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

Radiation Safety Office (Mail Code 115)
V. A. Medical Center
500 Foothill Drive
Salt Lake City, UT 84148

TELEPHONE NO.: AREA CODE (801) 582 1565

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

V. A. Medical Center
500 Foothill Drive
Salt Lake City, UT 84148

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Wesley W. Wooten, Ph.D.
FTS: 588-1584

TELEPHONE NO.: AREA CODE (801) 582- 1565

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 43-03299-01
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.)*

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.)*

Wesley W. Wooten, Ph.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		
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.		

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

1220:

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: October 1980

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	☐ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	☐ Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ 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
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
☐ 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**
☐ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☐ 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)**
☐ Detailed Information Attached	XX 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**
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
☐ Equivalent Procedures Attached	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		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:
Exempt, federal agency

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
R. E. Lindsey Jr.

(1) NAME *(Type or Print)*
R. E. LINDSEY, Jr.

(2) TITLE
Medical Center Director

c. DATE
5.7.82

12206

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.

SUPPORTING DOCUMENTATION FOR THE USE OF XENON-133

A. Quantities Used

An average of seven studies per week are expected. The Xenon delivery system is a rebreathing system loaded with approximately 100 mCi of Xe-133. The same 100 mCi will be reused on a number of patients and the total amount of Xe-133 brought into the lab per week is expected to be less than 200 mCi.

B. Use and Storage Area

Xenon-133 is received from Intermountain Radiopharmacy (license 43-01884-01) on an as needed basis. Xenon is stored for use in the rebreathing system which is a RADX Ventil-Con II. The attached figure shows the location of the Ventil-Con II when not is use for a patient study. The Ventil-Con II will normally contain approximately 100 mCi of Xe-133. When the activity falls to about 70 mCi, a make up dose will be ordered from the radiopharmacy and added to the Ventil-Con II. The Ventil-Con II is shielded with 5/16" lead on the arm, 1/8" lead on the spirometer, and 1/4" lead on the trap. When the instrument contains 100 mCi of Xe-133, the exposure rate at the surface will be less than 1 mR/hour.

C. Procedures for Routine Use

The Ventil-Con II is a rebreathing system. The patient breaths in from the internal atmosphere of the machine by normal tidal breathing. The patient's exhaled breath is filtered for bacteria, passed through a CO_2 absorber, a moisture absorber, and returned to the internal atmosphere of the machine. The volume lost by CO_2 absorption is made up by O_2 which is automatically injected into the internal atmosphere. During rebreathing, all Xe-133 is returned to the internal atmosphere of the machine. The system is switched over from rebreathing to wash-out at the end of an exhalation to minimize the amount of Xe-133 taken away from the internal atmosphere of the machine. During wash-out the patient breathes in room air and exhales through an interface and a Xenon trap. The interface controls the rate at which exhaled breath is passed through the trap to 5 liter/min.

The discharge from the trap is continuously monitored by an end window G-M tube which activates an audio visual alarm when the concentration in the exhaust port exceeds 1×10^{-2} micro-Ci/ml. The proper functioning of the monitor will be verified weekly by placing a standard Cs-137 source at a fixed distance from the G-M tube. A log of these checks will be kept with the Ventil-Con II.

The Xenon trap filters, when removed, will be isolated and held for at least ten half lives before being reused.

Careful instruction (in simple, explicit language) is given to the patient participating in studies using radioactive Xenon-133. Use of nose clamps are employed to reduce leakage.

D. Emergency Procedures

1. In the event that a full 100 mCi were accidentally vented to the room, the following airborne concentration of activity is predicted (assuming complete mixing):

Room volume - 38 ft x 17 ft x 9.5 ft = 6,137 ft^3 or 1.74×10^8 ml.

$$\frac{100 \text{ mCi}}{1.74 \times 10^8 \text{ ml}} = 5.8 \times 10^{-4} \text{ micro-Ci/ml}$$

2. In the event that a full 100 mCi dose escapes, the following steps will be taken:

a. Nuclear Medicine personnel will open two outside windows to vent the room to outside atmosphere and minimize injection of Xe-133 into the building ventilation system.

b. All persons will be evacuated from the room as rapidly as possible.

c. The door to the hallway will be closed and attended to make sure it is not opened.

d. The Radiation Safety Office will be notified by telephone.

e. The room will not be entered or opened for at least 30 minutes. Based on a room volume of 6,137 ft^3 and an air exchange rate of 410 ft^3/min (see below), the complete volume of air in the room is exchanged in 15 minutes.

E. Air Concentrations of Xe-133 in the Nuclear Medicine Imaging Laboratory

1. Air exchange rate: The vent locations are shown on the attached figure. Vents A and B bring air in from the building ventilation system at measured rates of 70 ft^3/min and 40 ft^3/min, respectively. Vent C discharges air to the building ventilation system at a measured rate of 60 ft^3/min. Vent D is a window fan which is always turned on when Xenon is being used and discharges air directly outside at a measured rate of 350 ft^3/min. The room air exchange rate is based on the two discharge vents which total 410 ft^3/min.

