30-01565

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

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

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

St. Mary Hospital
129 North 8th St.
East St. Louis, Ill. 62201
TELEPHONE NO.: AREA CODE 618 274 1900

code 21

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

Same as 1a

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Michael Clemens
TELEPHONE NO.: AREA CODE (618) 274 1900

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 12-13189-01

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

John P. Crotty, M.D.
Joseph M. Dugan, M.D.
Francis H. Bihss, M.D.
Francisco Campos, M.D. (Group I only)

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 P. Crotty, 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	
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	as needed
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		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	25
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	25
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	100

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

19710022
19 release from Hold

FORM NRC-313M (8-78)

Control No. 01641

20

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	
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 original application for 12-13189-01
	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	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	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)*	
X	Appendix F Procedures Followed; or
	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
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	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	R.S. Landauer Co.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer Co.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

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: $ 190.00

b. APPLICANT OR CERTIFYING OFFICIAL (Signature) Thomas G. Walther

(1) NAME (Type or Print) THOMAS G. WALTHER

(2) TITLE ASSISTANT ADMINISTRATOR

c. DATE April 23, 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.

FORM NRC-313M
(8-78)

MEDICAL ISOTOPES COMMITTEE

1. NAME John P. Crotty,M.D. DUTY RSO
   Medical Specialty Radiologist

2. NAME Joseph M. Dugan, M.D.
   Medical Specialty Radiologist

3. NAME Francis E. Bhiss, M.D.
   Medical Specialty Radiologist

4. NAME Francisco Campos, M.D.
   Medical Specialty Pathologist

5. NAME Henry Withers, M.D.
   Medical Specialty Surgeon

6. NAME Albert Jolivert, M.D.
   Medical Specialty Internist

7. NAME Terry Watson,
   Medical Specialty Adm. Asst.

8. NAME Charles Ahrens,R.T.
   Medical Specialty Chief Diag. Tech.

9. NAME Michael Clements R.T.
   Medical Specialty Nuclear Medicine Tech.

10. NAME Randy Braasch, R.T.
    Medical Specialty Nuc. Tech.

22

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date Control No. 01641

MEDICAL ISOTOPES COMMITTEE

1. NAME Diane Mc Clary, R.T. DUTY RSO
   Medical Specialty Therapy Tech.

2. NAME Jim Spittler,
   Medical Specialty Chief Pharmacist

3. NAME
   Medical Specialty

4. NAME
   Medical Specialty

5. NAME
   Medical Specialty

6. NAME
   Medical Specialty

7. NAME
   Medical Specialty

8. NAME
   Medical Specialty

9. NAME
   Medical Specialty

10. NAME
    Medical Specialty

23

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victouren

   Manufacturer's model number: 740

   Number of instruments available: 1

   Minimum range: _____ mr/hr to _____ mr/hr
   Maximum range: _____ mr/hr to _____ mr/hr

   b. Manufacturer's name: Victouren
   Manufacturer's model number: 715
   Number of instruments available: 1
   ranges: _____

   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 - 16

   Number of instruments available: 1

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date 2-79

24

Control No. 01641

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	General Electric	Maxicamera LFOV - 1
Gamma Camera	Baird Atomic	Systom 77 - 1

4. Other

25

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date _____

PROCEDURES FOR SEALED CALIBRATION & REFERENCE SOURCES

1. All sealed calibration or reference sources will be kept in the proper storage area and shielded with lead.

2. The sources when required will be wipe/leak tested by a licensed consultant and records kept.

3. The sources will be used only for their intended purpose, either referance or calibration.

28

PERSONNEL TRAINING PROGRAM AND FREQUENCY

All personnel who will be involved in the receipt, handling, use or disposal of radionuclides will be instructed in all or parts of the following subjects:

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.

Training will be such that clerical, nursing, housekeeping and security personnel will have lectures to their understanding.

The time involved for the lectures or the listed topics will total approximately eight hours.

Personnel will also be instructed on the above topics during:

a. Annual refresher course.
b. Before assuming their duties in the vicinity of radioactive material.
c. Whenever a significant change in duties, regulations or conditions of the license occurs.

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date _____

Control No. 01641

We are currently licensed to possess and use Xenon 133 gas. We would like to increase our possession limit and submit the following information in support of our request.

The format will follow appendix M of our Guide for Preparation of Applications.

