

FORM NRC-313M

7-77

10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

## APPLICATION FOR MATERIALS LICENSE - MEDICAL

4/31/78

EX  
7B

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. Mail two copies 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 NRC Materials License. A 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

Tipton County Memorial Hospital  
1000 South Main Street  
Tipton, Indiana

TELEPHONE NO.: AREA CODE (317) 675 8500

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

Robert T. Anger, Jr., M.S.

TELEPHONE NO.: AREA CODE (317) 927 3572

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

a. ☐ NEW LICENSE

b. ☐ AMENDMENT TO LICENSE NO. \_\_\_\_\_

c. ☒ RENEWAL OF LICENSE NO. 13-01719-02

03209577

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

Richard Bilodeau, M.D.  
Bonnie Riley, M.D.  
Clarence Cobb, M.D.

5. RADIATION PROTECTION OFFICER (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Supplement A.)

Richard Bilodeau, M.D.

## 6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ITEM	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN-VITRO STUDIES	X	as needed	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM AND CARDIAC DYSFUNCTION		
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		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
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	100
10 CFR 35.100, SCHEDULE A, GROUP VI					

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Small sealed sources (up to 3m Ci) 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 MILLCURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
<div>RECEIVED BY LFMB</div> <div>Date DEC 12 1978</div> <div>Log Dec 14 1978</div> <div>By [Signature]</div> <div>g. To</div> <div>DEC 1 1978</div>			
Action Compl. ....			

FORM NRC-313M  
(7-77)

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REG3 LIC30  
13-01719-02 PDR

Control No. 01025

# INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

Submit a detailed description of all the information requested in Items 7 through 23. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right hand corner of each page. Two copies of each appended sheet should be submitted with the application.

## 7. MEDICAL ISOTOPES COMMITTEE.

- a. Committee's Duties and Responsibilities.
- b. Meeting Frequency.
- c. Name and Specialty of Each Committee Member.

## 8. TRAINING AND EXPERIENCE.

- a. Authorized User(s). *(Each physician must complete Supplements A and B.)*
- b. Radiation Safety Officer.  
*(Complete Supplement A, if other than a physician already listed.)*

## 9. INSTRUMENTATION. *(List by manufacturer's name and model number.)*

- a. Survey Instruments.
- b. Dose Calibrator.
- c. Diagnostic Instruments.
- d. Other *(e.g. liquid scintillation counter, area monitor.)*

## 10. CALIBRATION OF INSTRUMENTS.

- a. Methods.
- b. Frequency.
- c. Standards (Radionuclide and Activity).

## 11. FACILITIES AND EQUIPMENT. *(Complete description and diagram.)*

## 12. PERSONNEL TRAINING PROGRAM AND FREQUENCY.

## 13. PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL.

## 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL.

## 15. GENERAL LABORATORY RULES FOR THE SAFE USE OF RADIOACTIVE MATERIALS.

## 16. EMERGENCY PROCEDURES, INCLUDING NAMES AND TELEPHONE NUMBERS OF PERSONNEL TO BE NOTIFIED.

## 17. AREA SURVEY PROCEDURES.

## 18. WASTE DISPOSAL PROCEDURES.

## 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS.

- a. Procedures
- b. Precautions.
- c. Personnel Instructions.

## 20. THERAPEUTIC USE OF SEALED SOURCES.

- a. Procedures.
- b. Precautions.
- c. Personnel Instructions.