E. Air Concentrations of Xe-133 in the Nuclear Medicine Imaging Laboratory

2. The weekly amount of Xenon used is assumed to be 200 mCi.

3. The fraction lost is assumed to be 0.2.

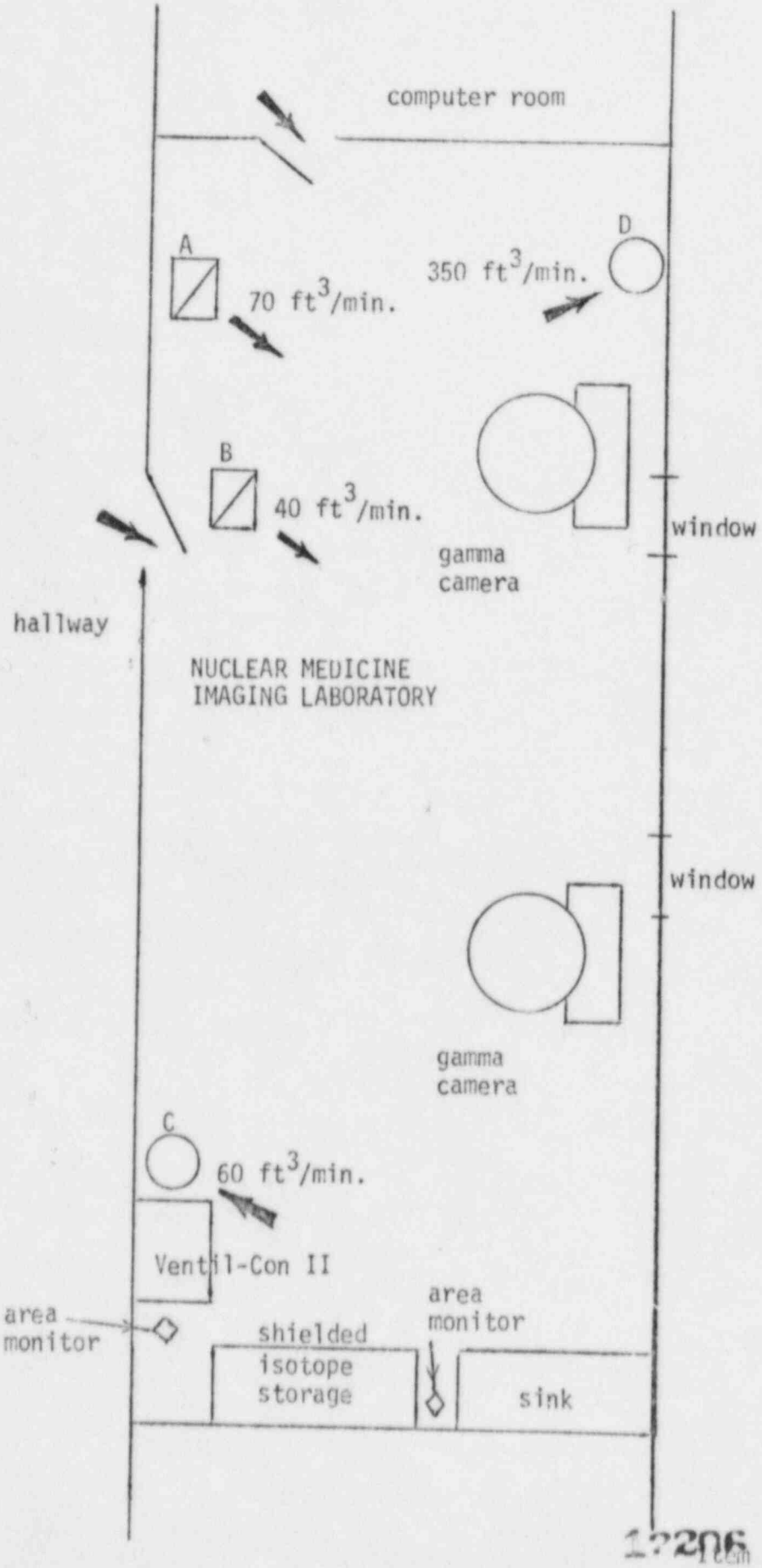
4. The concentration of Xe-133 in the laboratory will be: A x F/V

= 200 mCi x 0.2/ (410 ft^3/min x 6.79 x 10^7ml/40 hr wk)

= 1.44 x 10^{-9}mCi/ml

= 1.44 x 10^{-6} micro-Ci/ml

which is below the required minimum of 1 x 10^{-5} micro-Ci/ml.


computer room
A
70 ft3/min.
D
350 ft3/min.
B
40 ft3/min.
gamma
camera
window
hallway
NUCLEAR MEDICINE
IMAGING LABORATORY
window
gamma
camera
C
60 ft3/min.
Ventil-Con II
area
monitor
shielded
isotope
storage
area
monitor
sink