A. (1) (a) 15 studies per week.
(b) Average 10 MCi per patient.
(2) 750 milicurie possession limit.

B. (1) See attached No.1.
(2) See attached No.1.
(3) The storage area and the room the Xenon will be used in are under negative pressure. The air flow rates will be checked every two years using air flow determination equipment, or as necessary.

C. (1) See attached No.2 (Procedures)
(2) Atomic Products Model -
Delivery and trap system.
(3) Masks or nose clamps will be used to help reduce leakage.

D. See attached No. 3. (Emergency Procedures)

F. (1) 150 MCi (A)

Approximately 20% (f)
The air flow rate will be 616 CFM
The air flow volume is 11' x 15' x 8' = 1320 CFM
$1320 \times 2.832 \times 10^4$ ml = 3.738×10^8

$$A = \frac{15 \text{ PTS}}{\text{wk}} \times \frac{10 \text{ MCi}}{\text{patient}} \times \frac{10^3 \text{ uCi}}{\text{MCi}} \times \frac{52 \text{ weeks}}{\text{Year}} = 7.8 \times 10^6 \text{ uCi/yr}$$

$$A = 7.8 \times 10^6 \times .20 = 1.56 \times 10^6 \text{ uCi/yr.}$$

$$V = 616 \text{ CFM} \times 8 \text{ ft.}^2 \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3/\text{min.}}$$

$$V = 4928 \frac{\text{ft}}{\text{min}} \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3/\text{min.}}$$

$$V = 7.34 \times 10^{13} \text{ ml/year}$$

$$C = \frac{1.56 \times 10^6 \text{ uCi/year}}{7.34 \times 10^{13} \text{ ml/year}}$$

$C = .21 \times 10^{-7}$ uCi/ml fall below
3×10^{-7} uCi/ml

3/

(2) (i) See f (1) for calculations. The gas from leakage etc. will be vented to an exhaust point of the roof.

(ii) The trapping device will be checked by trapping a sample of air in a balloon and checking for activity with a GM survey meter. This will be performed initially and every six months to check for leakage.

(iii) When filters become saturated they will be replaced. The filters will be removed in the area with the ventilation system to the roof.

They will be stored in plastic bags which will be sealed, placed in a storage barrel with the top left on. The barrel will be kept in a leaded storage area. Concentrations of Xenon in the air will be extremely minimal.

32

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

To: William D. Miller, Chief
License Fee Management Branch
Office of Administration

From: John Cooper, Chief
Radioisotopes Licensing Section
RMSS, Region III

LICENSE FEE TRANSMITTAL

1. APPLICATION:

Applicant St. Mary's Hospital

Application dated 4-23-79

Control No. 01641

2. FEE:

Amount: 190.00

Check No. 013933

3. CHECK AND APPLICATION ARE ATTACHED HERETO.

Signed J W Cooper

Date: 5/15/79

Form 1

3

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

TO: John Cooper, Chief
Radioisotopes Licensing Section
NMSS, Region III

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

SUBJECT: LICENSE FEE INFORMATION

Applicant/Licensee St. Mary's Hosp.

City/State E. St. Louis Illinois

License No. — (ref. 12-13189-01)

Control No. 01641

Fee Information:

Type of Fee ( )Amendment ( )Renewal (4) Application

Check No. 013933

Amount $ 190

Fee Category 7B

Date Check Rec'd 5/22/79

OK to issue:

Amendment _____

Renewal _____

License —

Additional Fee Due _____

Signed Glenda Jackson
License Fee Management Branch

Date 5/23/79

FORM 2

RECEIVED
MAY 25 1979

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items

_X_ 1. Survey instruments will be calibrated at least annually and following repair.

_X_ 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

_X_ 3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(i) Calibration source
Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

(ii) The calibration procedures in Appendix D, Section I will be used.

or

(iii) The step-by-step procedures, including radiation safety procedures are attached.

