a radiation monitoring device (film badge or pocket dosimeter) and gloves.
3. Pregnant nurses are not to be assigned to this patient.
4. There are to be no visitors for the first 24 hours.
5. There are to be no visitors who are pregnant or under 18 years of age. Other visitors are limited to 30 minutes per day and must stay at least 6 feet from the patient.
6. The patient is to use disposable eating utensils.
7. Linen should be placed in a plastic bag and kept in the patient's bathroom or at the foot of the bed. Gloves and other disposable items should be placed in a separate plastic bag. Do not remove these bags from the room until they are checked by the Radiation Safety Officer.
8. Flush toilet (or rinse bedpan) several times after each use.
9. In the event of an emergency (vomiting, accidental spillage, etc.), contact the Radiation Safety Officer immediately. Cleanup should be performed only under the supervision of the Radiation Safety Officer.
10. Contact Radiation Safety Officer as soon as patient is discharged. Before this room is reassigned to another patient, it must be surveyed for contamination and decontaminated, if necessary.

PROCEDURES AND PRECAUTIONS FOR USE OF XENON-133

The Xenon-133 will be stored behind lead bricks in a properly labelled hood in the hot laboratory. The hood exhausts the hot lab at 280 cubic feet per minute straight to the roof of the hospital. Thus, the total air moved through the hood is 1.9×10^{10} cubic centimeters during a 40 hour working week and up to 190 millicuries per week could be released into the hood (or hot lab) per week without exceeding the average occupational MPC(air) of 10^{-5} uCi/cc. This is a conservative calculation since no account is made of the fact that the hood exhaust system is operational 24 hours per day, not just during the daily 8 hour occupational period. In terms of the more restrictive limits for release into unrestricted areas, the weekly (168 hour) exhaust from this room is 8×10^{10} cubic centimeters. Assuming this dilution volume, up to approximately 24 millicuries of Xenon-133 could be released into the room per week without exceeding the average MPC(air) for unrestricted areas of 3×10^{-7} uCi/cc. Assuming a 25% leakage rate, up to 760 millicuries could be stored in the hood without exceedin the occupational MPC(air) , but only 96 millicuries could be stored without exceeding the MPC(air) for unrestricted areas. An actual possession limit of 500 millicuries is being requested, however, in order to cover the total Xenon-133 present in the laboratory at any one time (new shipments, stored Xenon-133, and the Xenon-133 being held for decay in the Xenon trap).

The Xenon-133, obtained from an approved supplier, is administered to the patient using an Atomic Products Corp. model 130-330 Xenon Delivery Unit. The rebreathing system and the patient will be washed out through an Atomic Products Corp. model 127-313 Xenon Gas Trap. The effluent from the trap will be continuously monitored with an Atomic Products Corp. model 136-100 Xenon Gas Trap Efficiency Monitor. The exhaust from the imaging room is 600 cubic feet per minute straight to the roof. Thus, the total air moved from this room during a 40 hour and 168 hour period is 4.08×10^{10} cubic centimeters and 1.71×10^{11} cubic centimeters, respectively. Assuming a 25% leakage rate, up to 1632 millicuries can be handled in this room per week without exceeding the average occupational MPC(air) of 10^{-5} uCi/cc, but only up to 216 millicuries per week can be handled without exceeding the average MPC(air) for unrestricted areas of 3×10^{-7} uCi/cc.

Both the hot lab and the imaging room are maintained under negative pressure since the only makeup air is provided through the doorways (see diagram under facility description)

The average administered patient dose is 20 millicuries. Thus, up to an average of 11 patient studies per week can be performed in the existing imaging area.

There are approximately six air changes an hour in the imaging room. In the event that there is an accidental release of a full patient dose of Xenon-133 into the imaging room, the patient and staff will vacate the room for approximately one hour. The room will be surveyed upon reentry in order to verify that no detectable xenon-133 is remaining.