## 21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES. *(e.g., xenon-133)*

## 22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS.

## 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.B.

## 24. PERSONNEL MONITORING DEVICES

	TYPE <small>(Check appropriate box)</small>	SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	Landauer	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER <i>(Specify)</i>		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	Landauer	Monthly
	<input type="checkbox"/> OTHER <i>(Specify)</i>		

c. OTHER *(Specify)*

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			
NAME OF HOSPITAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.	
MAILING ADDRESS		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
CITY	STATE	ZIP CODE	

## 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, Part 30, 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 <i>(See Section 170.31, 10 CFR 170)</i>	b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i> (1) NAME <i>(Type of Print)</i> James C. Talley
(1) LICENSE FEE CATEGORY: No Fee Required	(2) TITLE Administrator
(2) LICENSE FEE ENCLOSED: \$ _____	c. DATE 11/27/78

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

3. CERTIFICATION

SPECIALITY BOARD  
A

CATEGORY  
B

MONTH AND YEAR CERTIFIED  
C

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	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			



## MEDICAL ISOTOPES COMMITTEE

### Committee's Duties and Responsibilities

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 Section 19.12, of 10CFR 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.
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 will meet at least quarterly.

### Name and Specialty of Each Committee Member

Richard Bilodeau, M.D., Radiologist  
Clarence Cobb, M.D., Pathologist  
M. Cossard, M.D., Surgeon  
James Talley, Administrator  
Robert Anger, M.S., Consulting Physicist

Item 7  
November 27, 1978

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## TRAINING AND EXPERIENCE

### Authorized User

Training and experience credentials for Dr. Richard Bilodeau were submitted with the last application dated May 21, 1973.

Training and experience credentials for Dr. Bonnie Riley are currently on file with the NRC as part of license number 13-16286-01 (Riverview Hospital, Noblesville, Indiana).

Training and experience credentials for Dr. Clarence Cobb were referenced in our letter of April 6, 1978, requesting that Dr. Cobb be added to our license.

### Radiation Safety Officer

Training and experience credentials for Dr. Richard Bilodeau were submitted with the last application dated May 21, 1973.

2. Dose calibrator

Manufacturer's name : Picker

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: 1

3. Diagnostic instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
Gamma Camera	Picker	Dynacamera 2C
Rectilinear Scanner	Raytheon	Dual Probe (5")
Thyroid Uptake System	Picker	Spectroscaler IV

4. Other

Item No. 9

Date: 11/27/78

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Eberline

Manufacturer's model number: E520

Number of instruments available: 1

Minimum range: 0 mr/hr to 0.2 mr/hr

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

b. Manufacturer's name: Nuclear-Chicago

Manufacturer's model number: 2612

Number of instruments available: 1

ranges: \_\_\_\_\_

Minimum range 0 mr/hr to 0.2 mr/hr

Maximum range 0 mr/hr to 20 mr/hr

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## CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

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

or

other\* (specify) \_\_\_\_\_

B. Sources Used for Instrument Accuracy and Constancy Tests:

Radionuclide	Activity (mCi)	Accuracy
57 Co	<u>3-5</u>	<u>5%</u>
133 Ba	<u>          </u>	<u>          </u>
137 Cs	<u>.2</u>	<u>5%</u>
other	<u>          </u>	<u>          </u>

Note: These sources  
have been ordered

C. x The procedures described in Appendix D Section 2 will be used for calibration of the dose calibrator.

or

Equivalent procedure are attached.

\*Must be equivalent to the highest activity used.