_X_ c. By a consultant or outside firm

(i) Name: Instrument Calibration Center
(ii) Location: 5213 West Lawrence Avenue
Chicago, Illinois

(iii) Procedures and sources

_X_ have been approved by NRC and are on file in License No. 12-14821-01

____ are attached

Hospital St. Mary's Hospital NRC License NO. 12-13189-01

Date _____

26

Control No. 01641

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

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

or

_X_ other* (specify) Tc^{99m} Calibrated Standard

B. Sources Used for Instrument Accuracy and Tests:

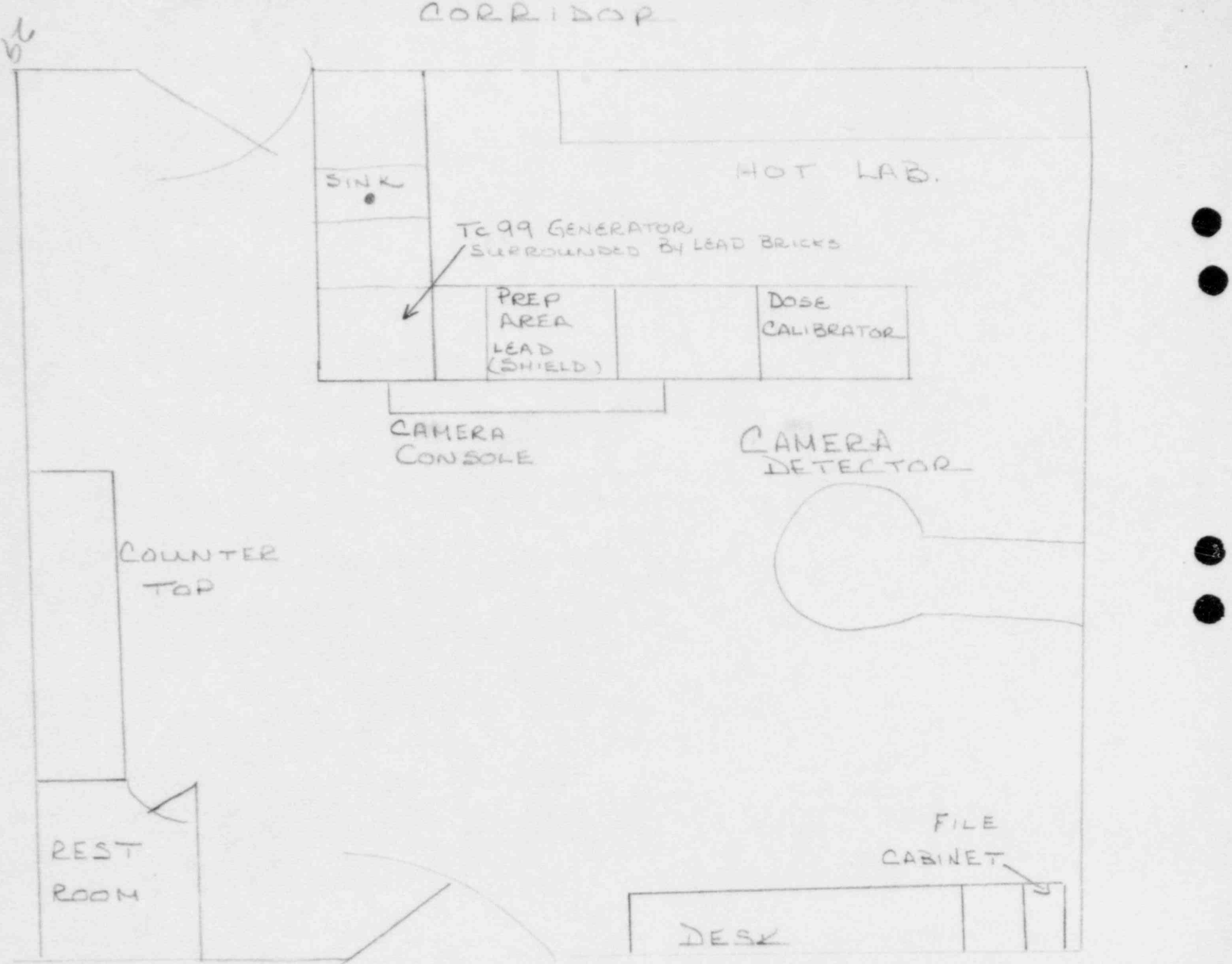
Radionuclide	Activity (mCi)	Accuracy
57 Co	____	+-5%
133 Ba	.200	+-5%
137 Cs	1	+-5%
other	____	____

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

or

_X_ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.


CORRIDOR
SINK
HOT LAB.
Tc 99 GENERATOR
SURROUNDED BY LEAD BRICKS
PREP
AREA
LEAD
(SHIELD)
DOSE
CALIBRATOR
CAMERA
CONSOLE
CAMERA
DETECTOR
COUNTER
TOP
REST
ROOM
FILE
CABINET
DESK