

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 30. 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

SAINT VINCENT CARMEL HOSPITAL
13500 NORTH MERIDIAN STREET
CARMEL, INDIANA

TELEPHONE NO.: AREA CODE (317) 849 0808

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

LEL 23543

2. PERSON TO CONTACT REGARDING THIS APPLICATION

JAMES E. DURLACHER

TELEPHONE NO.: AREA CODE (317) 871 2246

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

a. ☒ NEW LICENSE

b. ☐ AMENDMENT TO LICENSE NO. _____

c. ☐ RENEWAL OF LICENSE NO. _____

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

See Enclosure # 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.)

JAMES E. DURLACHER

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			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
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	1000	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
57-Co	Metal/Alloy	5.0	Reference Source Camera Floods

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Applicant: *July 5th*
Check No. *019835 \$580*
Amount Paid *76*
Type *appl*
Date Check Rec'd *7/12/85*
Received By *CG*

8511180574 851001
REG3 LIC30
13-23543-01 PDR

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: Oct 1980

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input checked="" type="checkbox"/>	Names and Specialties Attached; and	<input checked="" type="checkbox"/>	Appendix G Rules Followed; or
<input checked="" type="checkbox"/>	Duties as in Appendix B; or (Check One)		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input checked="" type="checkbox"/>	Appendix H Procedures Followed; or
<input checked="" type="checkbox"/>	Supplements A & B Attached for Each Individual User; and See Enclosure		Equivalent Procedures Attached
<input checked="" type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input checked="" type="checkbox"/>	Appendix I Procedures Followed; or
<input checked="" type="checkbox"/>	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or (Check One)	<input checked="" type="checkbox"/>	Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or (Check One)		Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input checked="" type="checkbox"/>	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or (Check One)
<input checked="" type="checkbox"/>	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)	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input checked="" type="checkbox"/>	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	
	Appendix F Procedures Followed; or		Detailed Information Attached
	Equivalent Procedures 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	<input checked="" type="checkbox"/> FILM	R.S. LANDAUER JR. & CO.	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	R.S. LANDAUER JR., & CO.	Monthly
	<input type="checkbox"/> OTHER (Specify)		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

d. 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 PRECAU-
TIONS 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, 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)

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

(1) NAME (Type of Print)

FRANK T. MAGLIERY

(1) LICENSE FEE CATEGORY:

170.31

(2) TITLE

ADMINISTRATOR

(2) LICENSE FEE ENCLOSED: \$ 580.00

c. DATE

6/29/85

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.

ENCLOSURE # 1

ITEM # 4 - INDIVIDUAL USERS

Edward C. Wheeler, M.D.

Daniel R. Elliott, M.D.

John W. Courtney, M.D.

Miguel Dizon, M.D.

Peter D. Arfken, M.D.

John A. Morton, M.D.

Rosalind H. Webb, M.D.

All of the above are approved users on license # 13-00133-02

Note: For item # 8 - James E. Durlacher approved R.S.O. on license # 13-00133-02
up to 1985.

MEMBERSHIP OF RADIATION SAFETY COMMITTEE

WILLIAM M. WAHLE, M.D. PATHOLOGIST

WILLIAM C. ERDEL, M.D. INTERNIST

HOMER F. BELTZ, M.D. RADIOLOGIST

TIMOTHY A. HARE - ADMINISTRATIVE REP.

ANN COLE, R.T. - DEPT. MANAGER

JAMES, E. DURLACHER - PHYSICIST

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: LUDLUM
- Manufacturer's model number: 14-C
- 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: _____
- 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

