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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 License 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 Fairview General Hospital 18101 Lorain Road Cleveland, Ohio 44111 TELEPHONE NO.: AREA CODE <u>216</u> <u>476</u> <u>7000</u> | 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 William H. Miller, Consultant Nuclear Medicine Associates TELEPHONE NO.: AREA CODE <u>216</u> <u>641</u> <u>5799</u> | 3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. <u>34-02162-01</u> c. <input type="checkbox"/> 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.) Amend to increase authorized use for: Craig R. Irish, 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.) Retain: James A. Patterson, M.D. with consultation from Nuclear Medicine Associates, Cleveland, Ohio | |
| 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 |
| The purpose of this application is solely to increase the authorized use of I-131 by Dr. Irish to include the treatment of thyroid carcinoma. <div style="position: absolute; top: 10px; right: 10px; border: 1px solid black; padding: 5px; text-align: center;"> RECEIVED NOV 27 1985 REGION III </div> <div style="position: absolute; bottom: 10px; left: 10px;"> Date Check Rec'd <u>12/2/85</u> CONTROL NO. 80223 <i>sk</i> Received by _____ </div> | | |

NRC FORM 313M

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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. 10.8, Date: October, 1978

For all items below except #8, refer to the renewal application and March 25, 1983 and letters and applications that followed. For Item #8, see below.

| | | | |
|---|---|--|--|
| 7. MEDICAL ISOTOPES COMMITTEE | | 15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One) | |
| <input type="checkbox"/> | Names and Specialties Attached; and | <input type="checkbox"/> | Appendix G Rules Followed; or |
| <input type="checkbox"/> | Duties as in Appendix B; or (Check One) | <input type="checkbox"/> | Equivalent Rules Attached |
| <input type="checkbox"/> | Equivalent Duties Attached | 16. EMERGENCY PROCEDURES (Check One) | |
| 8. TRAINING AND EXPERIENCE | | <input type="checkbox"/> | Appendix H Procedures Followed; or |
| X | Supplements B Attached for: Dr. Irish | <input type="checkbox"/> | Equivalent Procedures Attached |
| <input type="checkbox"/> | Supplement A Attached for RSO. | 17. AREA SURVEY PROCEDURES (Check One) | |
| 9. INSTRUMENTATION (Check One) | | <input type="checkbox"/> | Appendix I Procedures Followed; or |
| <input type="checkbox"/> | Appendix C Form Attached; or | <input type="checkbox"/> | Equivalent Procedures Attached |
| <input type="checkbox"/> | List by Name and Model Number | 18. WASTE DISPOSAL (Check One) | |
| 10. CALIBRATION OF INSTRUMENTS | | <input type="checkbox"/> | Appendix J Form Attached; or |
| <input type="checkbox"/> | Appendix D Procedures Followed for Survey Instruments; or (Check One) | <input type="checkbox"/> | Equivalent Information Attached |
| <input type="checkbox"/> | Equivalent Procedures Attached; and | 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One) | |
| <input type="checkbox"/> | Appendix D Procedures Followed for Dose Calibrator; or (Check One) | <input type="checkbox"/> | Appendix K Procedures Followed; or |
| <input type="checkbox"/> | Equivalent Procedures Attached | <input type="checkbox"/> | Equivalent Procedures Attached |
| 11. FACILITIES AND EQUIPMENT | | 20. THERAPEUTIC USE OF SEALED SOURCES | |
| <input type="checkbox"/> | Description and Diagram Attached | <input type="checkbox"/> | Detailed Information Attached; and |
| 12. PERSONNEL TRAINING PROGRAM | | <input type="checkbox"/> | Appendix L Procedures Followed; or (Check One) |
| <input type="checkbox"/> | Description of Training Attached | <input type="checkbox"/> | 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 type="checkbox"/> | Detailed Information Attached | <input 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 | |
| <input type="checkbox"/> | Appendix F Procedures Followed; or | <input type="checkbox"/> | Detailed Information Attached |
| <input type="checkbox"/> | Equivalent Procedures Attached | 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b | |
| <input type="checkbox"/> | | <input type="checkbox"/> | Detailed Information Attached |

24. PERSONNEL MONITORING DEVICES

| TYPE <small>(Check appropriate box)</small> | | SUPPLIER | EXCHANGE FREQUENCY |
|--|-----------------|--|--------------------|
| a. WHOLE BODY | FILM | | |
| | TLD | Refer to application for license #34-02162-01 | |
| | 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 | | 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. | |
| MAILING ADDRESS | | | |
| CITY | STATE | | |

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 <small>(See Section 170.31, 10 CFR 170)</small> | b. APPLICANT OR CERTIFYING OFFICIAL (Signature) X |
| | (1) NAME (Type of Print) X <u>Mr. Joseph Mitrick</u> |
| (1) LICENSE FEE CATEGORY: 7C | (2) TITLE X <u>Administrator</u> |
| (2) LICENSE FEE ENCLOSED \$ <u>120.00</u> | c. DATE X <u>11-12-85</u> |

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 an 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

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Craig R. Irish, M.D.

STREET ADDRESS

21010 ABERDEEN RD.

~~1117 5th Avenue~~

CITY

ROCKY RIVER

STATE

OHIO

ZIP CODE

44116

~~Lakewood, Ohio 44107~~

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

- 1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
- 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
- 3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE | CONDITIONS DIAGNOSED OR TREATED | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) |
|----------------------|---|---|---|
| A | B | C | D |
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | 120 | |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | 150 | |
| | IN VITRO STUDIES | | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | 40 | |
| P-32 | EYE TUMOR LOCALIZATION | 0 | |
| Sr-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | 6 | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | 30 | |
| OTHER | ⁶⁷ Ga Soft Tissue Imaging | 20 | |
| Tc-99m | BRAIN IMAGING | 5 | |
| | CARDIAC IMAGING | 6 | |
| | THYROID IMAGING | 5 | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | 110 | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | 255 | |
| | LUNG IMAGING | 75 | |
| OTHER | BONE IMAGING | 305 | |
| | ²⁰¹ Tl Cardiac Imaging | 140 | |

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D |
|-----------------------|--|--|--|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | 0 | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 3 | |
| | TREATMENT OF HYPERTHYROIDISM | 10 | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | | |
| Other | | | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

January, 1979; February, 1979 and January, 1980 = 500 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Sebastian A. Cook, M.D.

b. NAME OF INSTITUTION
Cleveland Clinic Foundation

c. MAILING ADDRESS
9500 Euclid Avenue

d. CITY
Cleveland, Ohio 44106

5. MATERIALS LICENSE NUMBER(S)
34-00466-01

6. PRECEPTOR'S SIGNATURE

Sebastian A. Cook

7. PRECEPTOR'S NAME (Please type or print)

Sebastian A. Cook
Sebastian A. Cook, M.D.

8. DATE

July 30, 1980