Item No. 10

Date: 11/27/78

Check appropriate items

- Date: 11/27/78

## FACILITIES AND EQUIPMENT

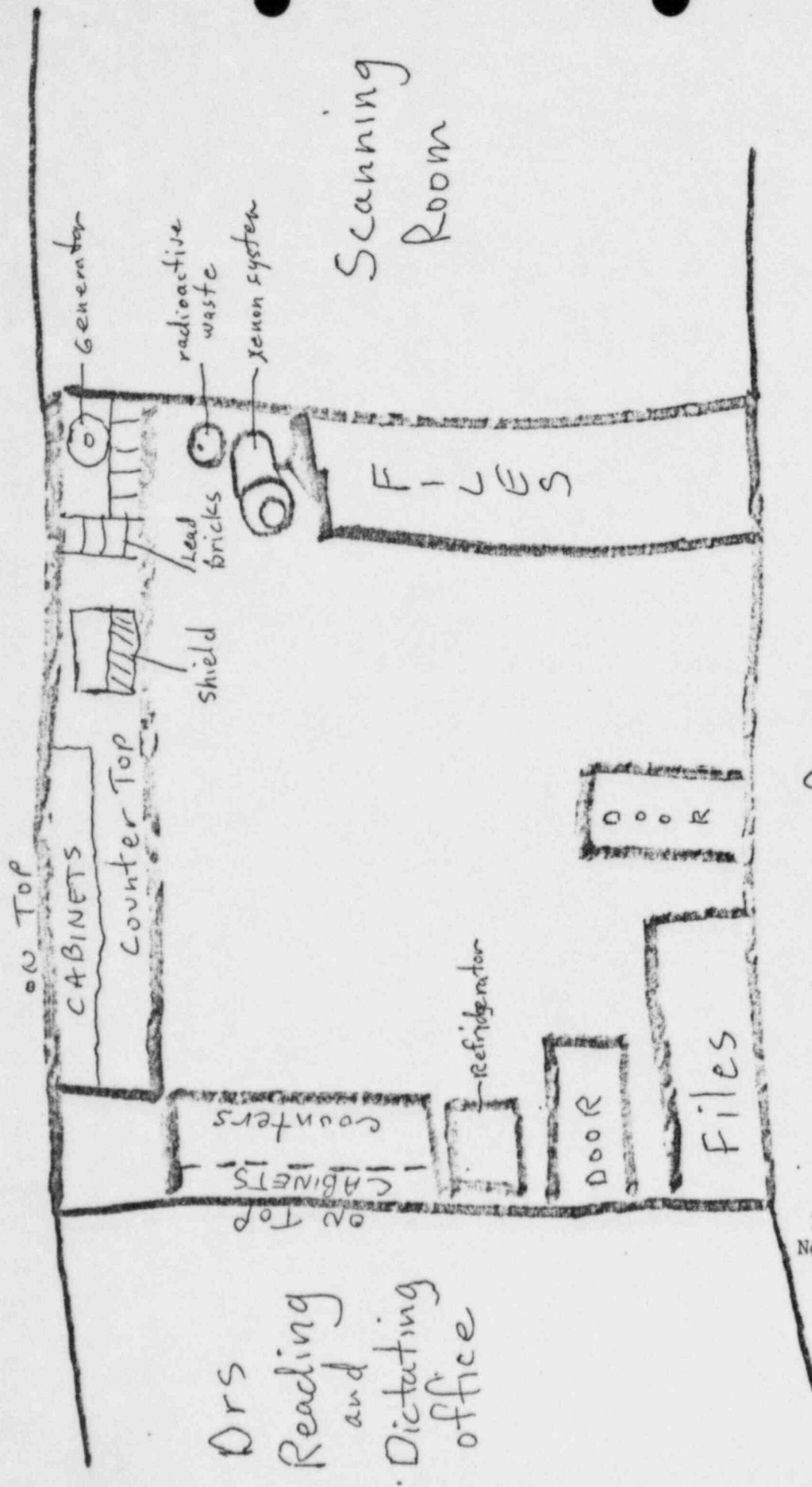
Work benches are routinely covered with absorbent paper ( changed weekly or more often if necessary). Remote handling tongs are used for handling and preparing "hot" materials. The Mo-99/Tc-99m generator is contained in its own shield behind lead bricks. All other radioactive sources are kept in an appropriate lead pig ( original shipping container when possible) with lead bricks used as supplemental shielding. The shielding for the generator and isotope storage area is sufficient to insure that exposures in both restricted and unrestricted areas are kept as far below the appropriate limits in 10CFR Part 20 as is reasonably achievable.

Expired Mo-99/tc-99m generators are stored for at least two months in a locked and posted room in the basement of the hospital. The generators are then dismantled and the columns disposed in accordance with item no. 18 of this application.

