

NRC FORM 313M

(8-86)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

Approved by OMB

3150-0041

Expires 6-30-89

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. Joseph Hospital
Fifth and Foster
Mitchell, South Dakota 57301-2999

TELEPHONE NO.: AREA CODE (605) 995 2245

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

JUN 20 1988

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Fredrick W. Slunecka
Executive Director

TELEPHONE NO.: AREA CODE (605) 995 2250

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

a. ☐ NEW LICENSE

b. ☒ AMENDMENT TO LICENSE NO. 40-15633-01

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.)

See attached forms

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.)

Charles E. Flohr, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

| RADIOACTIVE MATERIAL LISTED IN: | ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS (In millicuries) | ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS (In millicuries) |
|--------------------------------------|----------------------|---|---|---------------------------|---|
| | | | | | |
| 10 CFR 31.11 FOR IN VITRO STUDIES | x | 1 mCi | IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | | |
| 10 CFR 35.100, SCHEDULE A, GROUP I | x | AS NEEDED | PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | | |
| 10 CFR 35.100, SCHEDULE A, GROUP II | x | AS NEEDED | PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| 10 CFR 35.100, SCHEDULE A, GROUP III | x | 2 Curies | GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | | AS NEEDED | IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | | |
| 10 CFR 35.100, SCHEDULE A, GROUP V | | AS NEEDED | XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES. | | |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | x | 50mCi | | | |

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 |
|---|-------------------------------|--|-------------------------|
| See Item 4-14 Check No. 89635 Amount 8120 Fee Category 2C Type of Fee And Date Check 6/24/88 Date Completed 6/24/88 | | 8907250087 880923 REG4 LIC30 40-15633-01 | PDR |

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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. 1 Date: October 1980

| | | | |
|--|---|---|------------------------------------|
| 7. MEDICAL ISOTOPES COMMITTEE | | 15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One) | |
| <input checked="" type="checkbox"/> | Names and Specialties Attached; and | <input type="checkbox"/> | Appendix G Rules Followed; or |
| <input checked="" type="checkbox"/> | Duties as in Appendix B; or | <input type="checkbox"/> | Equivalent Rules Attached |
| | (Check One) | | |
| <input type="checkbox"/> | Equivalent Duties Attached | 16. EMERGENCY PROCEDURES (Check One) | |
| 8. TRAINING AND EXPERIENCE | | <input type="checkbox"/> | Appendix H Procedures Followed; or |
| <input type="checkbox"/> | Supplements A & B Attached for Each Individual User; and | <input type="checkbox"/> | Equivalent Procedures Attached |
| <input checked="" type="checkbox"/> | Supplement A Attached for RSO. Change of name A on file | 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 checked="" type="checkbox"/> | List by Name and Model Number | 18. WASTE DISPOSAL (Check One) | |
| 10. CALIBRATION OF INSTRUMENTS | | <input checked="" type="checkbox"/> | Appendix J Form Attached; or |
| <input type="checkbox"/> | Appendix D Procedures Followed for Survey Instruments; or | <input type="checkbox"/> | Equivalent Information Attached |
| | (Check One) | 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One) | |
| <input type="checkbox"/> | Equivalent Procedures Attached; and | <input type="checkbox"/> | Appendix K Procedures Followed; or |
| <input type="checkbox"/> | Appendix D Procedures Followed for Dose Calibrator; or | <input type="checkbox"/> | Equivalent Procedures Attached |
| | (Check One) | | |
| <input type="checkbox"/> | Equivalent Procedures Attached | 20. THERAPEUTIC USE OF SEALED SOURCES | |
| 11. FACILITIES AND EQUIPMENT | | <input checked="" type="checkbox"/> | Detailed Information Attached; and |
| <input checked="" type="checkbox"/> | Description and Diagram Attached | 21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133) | |
| 12. PERSONNEL TRAINING PROGRAM | | <input type="checkbox"/> | Appendix L Procedures Followed; or |
| <input checked="" type="checkbox"/> | Description of Training Attached | | (Check One) |
| <input type="checkbox"/> | Equivalent Procedures Attached | 22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS | |
| 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL | | <input type="checkbox"/> | Detailed Information Attached |
| <input type="checkbox"/> | Detailed Information Attached | 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b | |
| 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One) | | <input type="checkbox"/> | Detailed Information Attached |
| <input type="checkbox"/> | Appendix F Procedures Followed; or | | |
| <input type="checkbox"/> | Equivalent Procedures Attached | | |

