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

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

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

Logan General Hospital
20 Hospital Drive
Logan, West Virginia 25601

TELEPHONE NO.: AREA CODE (304) 752 - 1101

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

Frank T. Bloe, Consultant
Nuclear Medicine Associates
TELEPHONE NO.: AREA CODE (216) 641 - 5799

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 47-19919-01
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.)*

No change

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.)*

No change

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		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		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		
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

The purpose of this application is to identify the new proposed department that will be occupied in the near future. The abandoned portion of the facility will be surveyed and wipe tested for contamination. When the results show no exposures above background, the room can be reassigned. Survey results will be filed with our other survey records for review.

Xenon program changes are attached.

50649
8/27/85

Official Copy

NRC FORM

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REG2 LIC30
47-19919-01 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	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	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)*
	Equivalent Procedures Attached; and
	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	
	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	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		FILM	No change	
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	No change	
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Aug -3 II

Applicant.....
Check No. 01228
Amount Fee Category 170-K
Type of Fee Amendment
Date Check Rec'd 8/16/85
Received By Jackson

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: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
X C. David Morrison

(1) NAME (Type or Print)
X C. DAVID MORRISON

(2) TITLE
X ADMINISTRATOR

c. DATE
X AUGUST 1, 1985

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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.

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Facilities and Equipment

Diagram

- Air Supply
- Air Exhaust
- ___ Scanner
- ___ Uptake/Well
- 1 Camera
- 2 Lockable Door
- 3 Receipt Area
- 4 Generator
- 5 Kit Preparation
- 6 Isotope Storage
- 7 Dose Preparation
- 8 Waste Storage
- 9 Dose Calibrator
- ___ Refrigerator

Adjacent Areas

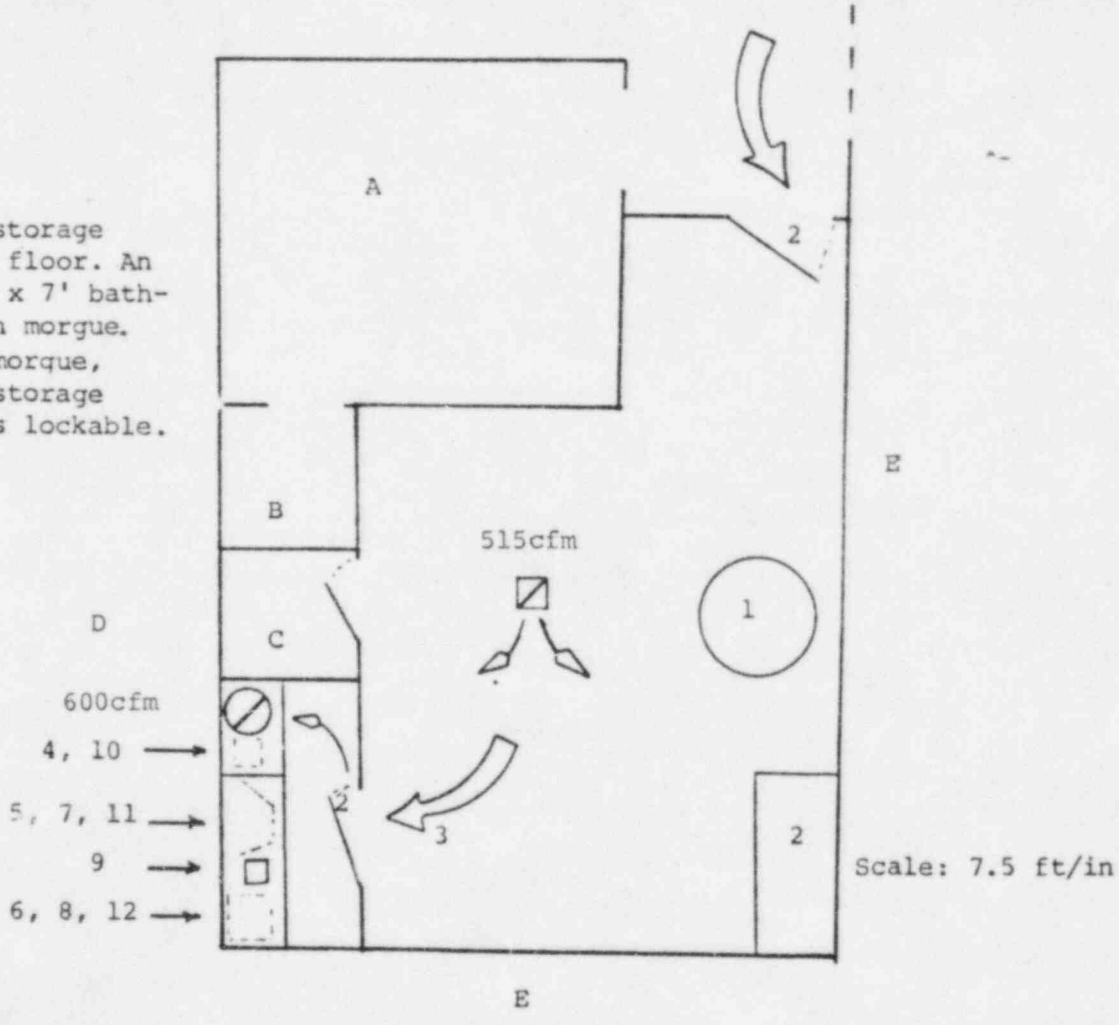
- A Ultrasound
- B Ultrasound restroom
- C Nuclear Med. restroom
- D X-ray
- E. Exterior
- ___
- ___
- ___