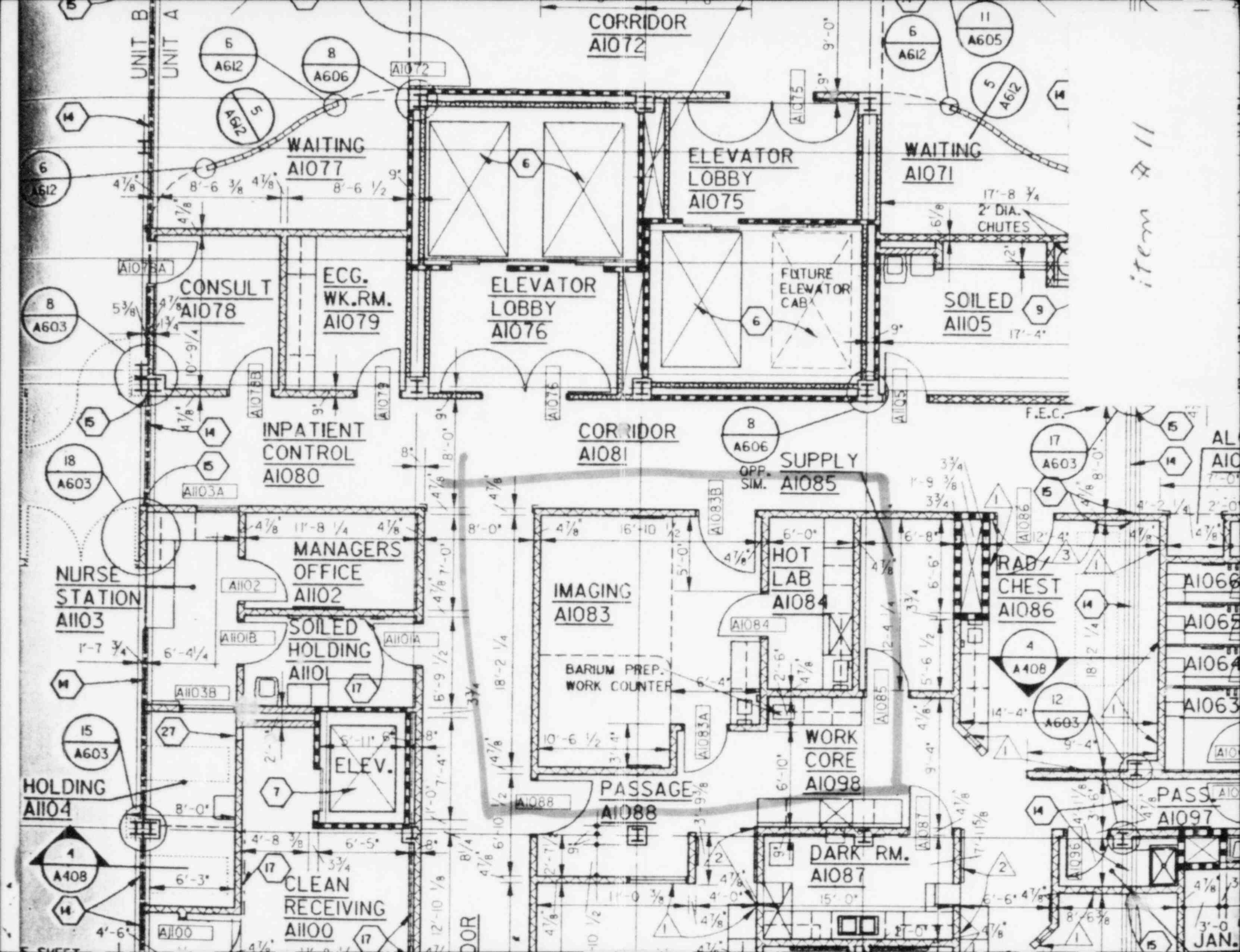
- Manufacturer's name: CAPINTEC
- Manufacturer's model number: CRC-7 086307
- Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Probe	ADC Medical	111-S
Camera	Siemens	ZLC-37

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

Xenon Trap/Dispenser Pulmonex System	Atomic Products	130-500
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PERSONNEL TRAINING PROGRAM

An experienced Nuclear Medicine Technician will be the only individual performing the studies under this license. This individual will participate in in-service meetings, programs, etc. provided by Saint Vincent Hospital in Indianapolis.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

All materials will be ordered from and delivered by Syncor.

WASTE DISPOSAL

Radioactive waste will be minimal since there will be no therapy, no generators, and most material will be returned to supplier - Syncor.

Any vials, syringes, etc. that are contaminated will be set aside for decay and when radiation levels are at determined background they will be disposed of in the normal hospital trash.

PROCEDURES & PRECAUTIONS FOR USE OF RADIOACTIVE GASES (XENON-133)

On the average, there will be one to two patients per week. Average activity will be 10 millicuries per patient.

The material will be used for pulmonary function studies and will be supplied by Syncor as required.

There will be two vents in the room with flow rates of + 640 CFM and - 740 CFM (exhaust). The exhaust will be to the roof. The system is a dedicated one and the room is only one in the exhaust system.

From room dimensions, it is calculated that there will be approximately 15 air changes per hour.

We have calculated that the required ventilation rate is 6 cu ft/minute.

As previously noted, we will have a Xenon trap.

Assuming that as much as 20% may be lost from the trap, then based on the average of 2 patients per week, no more than 4 millicuries would escape. Based on the table in Regulatory Guide 10.8, the exhaust rate will be more than ample without exceeding the permissible concentration of 3×10^{-7} uCi/ml.

item #21
19084