24. PERSONNEL MONITORING DEVICES

| TYPE <small>(Check appropriate box)</small> | | SUPPLIER | EXCHANGE FREQUENCY |
|--|---|-----------------------------|--------------------|
| a. WHOLE BODY | <input checked="" type="checkbox"/> FILM | R.S. Landauer, Jr. and Co. | monthly |
| | <input type="checkbox"/> TLD | | |
| | <input type="checkbox"/> OTHER <small>(Specify)</small> | | |
| b. FINGER | <input checked="" type="checkbox"/> FILM | R. S. Landauer, Jr. and Co. | monthly |
| | <input type="checkbox"/> TLD | | |
| | <input type="checkbox"/> OTHER <small>(Specify)</small> | | |
| c. WRIST | <input type="checkbox"/> FILM | | |
| | <input type="checkbox"/> TLD | | |
| | <input type="checkbox"/> OTHER <small>(Specify)</small> | | |

d. OTHER (Specify)

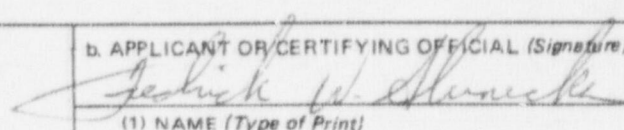
25. FOR PRIVATE PRACTICE APPLICANTS ONLY

| | | |
|--|-------------------|--|
| 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. |
| MAILING ADDRESS | | |
| CITY | STATE ZIP CODE | |
| 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 <small>(See Section 170.31, 10 CFR 170)</small> | b. APPLICANT OR CERTIFYING OFFICIAL <small>(Signature)</small>  (1) NAME <small>(Type of Print)</small> Fredrick W. Slunecka |
| (1) LICENSE FEE CATEGORY: Human Uses of Byproduct Material--amendments | (2) TITLE Executive Director |
| (2) LICENSE FEE ENCLOSED: \$ <u>7-C</u> \$120 | c. DATE May 23, 1988 |

THERAPEUTIC USE OF SEALED SOURCES

The Strontium 90 applicator is no longer used for patient care. The applicator is stored with other radioactive sources on 4th floor.

Item 19

May 23, 1988

TRAINING AND EXPERIENCE

The following Authorized Users have been listed on our former license. Supplements A & B are not included for renewal.

John O. Judge, M.D.

Judson O. Mabee, M.D.

Charles E. Flohr, M.D.

RADIATION SAFETY OFFICER

The Radiation Safety Officer is Charles E. Flohr, M.D.

INSTRUMENTATION:

1. Survey Meters G.M. SURVEY METER

- a. Manufacturer's name: Picker Corporation
Manufacturer's model# 635-186
Number of instruments available: 1
Minimum range: .01 mr/hr to mr/hr
Maximum range: mr/hr to 25000 mr/hr

SURVEY METER: G. M. SURVEY METER

- a. Manufacturer's name: Victoreen/Civil Defense
Manufacturer's model: OCD CDV-715
Number of instruments available 6
Minimum range: 0 mr/hr to
Maximum range: mr/hr to 30000

Survey Meter: VICTOREEN R METER (Cutie Pie)

- a. Manufacturer's name: Victoreen Instrument Div. of VLN
Manufacturer's model #740 F
Number of instruments available: 1
Minimum range: 0-25 mr/hr to mr/hr
Maximum range: mr/hr to 0-25000 mr/hr

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

_____ By commercial waste disposal service (see item 4 below)

☒ In the sanitary sewer system in accordance with 20.303 of 10CFR Part 20

_____ Other (specify) _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

☒ Returned to the manufacturer for disposal.

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

_____ Disposed of by commercial waste disposal service (see item 4 below).

_____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

☒ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify) _____

4. The commercial waste disposal service used will be:

Name _____

City and State _____

NRC/Agreement State License No. _____

MEDICAL ISOTOPES COMMITTEE
(RADIATION SAFETY COMMITTEE)

| | |
|------------------------|-------------------------------|
| John D. Judge, M.D. | Radiologist |
| Fredrick W. Slunecka | Executive Director |
| Anne Moke, R.T. RDMS | Radiology Director |
| Nanci Timmins, R.T. | Staff Technologist |
| Iris A. Bauer HT | In-vitro Technologist |
| Vaugh C. Moore, Ph.D. | Radiation Consultant |
| Bonnie Krcil, R.N. | Director of Nursing |
| Charles E. Flohr, M.D. | Radiologist |
| Terry Hurlbert, CNMT | Nuclear Medicine Technologist |

The responsibilities and duties of the Medical Isotopes Committee are as described in Appendix B.

