

24-00794-03

St. John's Mercy
Medical Center

DCD/DCB

615 South New Ballas Road
St. Louis, MO 63141-8277
314/569-6000

A Member of the Sisters of Mercy Health System--St. Louis

November 5, 1992

Kevin Null
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Control # 91084

Dear Mr. Null:

We wish to withdraw our request for exemption to 10 CFR 35.75 as stated in renewal application dated 2/26/91 and described in ATT 10.14. Revised ATT 10.14 is enclosed to reflect acceptance of 5 mR/hr at one meter as the exposure limit for release of patients following radiopharmaceutical therapy.

The intent of our request was to have the flexibility to apply different limits depending on the conditions in the home (as described in NCRP 37), to protect the public while avoiding creating undue hardship on patient and family. If such a case should arise we will make a specific request of NRC Region III for single exemption as was the case on June 30 of this year. We had no intention to apply higher limits to all patients (in fact, routine preferred limit is 1.8 mR/hr as described in NCRP 37); however, we appreciate having the opportunity to apply to the NRC on a case by case basis when medical emergency or undue hardship are involved.

Sincerely,

Sister Mary Angelique Foto, RSM

Sr. Mary Angelique Foto, RSM

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PDR ADDCK 03002283
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NOV 13 1992

REGION III

St. John's Mercy Medical Center includes St. John's Mercy Hospital (Washington, Missouri), St. John's Mercy Home Health Services, St. John's Mercy Skilled Nursing Center, St. John's Surgery Center, The Edgewood Program and Meacham Park Health Center.

St. John's Mercy Medical Center is an equal opportunity employer and equal access provider of health care services.

NOV 13 1992

ATT 10.14 - Radiation Safety During Therapeutic Use of Radiopharmaceuticals
at St. John's Mercy Medical Center

Procedures for Therapeutic Doses of Iodine-131 Over 30 Millicuries

1. The commercial supplier of the radiopharmaceutical will either be Mallinckrodt or Squibb. The therapeutic oral solution from the two manufacturers is very stable and the formation of volatile I-131 either as iodine or hydroiodic acid during storage is unlikely. The therapeutic oral solution will be vented in an exhaust hood before administration to a patient. This step will further minimize the possibility of inhaling any volatile I-131. Therapeutic capsules from the above manufacturers may also be used, the encapsulated form of I-131 sodium iodide also has minimal risks from volatile I-131.
2. Patients receiving more than 30 mCi of I-131 will be placed in a private room with private sanitary facilities. It will also be far away from the nursing station and heavy hallway traffic. The preferred room for the patient is one of the two rooms with lead shielding in the walls, at the end of the hallway.
3. Prepare the patient's room as follows:
 - a. Cover with absorbent paper, the night stand top, food stand tray and floor areas around the sink and toilet.
 - b. Cover with plastic wrap, the telephone, water faucets, all components of the toilet, (seat, lid, etc.), TV controls and nurses call cord.
 - c. Prepare two yellow plastic barrels with plastic bag liners, one for linen and the other for disposable waste.
 - d. Label the room's door and patient's chart with radioactive warning labels.
 - e. Prepare collection containers if urine will be collected.
 - (1) To avoid room contamination, place containers in a box lined with a plastic bag.
 - (2) Supply a wide mouth funnel if needed.
 - (3) Supply shielding for each container.
 - f. Stock additional disposable gloves, absorbent paper and plastic bags in the room for use as necessary by staff.
 - g. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Place Iodine-131 Therapy: Supplement, in the patient's chart. See Form 10.14/2/90. The Nuclear Medicine physician may provide additional information in the chart.
5. The Physician will brief the patient on radiation safety procedures, visitor control, radioactive wastes and other items as applicable.
6. Following administration of the dose, measure the exposure rate in mR/hr at:
 - a. one meter from the patient.
 - b. at the room's door; this rate must not exceed the exposure rates of 20.105(b).
 - (1) Radiation levels such that an individual would receive in excess two millirems in any one hour, or
 - (2) Radiation levels such that an individual continuously present for seven days would receive in excess 100 millirems.
 - c. Record exposure rates in the progress notes of the patient's chart.

7. Thyroid bioassays will be performed in compliance with regulatory guide 8.20.
8. Do not release any patient until the exposure rate from the patient is less than 5 mR/hr at one meter.
9. Upon discontinuation of radiologic safety restrictions the RSO or a member of the Nuclear Medicine staff will perform the following:
 - a. Remove all absorbent paper, plastic wrap and place in appropriate barrel.
 - b. Survey disposable waste and linen barrel with a low range survey meter, if exposure rate is below 0.05 mR/hr, release the contents. If it is higher than 0.05 mR/hr, transfer contents to decay-in-storage.
 - c. Use a low range survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm². If contamination is fixed, exposure rates will be less than 1 mR/hr with the GM detector in contact with the contaminated surface, before the cleaning restrictions are lifted. See Form 10.14/3.
 - d. Notify Housekeeping office that cleaning restrictions have been lifted.
10. Monitor nurses with indirect reading pocket ionization chambers or with film badges.

Procedure for Therapeutic Doses of Phosphorus-32 or Gold-198

1. Patients will be placed in a private room with private sanitary facilities. It will also be far away from the nursing station and heavy hallway traffic. The preferred room for the patient is one of the two rooms with lead shielding in the walls, at the end of the hallway.
2. Prepare separate barrels for linen, disposable waste and nondisposable contaminated items. Place a single large reclosable plastic bag in each barrel, or supply several small plastic bags.
3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Brief the nurses on radiation safety precautions. Use Form 10.14/1, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198." Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
5. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste and other items as applicable.
6. Only those persons needed for medical, safety or training purposes should be present during the administration.
7. Measure the exposure rate in mR/hr at one meter from the patient and at the doorway (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instructions form.
8. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
9. Do not release any patient until either the exposure rate from the patient is less than 5 mR/hr at one meter.
10. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
 - a. Remove all absorbent paper, and place in the appropriate container.
 - b. Transfer all containers to a decay-in-storage or decontamination area.
 - c. Use a low-range GM survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm². If the contamination is fixed, exposure rates will be less than 1 mR/hr with the GM detector in contact with the contaminated surface.
 - d. Notify Housekeeping office that cleaning restrictions have been lifted.
11. Monitor nurses with indirect reading pocket ionization chambers or with film badges.

CONVERSATION RECORD

TIME

DATE

3:00 P.M. 11/4/92

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Shan Quint

SUBJECT

HQ response to TAR re: licensee's request for an exemption to 35.75.

SU: MARY

I called to inform the licensee that their request for an exemption to 35.75 has been reviewed by our headquarters office and subsequently denied.

Approval may be granted on an individual patient basis due to undue hardship or medical emergency.

Option for the licensee would be to withdraw the request or receive a denial from Region III.

Ms. Quint stated that they will submit a letter withdrawing their request.

ACTION REQUIRED

Wait for letter from licensee.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Kevin G. Null

ACTION TAKEN

SIGNATURE

TITLE

DATE