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

Lakewood Hospital
14519 Detroit Avenue
Lakewood, Ohio 44107

TELEPHONE NO.: AREA CODE (216) 521 4200

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, Inc.
TELEPHONE NO.: AREA CODE (216) 663 7000

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 34-01197-01
c. ☐ RENEWAL OF LICENSE NO. 030-02621

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

William J. Fayen, M.D.
William R. Pudvan, M.D.
Wilfred M. Gill, M.D.

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.)*

Wilfred M. Gill, M.D. with consultation from Nuclear Medicine Assoc., Inc., Cleveland, Ohio 44125

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	1300

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

A58

SER 10/87 Control No. 02237

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: _____

For all Items excpet #9, #11 and #21, refer to applications for license #24-01197-01. For Items #9, #11 and #21, see attached.

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	☒ 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	X	FILM	R. S. Landauer, Jr. & Sons, Inc.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer, Jr. & Sons, Inc.	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: Exempt

(2) LICENSE FEE ENCLOSED: $ Exempt

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
X [signature]

(1) NAME *(Type or Print)*
X John Zanghi

(2) TITLE
X Administrator

c. DATE
X September 6, 1979

FEE

FORM NRC-313M (8-78)

Prepared 7/19/79

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)

PROCEDURES & PRECAUTIONS FOR USE OF RADIOACTIVE GASES

I. Quantities to be Used:

A. Patient information
1. It is expected 10 or more studies per week will be performed
2. The average patient dose will be approximately 5 mCi

B. Possession limit of 1300 mCi is requested.

II. Use and Storage Areas:

A. Xenon will be used in either the Special Procedures room or the CBFA room. Proximity to unrestricted areas is indicated on the attached diagram. One eight inch thick lead shipping containers will be used for primary shielding and will be stored in the CBFA room in a vented wall cabinet.

B. The vented wall cabinet has air access holes in the bottom. A closed duct system connects it directly to a 66 cfm dedicated roof exhaust blower. Air is drawn continuously through the cabinet and discharged to the outside. There is an access port to this exhaust system in the Special Procedures room also.

During Xenon examinations, a second high capacity exhaust system will be activated. A roof mounted blower is connected to both the Special Procedures room and the CBFA room. Room selection is controlled by motorized dampers within the duct system. Existing air return ducts have similar motorized dampers installed to defeat return air flow during Xenon procedures.

An additional dedicated air condition system exchanges approximately 800 cfm of air in the Special Procedures room. This system brings air down from the roof and exhausts it directly to the roof again. The air is not shared with any other portion of the hospital ventilation system when Xenon examinations are performed.

C. During Xenon storage, the cabinet is continuously under negative pressure. During Xenon usage, air exhaust in the Special Procedures room exceeds air intake by 570 cfm, maintaining the room under negative pressure.

Total air exhausted = 1100 cfm + 800 cfm = 1900 cfm
Total air supplied = 800 cfm + 530 cfm = 1330 cfm
Difference = 570 cfm

When Xenon is used in the CBFA room, air is exhausted at 1100 cfm from this room by activating the appropriate motorized dampers. There is no other air supplied to this room. The ventilation system will be checked periodically to verify air flow and rates have not changed.

III. Procedures for Routine Use:

A. The 1100 cfm exhaust fan will be turned on. The door will be

adjusted so a sensible draft is felt at the opening. A rebreathing apparatus will be fitted to the patient. Valving and tubing will be examined for continuity. The dose will be shielded at all times, except during transfer between containers and at the time of patient administration. TLD finger badges and whole body film badges will be worn by all personnel handling Xenon. Other occupational personnel present during the exam will wear whole body film badges. Visitors will be excluded from the room during ventilation studies unless their presence is needed or desired.

Xenon will be administered to the patient and the examination will be conducted. The gas will be collected in a washout bag until practically no Xenon remains in the patient.

B. Patient studies will be performed using a Rad-X Model #143 Ventil-Con II gas delivery system. Brochure information is attached. The equipment houses a 15 liter reservoir of air (this includes the transfer tubing) containing 3-5 mCi/l of radioactive Xenon. Concentration of this gas is monitored by a G-M detector and subsequently displayed on the console. During examination, the patient will be allowed to breath this mixture for a short interval of time (approximately one minute). Xenon clearance from the cerebral region will then be monitored for 10-15 minutes using a Harshaw TASC-5 CBF (Cerbral Blood Flow) system. The expired gas will be collected in an expandable interface (a temporary holding bag) until it can be pumped through charcoal filters which will extract in excess of 90% of the Xenon. The final exhaust port from the Ventil-Con II will be connected by an expandable hose to the 66 cfm exhaust system. Hook-ups are available in both the Special Procedures room and the CBFA room for this purpose. Discharged gas from the Ventil-Con is monitored by a G-M detector, which trips an alarm when concentrations exceed 1 x 10^{-2} uCi/ml.

When the charcoal trap becomes saturated, it will be replaced. The used trap will be allowed to decay, stored in the CBFA room vented wall cabinet. If necessary, additional lead shielding will be used to reduce exposure levels to 2 mR/hr or less at the exterior surface of the wall cabinet.

C. Patients will be fitted with a specially designed face mask which will minimize leakage during examinations. A mask is also necessary for data acquisition during examinations. Patients will be instructed on the details of the procedure. Special emphasis will be given on those aspects that require their cooperation.

IV. Emergency Procedures:

In the event there is an accidental patient associated loss of Xenon into either room, the exhaust blower will clear the room to levels of 1 x 10^{-5} uCi/ml in a time to be described. During this time period, the room will be evacuated, provided patient safety and comfort can be assured. All unnecessary personnel will evacuate the room and the door will be guarded against inadvertant entry.