All patient doses are prepared behind a leaded face and body shield and are assayed in the dose calibrator immediately prior to injection.

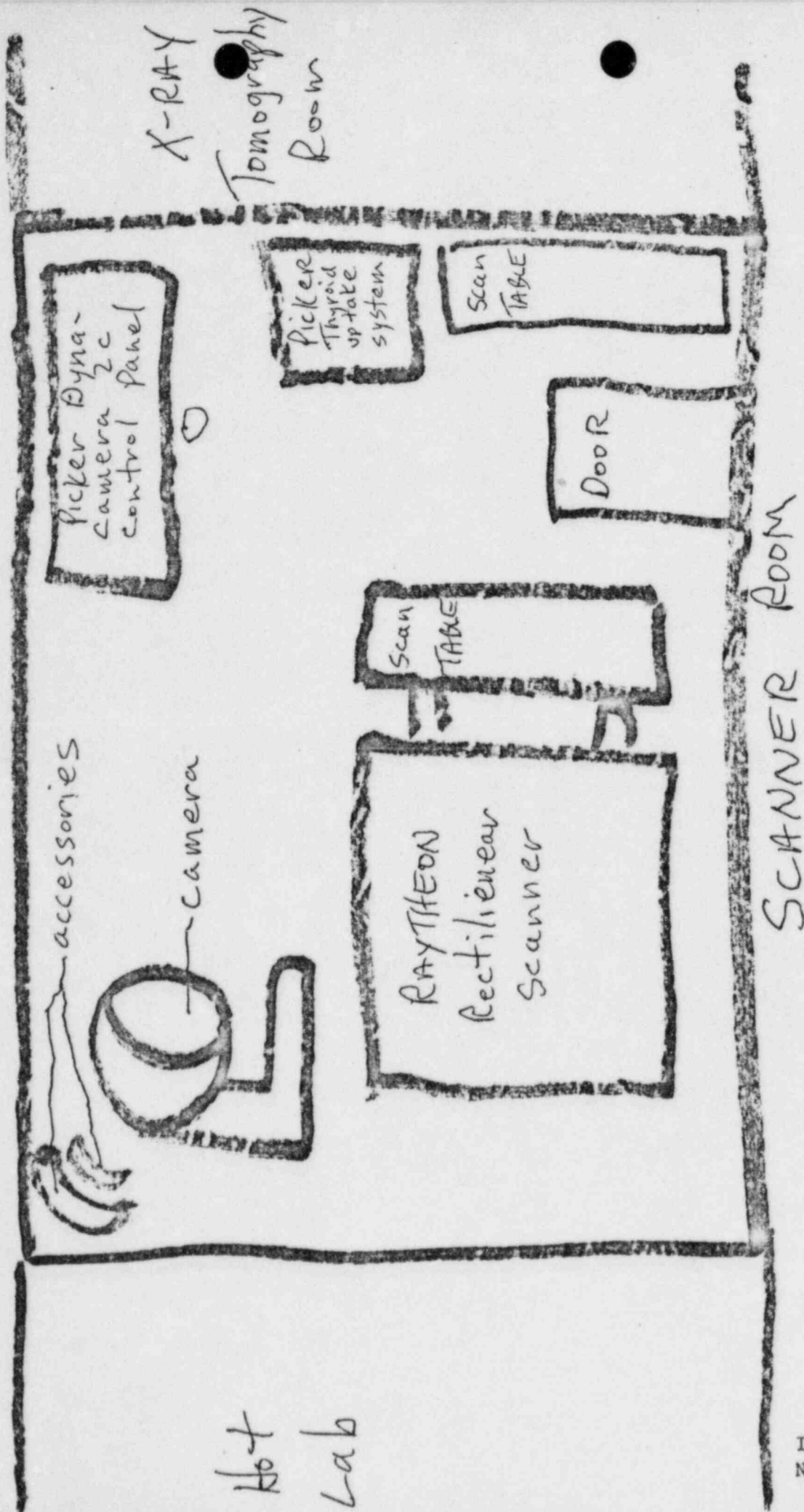
See attached room diagrams.

outside of building



Item 11  
November 27, 1978

outside of Building





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.