Form NRC-313M
Item 7
May 23, 1988

PERSONNEL TRAINING PROGRAM

The specific training give certain groups of individuals who may become in contact with the Nuclear Medicine Department is as stated below:

- | | |
|-----------------------|---|
| Clerical | There are no clerical personnel directly employed in the department. |
| Housekeeping | Housekeeping personnel will be allowed to wash and mop floors in the area, dust all ledge areas and desks where only paperwork is performed, and clean all sinks <u>except</u> the sink designated as radioactive waste disposal sink. Technologists in the Nuclear Medicine Department will be responsible for decontaminating and cleaning of countertop areas where radioactive materials are routinely used and radioactive waste disposal sink. |
| Janitors: | Janitors will be allowed to empty all waste containers in the Nuclear Medicine area, <u>except</u> the one container labeled as radioactive waste. |
| Maintenance Personnel | Most equipment in the Nuclear Medicine Department is serviced by company based service representatives. In the event that any equipment in the area need servicing by hospital based personnel, all radionuclides will be removed from the equipment being repaired and if possible the piece of equipment will be moved out of the area for servicing. |
| Nursing Personnel | Nursing personnel are only allowed into the Nuclear Medicine area when imaging is done on a patient needing continuous monitoring. They are not responsible for injecting radionuclides into patients nor for using radionuclides in any other manner. |

All personnel, including medical technologists, clerical, housekeeping, and other individuals will be instructed in the following items prior to being allowed to work in the area:

- a. Areas where radioactive materials used or stored.
- b. Potential hazards associated with radioactive material.

- c. Radiological safety procedures that must be used while working in the department.
- d. Rules, regulations and pertinent terms of the license.
- e. Pertinent NRC regulations and where the copies of the license and pertinent regulations and conditions are posted.
- f. Their obligation to report unsafe conditions.
- g. Appropriate response to emergencies or unsafe conditions.
- h. Their right to be informed of their radiation exposure and bioassay results.

Verification that personnel have been instructed in the above criteria before they assume duties, during annual refresher training or whenever there is a significant change in duties, regulations or the terms of the license will consist of a written record in which the person receiving the instruction states that the instruction has been given and he/she fully understands the material that has been presented.

The Nuclear Medicine Department and Hot Lab are posted with the following notices and instructions:

- 1) "Radiation Area" placard with the name and phone # of R.S.D.
- 2) "No eating, Drinking, Smoking"
- 3) "If you are pregnant, please inform the technologist"
- 4) "Rules for Safe Handling of Radioisotopes for Personnel"
- 5) "Notice to Employees" (10CFR parts 19 & 20)
- 6) Current Film Badge Reports (Landauer)
- 7) A notice as to the location of the documents referred to in Parts 19 & 20 CFR within the nuclear medicine files.

The Nuclear Medicine Department is off-limits to all non-radiation workers. When it becomes necessary for a non-radiation worker to enter the area, a nuclear medicine worker is also in attendance.

The Nuclear Medicine Department is locked at all times when not in use.

FACILITIES AND EQUIPMENT

FACILITIES: The Nuclear Medicine Department consists of a Scanning Room, Hot-Lab, and a Radioactive Storage Room.

The scanning room and hot-lab adjoin, and are located on the ground floor of the St. Joseph Hospital 1974 addition. This area is well lighted, and of sufficient size to allow ample space for scanning operations.

The radioactive storage room is located on the 4th floor of the 1921 building, and is the former X-ray therapy Room.

All rooms are posted with "Radiation Area" signs and are kept locked when not in use.

EQUIPMENT: The scanning room contains adequate space for imaging equipment, cart, sink, storage cupboards, desk, files, view boxes, complete records and all accessory items necessary to perform scans and maintain the standards of safety, as set by the Radiation Safety Committee.

the Hot-lab consists of a vented fume hood, sink, counter, portable (lead glass window) barrier on rollabout cart, wall faucet with hose, floor drain and lead lined boxes for waste storage. A lead brick barrier has been constructed inside the hood area to harbor radioactive materials and waste, pending removal to the radioactive storage room.

A complete assortment of sterile disposable injection supplies, gloves, lead pigs, syringe shields, tongs, forceps, trays is located in this room.

Radiation monitors and safety devices used are: Survey Meters, Cutie Pie, 2 room monitors, film badges, ring badges and dose calibrator, 2 civil defense boxes are available for emergency use (6 survey meters).

A decontamination kit has been prepared for use, not only within the Nuclear Medicine Department, but as a measure to be used in the event of a radiation accident outside the department. This kit is properly labeled and is located in the scanning room on the counter top for easy accessibility in an emergency situation. It contains all necessary supplies for decontamination, and complete instructions for use.

There is a reception area, waiting room, dressing room and toilet facilities in close approximity of the scanning room and hot lab.

FACILITIES AND EQUIPMENT

Equipment available in the department includes the following:

1. CRC4 Dose Calibrator
2. SEARLE PHO-GAMMA CAMERA, LARGE FIELD OF VIEW FOR ORGAN IMAGING.
3. MICRO DELTA COMPUTER.
4. PORTABLE SEARLE LEM PHO-GAMMA CAMERA
5. SEARLE MICRO DOT IMAGER.