

APPENDIX N

Radiation Safety During Radiopharmaceutical Therapy

PROCEDURES FOR ADMINISTERING THERAPEUTIC RADIOPHARMACEUTICALS

1. An authorized user will personally review the patient's case to assure that the therapeutic procedure is appropriate.
2. An authorized user will prepare a written directive for each therapy procedure.
3. An authorized user will use radioactive material or direct technologists in using radioactive material. At facilities authorized for physician training, an authorized user will use radioactive material or direct physicians in training in using radioactive material, with the approval of the radiation safety committee.
4. An authorized user will regularly review the progress of the patient receiving therapy and modify the originally prescribed dose if needed.
5. Check each patient's name and identification number (or other identifier as specified in the quality management program) and the prescribed radionuclide, chemical form, and dosage before administering.
6. Each therapeutic radiopharmaceutical dosage will be assayed in the dose calibrator before it is administered to a patient. Do not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent, except for prescribed dosages of less than 10 microcuries. (When measuring the dosage the radioactivity that adheres to the syringe wall or remains in the needle need not be considered.)
7. Each therapeutic radiopharmaceutical dose will be assayed within 30 minutes before it is administered to a patient. A record of the assay will be made in accordance with 64E-5.616(1), Florida Administrative Code.

SAFETY PROCEDURES FOR USE OF THERAPEUTIC RADIOPHARMACEUTICALS REQUIRING HOSPITALIZATION

1. The patient's room is as far away from the nursing station and heavily trafficked hallways as is consistent with good medical care. It is a non carpeted private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released under Rule 64E-5.622, F.A.C.
2. Room preparation
 - A. Use leak-proof absorbent paper to cover large surfaces that are likely to be contaminated, such as the bed, chairs, and the floor around the toilet. Small items, such as the telephone, door knobs, the nurse call cord, the bed remote control, and the television control may be covered with absorbent paper or plastic bags.
 - B. Prepare separate containers for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each container, or supply several small plastic bags.
 - C. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use by nursing, nuclear medicine, and radiation safety personnel.

2. D. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine is collected, prepare collection containers.
 - Urine collection containers are unbreakable and closable.
 - When no assay or volumetric determination is required and urine is decayed in storage, add an absorbent such as vermiculite to each container.
 - Place containers in a box or deep tray lined with a plastic bag and absorbent paper or vermiculite, to avoid room contamination in the case of a spill.
 - Supply a few half-value layers of shielding for each container. (One half-value layer of iodine-131 is approximately 3 mm of lead.)
 - Supply a wide-mouth anti-splash funnel.
3. Order disposable table service (i.e. paper or plastic plates, cups, and utensils) for the duration of the patient's stay.
4. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
5. Supply the nurses with film badges, TLDs, OSLDs or pocket ionization chambers.
6. Ensure that nurses have received current radiation safety training as specified by 64E-5.625(1) Florida Administrative Code, (F.A.C.), and the facility training program. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
7. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
8. Post the room with a "Caution - Radioactive Materials" or "Danger, Radioactive Materials" sign. In addition, if the survey results indicate 5 mrem per hour at 30 centimeters from the patient, a conspicuous sign or signs bearing the radiation symbol and stating "Caution, Radiation Area" will be used and if 100 mrem per hour at 30 centimeters from the patient then the area will need to be posted with a sign indicating "Caution, High Radiation Area" or, "Danger, High Radiation Area".
9. Only individuals needed for medical, safety, or training purposes will be present during the administration.
10. After administering the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the likely point for the "visitors' safe line," and in the surrounding hallways and rooms. The dose to members of the public will not exceed 2 mrem in any one hour or 100 mrem per year as described in 64E-5.312, F.A.C. The radiation dose may exceed 0.1 rem (1 mSv) to permitted visitors to an individual who cannot be released under Rule 64E-5.622, F.A.C. provided the dose does not exceed 0.5 rem (5 mSv) and the authorized user has determined before the visit that it is appropriate according to 64E-5.312(5), F.A.C.
11. Mark the "visitors' safe line" on the floor. Determine where the safe line should be based on the survey measurements.
12. Record survey results and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form.
13. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area. Materials and items removed from the patient's or human research subject's room will be monitored to determine any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or these materials and items will be handled as radioactive waste according to Rule 64E-5.625(8)(a), F.A.C.

14. Do not release any patient until either the exposure rate from the patient is less than 5 mR/hour at 1 meter - *or* - the radioactivity retained in the patient is less than 30 millicuries. When using the exposure rate as the release criterion, measure it with a radiation survey meter at a distance of 1 meter from the umbilicus while the patient is standing, or if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
15. Provide the patient with written radiation safety instructions. These instructions will include steps the patient may take to lessen radiation exposure to family members or others in contact with the patient.

RELEASING A ROOM FOR UNRESTRICTED USE

1. Remove all absorbent paper, and place it in the appropriate radioactive waste container.
2. Transfer all containers to a decay-in-storage or decontamination area.
3. Use a radiation detection survey meter to check for room contamination.
4. Conduct wipe tests for removable contamination in the patient's room and private sanitary facilities.
5. Clean contaminated areas until removable contamination is at background levels when surveyed with a G-M survey meter, or less than 200 dpm/100 cm².
6. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

USE OF OTHER THERAPEUTIC RADIOPHARMACEUTICALS

Ensure that nurses have received current radiation safety training as specified by subsection 64E-5.625(1), F.A.C., and the facility training program. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

EARLY RELEASE OF PATIENTS CONTAINING THERAPEUTIC RADIOPHARMACEUTICALS

Licensees and license applicants whose proposed procedures to release individuals who have been administered radiopharmaceuticals containing radioactive material from the control of the licensee that differ from the specifications in number 14 above must submit their proposed procedures to the department for approval according to 64E-5.622(4), F.A.C. NUREG 1556, Volume 9 may be accessed at the NRC's web-site www.nrc.gov for guidance on procedures and calculations.

The procedures must:

1. Demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 μ Sv);
2. Contain a copy of the instructions including written instructions to be given to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1 μ Sv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 μ Sv) if there were no interruption of breast-feeding, the instructions also shall include:
 - (a) Guidance on the interruption or discontinuance of breast-feeding and
 - (b) Information on the consequences of failing to follow the guidance.
3. Include a record of the basis for authorizing the release of an individual from control that has been administered radiopharmaceuticals for 3 years after the date of release.

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