- Sink
- Lead Castle

Lead Shielding

- 10 Castle 1.5' L x 2' W x 8" H x 2" T
- 11 L-Shield 18" L x 16" W x 24" H x 1/2" T
- 12 2' L x 2' W x 2' H x 1/4" T
- ___ ___ L x ___ W x ___ H x ___ T

Also retained storage area on ground floor. An approximate 5' x 7' bathroom located in morgue. Surrounded by morque, exterior, and storage areas. Door is lockable.



Scale: 7.5 ft/in

Proposed Department

Item #11
1 of 1 pages
Prepared 6/28/85
Lic. #47-19919-01

Item #21

Procedures and Precautions for use of Radioactive Gases

I. Quantities

A. An average of 10 exams per week may be done.
B. Average activity per exam is 15 mCi.
C. Possession limit is 500 mCi.

II. Use and Storage

A. The hot lab fumehood shown in the attached diagram will be used to store and dispose of all the Xenon received. The hot lab will be used to prepare individual doses and to assay them prior to use. The camera room will be used for all patient administrations and for the imaging procedures.

The Xenon will be stored in its original shipping safe until used. Accessory lead shielding will be used (i.e. 1/8" - 1/4" lead vials or sheet) whenever survey measurements at the face of the hot lab hood are 2.0 mR/hr or more. The closest unrestricted area is an X-ray Room, approximately 2.0 feet away. The brick and lead wall construction, cabinet steel wall, distance and accessory lead shielding will reduce levels in this room to well below 2.0 mR/hr during the manipulation and disposal of the gas.

B. The only exhaust is through the hood in the hot lab and it has a flow rate of 600 cfm. The hood exhaust stack goes directly to the roof of this one-story room. The nearest air return is in excess of 30 feet from the exhaust port. Air supply to the camera room is rated at 515 cfm. There is no recirculation of air.

C. With the roof fans in operation under aforementioned conditions, the designated rooms are at negative pressure at all times. The air flow will be toward this exhaust system and directed toward the roof. Air flow measurements will be taken at semi-annual intervals, after initiating the use of Xenon for examinations, to ensure that negative pressure is maintained during Xenon storage or use. The program is inactive at the present time and will not be restarted until after construction and the move is completed.

III. Procedures for Routine Use

A. The exhaust system runs continuously. The doors will be adjusted so a sensible draft is felt at the opening. The door between the hot lab and camera room (as indicated on the diagram in Item #11) will be open. The fumehood in the hot lab will be opened so as to utilize its exhaust when Xenon is being used in the camera room.

The patient will be fitted with the rebreathing apparatus and instructed as to the procedure. A trial run will be conducted when possible. The valving and tubing will be examined for continuity. The dose will be prepared and assayed in the dose calibrator. Xenon will be administered to the patient (intravenously or into the tubing airway) and the appropriate views obtained. The gas will be collected in the Pulmonex system until practically no Xenon remains in the patient. Shielding will be used except during times of Xenon transfer from the shielded vial to a shielded syringe (if used). TLD finger badges and whole body film badges will also be worn by all other occupational personnel present during Xenon usage. Visitors to the Nuclear Medicine Department will be excluded from the camera room during the use of Xenon, unless their presence is required or desired.

