

St. Francis Medical Center

700 West Avenue S. La Crosse, WI 54601-9968
608-785-0940



July 29, 1985

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Sir:

The following applications are included for amendment to our NRC license (#48-00810-02).

1) Radioactive Waste Disposal.

Included is a copy of Appendix J (Waste Disposal) from Regulatory Guide 10.8 October 1980, which we would like to have amended to our NRC license. The copy includes the addition of several disposal methods that we do not have on our license at the present time, but would like to incorporate in the future for disposal of radioactive waste. (See attached copy)

2) Calibration of Instruments -- Dose Calibrators

With the introduction of dose calibration linearity test kits, we would like to amend our license to include the use of these test kits. One of two kits would be considered for the quarterly linearity tests, they include the "Calicheck" from Victoreen Nuclear Associates or "The Lineator" from Atomic Products Corporation. The procedures for performing the linearity tests would be carried out as recommended by manufacturers instructions.

3) Transfer of Radioactive Materials Between NRC Licensed Medical Institutions

The following application is submitted for amendment to our NRC license, for the transfer of radioactive materials. This application is based on the requested information as outlined in the "TRANSFER OF RADIOACTIVE MATERIALS BETWEEN NRC LICENSED MEDICAL INSTITUTIONS -- SITUATIONS THAT DO NOT REQUIRE THE TRANSFER TO OBTAIN A DISTRIBUTION LICENSE". (See attached application)

Any questions may be directed to the Nuclear Medicine Department.
Telephone #608-785-0940 - Ext. 2651.

Sincerely,

Sister Celesta Day
Sr. Celesta Day
Administrator

APPLICANT St. Francis Medical Center
Check No. 103278
Category 3120 (7C)
Type of Fee AMT
Date Check Rec'd 7/23/85
Received By sk / cap

RECEIVED
SEP 19 1985
REGION III

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REG LIC30
48-00810-02 PDR

CONTROL NO. 79788

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

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

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

☐ By commercial waste disposal service (see also Item 4 below).

☒ Other (specify): Same as solid waste (#3)

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 in a low background area 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 will be disposed of as normal trash.**

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

☐ Disposed of by commercial waste disposal service (see also Item 4 below).

☐ Other (specify): _____

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

☒ Held for decay* until radiation levels, as measured in a low background area 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

Not applicable
(Name) (City, State)

NRC/Agreement State License No. _____

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June 4, 1985

The following is in reply to the application for the transfer of radioactive materials between NRC license medical institutions.

- 1) To meet the recent changes required of medical institutions, patient care and cost control must both be optimized. In doing so, St. Francis Medical Center and Gundersen Clinic/Lutheran Hospital feel that these goals can best be met, if the transfer of radiopharmaceuticals between our institutions would meet NRC approval.
- 2) See attached letter.
- 3) The types and amounts of radiopharmaceuticals to be transferred would include unit doses from Groups I, II, and III, Part 35.100 Schedule A. The number of unit doses to be transferred would be limited to those needed for scheduled patients.
- 4) Byproduct materials from Group IV would not be included in this application.
- 5) The transfer will be initiated by the institution in need of the radiopharmaceuticals. The Nuclear Medicine physician will initiate the transfer, once it has been confirmed that: A) The examination is needed immediately, B) No radiopharmaceuticals are available for the needed examination, C) The radiopharmaceutical is available at the other institution.
- 6) The transfer (transportation) of the radiopharmaceutical will be carried out by the Nuclear Medicine technologist from the institution receiving the radiopharmaceutical. Once the radiopharmaceutical has been transferred, the vehicle transferring the radiopharmaceutical will be surveyed with appropriate actions taken. The package will be handled, as outlined in Appendix E and F of the Regulatory Guide 10.8 October 1980.
- 7) The individuals involved in transferring the radiopharmaceuticals will be limited to the Nuclear Medicine technologist employed by the receiving institution. The training of these individuals would include the handling of radiopharmaceuticals, radiation accidents and emergencies, and items outlined in 10 CFR 19.12.
- 8) All transfer radiopharmaceuticals will be transported in a leadline box, with absorbant paper on the floor of the box, the box will be labeled with appropriate DOT labels, and will be locked in the trunk of the vehicle during transportation. The box and/or radiopharmaceuticals will not be left unattended.
- 9) In case of an accident, the emergency procedures will be carried out as outlined in Appendix H of the Regulatory Guide 10.8 October 1980. The transfers will have a decontamination kit and survey meter available.
- 10) Any vehicle used for transportation of radiopharmaceuticals will be surveyed for contamination after each transfer. Survey results and surveyors names will be recorded on the "Radioactive Shipment Receipt Report".

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11) All receipts and package opening procedures will be carried out as outlined in Appendix F of Regulatory Guide 10.8 October 1980.

Sincerely,

A handwritten signature in dark ink, appearing to read 'E. J. Valentini, M.D.', written in a cursive, flowing style.

E. J. Valentini, M.D.
Radiation Safety Officer

TRANSFER OF RADIOACTIVE MATERIALS BETWEEN NRC LICENSED MEDICAL INSTITUTIONS-
SITUATIONS THAT DO NOT REQUIRE THE TRANSFEROR TO OBTAIN A DISTRIBUTION LICENSE

The review and approval of requests of this nature require an exemption from the regulations contained in Section 35.14(b) of 10 CFR Part 35. These requests shall, therefore, be reviewed on a case-by-case basis. Please submit the following information in support of your application:

1. Justification for this request, i.e., the reason that the facilities involved cannot receive materials solely in accordance with 10 CFR 35.14.
2. Concurrence from the administrator of each participating institution.
3. Identification of each type and quantity of radiopharmaceuticals that will be transported (e.g., unit doses of Tc-sulfur colloid, etc.).
4. For transfers involving Group VI sources, procedures for maintaining source accountability at all participating institutions.
5. A general, but complete description of how a typical transfer will work (i.e. which institution will transfer material, how a typical transfer will be initiated, the title of the person responsible for initiating and implementing the transfer, a general description of the events that will follow once the materials are on the site of the receiving institution, etc.)
6. Identification of the individuals who will transport the material, and the training they will receive. This training should, as a minimum, include all the items outlined in 10 CFR 49.12 and decontamination procedures in case of spills.
7. Safety measures to be used in transporting the radioactive materials in the applicants' vehicles (e.g. security against unauthorized removal, away from passenger compartment, absorbent paper, lead shields, etc.).
8. Emergency procedures to be followed in case of accidents involving spills or loss of radioactive materials.
9. Confirmation that vehicles used for transporting materials will be surveyed for contamination after each transfer.
10. Confirmation that receipt and package opening procedures will be at least equivalent to those outlined in Appendix F of Regulatory Guide 10.8, October 1980.

June, 1982

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July 15, 1985

Dear Mr. Reiehhold:

As Administrator for St. Francis Medical Center, I approve this application for ammendment to our NRC license. The transfer of Radiopharmaceuticals between St. Francis Medical Center and Gundersen Clinic should greatly benefit patients having Nuclear Medicine examinations.

Sincerely,

A handwritten signature in cursive script that reads "Sister Celesta Day". The signature is fluid and legible, written in dark ink.

Sister Celesta Day
Administrator, St. Francis Medical Center

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The Supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:
 - a. Ordering of routinely used materials
 - (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
 - (2) The written records will be referenced when opening or storing radioactive shipment.
 - b. Ordering of specially used materials (e.g., therapeutic uses)
 - (1) A written request* will be obtained from the physician who will perform the procedure.
 - (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
 - (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
 - c. It is essential that written records* be maintained for all ordering and receipt procedures.
3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE** MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4 p.m. and 7 a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and lock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined whether or not the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

** Submit a copy of your own institution's memorandum.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 15 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds $0.01 \mu\text{Ci}/100 \text{ cm}^2$ or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).
2. For all packages, the following additional procedures for opening packages will be carried out:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect package for any sign of damage (e.g., wetness, crush). If damage is noted, stop procedure and notify Radiation Safety Officer.
 - c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If $>10 \text{ mR/hr}$, stop procedure and notify Radiation Safety Officer.
 - d. Measure surface exposure rate and record. If $>200 \text{ mR/hr}$, stop procedure and notify Radiation Safety Officer.
 - e. Open the package with the following precautionary steps:
 - (1) Open the outer package (following manufacturer's directions if supplied) and remove packing slip.
 - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.
 - (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
 - (4) Check also that shipment does not exceed possession limits.
 - f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., $\mu\text{Ci}/100 \text{ cm}^2$, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.
 - g. Monitor the packing material and packages for contamination before discarding.
 - (1) If contaminated, treat as radioactive waste.
 - (2) If not contaminated, obliterate radiation labels before discarding in regular trash.
3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. **NOTIFY:** Notify persons in the area that a spill has occurred.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
3. **CLEAN UP:** Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. **SURVEY:** With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.
5. **REPORT:** Report incident to the Radiation Safety Officer.
3. **SHIELD THE SOURCE:** If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **CALL FOR HELP:** Notify the Radiation Safety Officer immediately.
6. **PERSONNEL DECONTAMINATION:** Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____*
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS
DESIGNATED BY RADIATION SAFETY OFFICER:

Major Spills

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

RADIOACTIVE SHIPMENT REPORT

- 1) Date of Shipment _____ Time _____
Shipment From _____ To _____
- 2) a) Radionuclide _____
b) Amount _____
c) Chemical Form _____
- 3) Requesting Doctor _____
Nuclear Med Tech _____
(Shipper) _____
- 4) Radiation Unit of Label _____ units (mR/hr)
- 5) Measured Radiation Levels Prior To Shipment:
a) Background _____ mR/hr
b) Transport Box at Surface _____ mR/hr
c) 3 Feet or 1 Meter From Surface _____ mR/hr
- 6) Measured Radiation Levels Post Shipment:
a) Background _____ mR/hr
b) Transport Box at Surface _____ mR/hr
c) 3 Feet or 1 Meter From Surface _____ mR/hr
d) Transport Box Without Radio Pharm _____ mR/hr
e) Vehicle Transport Area _____ mR/hr
f) Wipe Test - Transport Box _____ mR/hr
- Vehicle _____ mR/hr
- 7) Comments _____

Requesting Physician - Date

Nuclear Medicine Technologist Shipper - Date

CONTRACT NO. 70723