Item 12 Personnel Training Program  
November 27, 1978

Control No. 01025

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: Richard Bilodeau, M.D.  
Office: 675-8527  
Home: 773-5220

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Packages containing radioactive material are to be opened only in the hot laboratory by authorized individuals.
2. Individual opening package must 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 and forceps. Assay the filter paper with a thin end-window GM tube. If counts above 22,000 dpm, notify Radiation Safety Officer and do not open package. Record wipe test result.
4. All packages must be surveyed for radioactive contamination with a GM meter prior to opening. Record results.
  - A. Measure exposure rate at 3' from package surface with thin window GM detector. If this reading is  $> 10$  mR/h, immediately notify the Radiation Safety Officer and do not open the package.
  - B. Measure exposure rate at package surface with thin window GM Detector. 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 2x background, then final radioactive container must be wipe tested and the results recorded.
  - 1) Wipe test with filter paper using forceps. Assay the filter paper with a thin end-window GM tube. If counts above 22,000 dpm, notify Radiation Safety Officer.
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 regular trash.

Radiation Safety Officer: Richard Bilodeau, M.D.  
Office: 675-8527  
Home: 7735220

APPENDIX G  
LABORATORY RULES FOR THE USE OF  
RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.
5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

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7. Wear personnel monitoring devices (Film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specially designated receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labelled with name of compound, radionuclide, date, activity, and radiation level if applicable.
13. Always transport radioactive material in shielded containers.

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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: Richard Bilodeau, M.D.  
OFFICE PHONE: 675-8527  
HOME PHONE: 773-5220

Item No. 16  
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1. Location, date, and type of equipment used.
  2. Name of person conducting the survey.
  3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
  4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).
  5. Detected contamination levels, keyed to locations on drawing.
  6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
- F. Area will be cleaned if the contamination level exceeds 100 dpm/  
100 cm<sup>2</sup>.

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

Item No. 17

Date: 11/27/78

APPENDIX I  
SURVEY PROCEDURES

- A. All elution, preparation and injection areas will be surveyed daily with a G-M survey meter and decontaminated if necessary.
- B. Laboratory areas where only small quantities of radioactive material are used (less than 100  $\mu$ Ci) will be surveyed monthly.
- C. All other laboratory areas will be surveyed weekly.
- D. The weekly and monthly survey will consist of:
  - 1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
  - 2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm.
- E. A permanent record will be kept of all survey results, including negative results. The record will include:

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APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

- ☐ By commercial waste disposal service (See also No. 4 below)
- ☐ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.
- ☒ Other (specify): Stored for Decay

2. Mo-99/Tc-99m generators will be:

(Check as appropriate)

- ☐ Returned to the manufacturer for disposal
- ☒ 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 No. 4 below)
- ☐ Other (specify): \_\_\_\_\_

3. Other Solid Waste will be:

(Check as appropriate)

- ☒ 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.

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\_\_\_\_ Disposed by commercial waste disposal service (See also  
No. 4 below)

\_\_\_\_ Other (Specify): \_\_\_\_\_  
\_\_\_\_\_

4. The commercial waste disposal service used will be: \_\_\_\_\_  
(Name) (City, State)

NRC/Agreement State License No. \_\_\_\_\_

Item No. 18

Date: 11/27/78



PROCEDURES AND PRECAUTIONS FOR USE  
OF RADIOACTIVE GASES

The procedures and precautions utilized in the handling and disposal of Xenon-133 at Tipton County Hospital were described in detail in our letters dated January 24, 1975 and April 4, 1975.

Item 21  
November 27, 1978

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