B. The Pulmonex controlled gas delivery system and charcoal trap will be used.

C. Face masks that cover both mouth and nose and nose clamps for use with the mouthpiece delivery systems will be employed to reduce leaking of the Xenon into the camera room.

IV. Accidental Release of Xenon-133

In order to implement the ALARA philosophy in 10 CFR 20.1(c), the accidental release of Xe-133 into the camera room will result in evacuation of the room for a time period of less than 20 minutes, if the patient's condition permits. During this time, the concentration will be reduced as follows:

Activity per loss (A) = 15 mCi = 1.5×10^4 uCi

Room volume (V) = 8' x 20' x 18' + 8' x 9' x 7.5' + 8' x 6` x 10'

Hot Lab & Camera Room = 3900 $ft.^3$

= 1.1×10^8 ml

Clearance rate (λ) = $\frac{600 \text{ cfm}}{3900 \text{ ft.}^3}$

= .15 $min.^{-1}$

Initial concentration (C_o) = $\frac{1.5 \times 10^4 \text{ uCi}}{1.1 \times 10^8 \text{ ml}}$

= 1.4×10^{-4} uCi/ml

Evacuation time = 20 minutes

Final concentration (C) = $C_o e^{-\lambda t}$

= $(1.4 \times 10^{-4})\ e^{-.15 \times 20}$

= 7.0×10^{-6} uCi/ml

This value is less than 1×10^{-5} uCi/ml.

All unnecessary personnel will evacuate the room. The camera room door will be guarded against inadvertant entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered.

V. Air Concentration of Xenon-133 in Restricted Areas

A. It is estimated that 150 mCi will be used per week (A).

B. 20% of the Xenon will be lost into the camera room due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon (f).

C. A minimum room exhaust rate of 600 cfm will be used in this calculation. The total area for both hot lab and camera rooms is also used in the calculations.

$V = 600 \text{ cfm} \times 6.797 \times 10^{7} \text{ ml}/40 \text{ hr/wk-cfm}$

$V = 4.1 \times 10^{10} \text{ ml}/40 \text{ hr/wk}$

D. The average concentration (C) will be:

$$C = \frac{A \times f}{V}$$

$$= \frac{150 \text{ mCi} \times 1 \times 10^{3} \text{ uCi/mCi} \times .20}{4.1 \times 10^{10}}$$

$$= 7.3 \times 10^{-7} \text{ uCi/ml}$$

This value is less than required for restricted areas.

(1×10^{-5} uCi/ml).

VI. Methods of Xenon-133 Disposal

A. All Xenon unused will be disposed of by decay in storage in the hood. Containers and apparatus will be surveyed unshielded with the low level survey meter held on contact with source containing device. If levels are the same as background the containers will be disposed after defacing the labels.

All escaped Xenon will be vented through the exhaust system.

1. It is anticipated that 1.6 Curies of Xenon will be vented to the atmosphere per year. This includes activity liberated as accidental losses and leakage.

2. An air flow rate of 600 cfm will be used in the calculation:

3. Air flow per year is (V):

$$V = 600 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr-cfm}$$

$$V = 8.9 \times 10^{12} \text{ ml/yr}$$

4. The average concentration of air to the environment is (C):

$$C = \frac{A}{V}$$

$$= \frac{1.6 \text{ Ci} \times 10^{6} \text{ uCi/Ci}}{8.9 \times 10^{12} \text{ ml}}$$

$$= 1.8 \times 10^{-7} \text{ uCi/ml}$$

The value does not exceed the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

B. After approximately every twenty patients, the discharge air from the gas trap will be monitored with the G-M survey meter held against the tubing to detect Xenon "pass through". When discharge air readings reach 1/10 of air intake maximum readings during the equilibrium phase of the study, it will be assumed the charcoal trap efficiency has fallen to less than 90%. At that time, the cartridge will be exchanged.

Saturated filters will be stored for decay in the fumehood such that levels do not exceed 2.0 mR/hr at the exterior. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded.