

University of Maryland Baltimore

Radiation Safety Procedure

Procedure Number: 4.4

Title: Radiation Safety During Therapeutic Radiopharmaceutical Procedures

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Technical Review and Approval:

Radiation Safety Officer

Date: _____

Radiation Safety Committee Approval:

Chair, Radiation Safety Committee

Date: _____

PROCEDURE 4.4, RADIATION SAFETY DURING THERAPEUTIC RADIOPHARMACEUTICAL PROCEDURES

1.0 Purpose:

This procedure establishes measures to be implemented when a therapeutic dose of Iodine-131 (I-131) is administered to a patient. A therapeutic dose of I-131 is typically greater than 30 millicuries. A patient with this amount of I-131 must be carefully controlled to preclude unnecessary radiation dose to hospital personnel, other patients, and visitors. Such patients present an external radiation exposure and external contamination hazard as well as potential source of internal radionuclide contamination as a result of the elimination of the isotope from the body.

2.0 Scope:

This procedure applies to all uses of therapeutic doses of radioiodine.

3.0 Procedure:

3.1 *Authorized Users*

Radiopharmaceutical procedures may only be conducted under the supervision of a physician who has been approved as an authorized user by the Radiation Safety Committee under the provisions of COMAR G.67. This physician is responsible for the following:

- Examination of the patients and medical records to determine if radiation procedure is appropriate,
- Preparation of the written directive detailing the radiation dose and how it is to be administered in accordance with the Quality Management Program (QMP) [G.6(c)],
- Actual use of radioactive material, and
- Evaluation of results of therapy procedures.

3.2 *Treatment Room*

Normally, a designated room will be used for all radiopharmaceutical therapies. Other rooms may be used at the discretion of the Radiation Safety Officer in consultation with the Nuclear Medicine Division. The patient's room shall be a private room (this includes a multi-bed room reserved for the exclusive use of the therapy patient) as far away from the nursing station and occupied hallways as is

consistent with good medical care. Ideally, this would be a corner room on the top or bottom floor.

3.3 Patient Radiation Safety Briefing

The physician and a trained member of the nursing staff or radiation safety staff shall brief patient regarding expectations and the precautions necessary to protect others [G.37(a)(6)]. In addition, the Radiation Safety Office staff shall also train/brief all staff personnel who may be called upon to attend the patient [G.36(a)].

3.4 Transportation of Therapy Radiopharmaceuticals

3.4.1 All therapy radiopharmaceuticals shall be transported to the patient's room in either a shielded cart or the manufacturer's shipping container under constant surveillance and control of trained radiation safety workers. The transportation container must be locked or securely latched to ensure that radiopharmaceutical will not be released if the container is dropped or turned over.

3.4.2 Before moving the radiopharmaceuticals from the Nuclear Medicine Division, perform a survey to that the radiopharmaceuticals are adequately shielded.

3.5 Personnel Dosimetry Requirements

All staff members attending to Nuclear Medicine therapy patients must wear whole body radiation dosimeters when in the patient's room. All personnel who handle the therapy dose must wear a ring dosimeter in addition to a whole body dosimeter. Visitors shall not be issued a dosimeter. All personnel directly assisting in the administration of the therapy dose shall undergo bioassay within 72 hours of the dosing [G.37(a)(8)].

3.6 Precautions

3.6.1 Absorbent paper or plastic shall be used to cover the floor and items in the room that are likely to be contaminated.

3.6.2 Plastic bags or containers shall be supplied for linen and contaminated trash. No items that come in direct contact with the patient will be removed from the room without the approval by staff from the Radiation Safety Office.

3.6.3 Urine collection shall be avoided if at all possible. If urine must be collected, the applicable regulatory guidance (e.g., Regulatory Guide 10.8, Appendix P) shall be followed.

3.6.4 Disposable trays and utensils shall be used.

3.6.5 No housekeeping personnel shall be allowed in the room until the room is released by staff from the Radiation Safety Office.

3.6.6 Nursing staff shall be provided with dosimeters.

3.6.7 Only necessary personnel shall be present during the administration of radioiodine.

3.7 Radiation Surveys

3.7.1 After administration, exposure shall be measured in the affected restricted and unrestricted areas to ensure compliance with applicable regulatory limits [G.37(a)(4)]. If the patient is ambulatory, he should stand at the bedside for all measurements. If the patient is not ambulatory all measurements shall be made with the patient supine, and the measurement taken at 1 meter from the bedside shall be used to determine exposure rate for release.

3.7.2 All readings shall be recorded.

3.8 Posting

The room door shall be posted with a "Caution, Radioactive Materials" sign [G.37(a)(2)]. The door should also be marked with a "No Housekeeping Services" sign and a copy of the Nursing Instructions. Because this room is a restricted area, all employees entering are required to receive training. All nursing staff receive special training. Other medical personnel, such as dietitians, may enter for brief periods, but shall stay within established safe areas.

3.9 Visitors

3.9.1 Controls on visitors' locations and visit durations shall be established to ensure doses to members of the public are less than 0.1 rem in a year and ALARA [D.301].

3.9.2 Pregnant women and minors shall not normally be allowed to visit patients with an appreciable external radiation exposure rate. Exceptions can be made in the case of urgency, but the AU and RSO shall be consulted prior to allowing these visits [G.37(a)(3)].

3.10 Release of Patient

The patient may not be released until the measured dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter or the activity of

the patient is less than 30 millicuries (1.11 GBq) [G.25]. Prior to release, the patient should receive written instructions on ways to minimize exposure to others after release [G.37(a)(6)].

3.11 Decontamination

- 3.11.1 All contaminated trash and linens shall be sealed, tagged, and properly documented prior to waste disposal or Decay-in-Storage (DIS).
- 3.11.2 Removable Contamination Surveys of the patient's room shall be conducted. All areas shall be cleaned until removable contamination is less than 200 dpm/100 cm². The room shall be sealed by staff from the Radiation Safety Office until all contamination has been removed or has naturally decayed below the 200 dpm/100 cm² limit [G.37(a)(7)].
- 3.11.3 The Radiation Safety Office staff will notify Housekeeping and the Nuclear Medicine management when the room is released to general use and will make certain that all postings on the door and in the patient chart are removed.

3.12 Emergency Surgery or Death Of The Radioactive Implant Patient

- 3.12.1 At no time should emergency medical care be delayed because of the presence of a radiopharmaceutical. The hazard to personnel due to exposure is very small compared to the risk to the patient if necessary emergency care is delayed.
- 3.12.2 If surgery is being contemplated or is necessary, the attending physician and the Radiation Safety Office shall be notified immediately. Items that become contaminated during surgery must be held for Decay-in-Storage or waste disposal by the Radiation Safety Office.
- 3.12.3 If a Nuclear Medicine therapy patient should die or require emergency treatment prior to release by the Radiation Safety Office, notify the attending physician and the RSO [G.37(b)]. In the event of patient death, the body should not be moved until these individuals arrive. If an autopsy is to be performed, it should be carried out only after consulting with the RSO.

3.13 Radiation Safety Instructions

- 3.13.1 UMB shall provide oral and written radiation safety instructions to all personnel involved in patient and human research care involving implant therapy [G.36(a)]. UMB shall provide refresher training at intervals not to exceed one year [G.36(a)].
- 3.13.2 At a minimum, the radiation safety instructions shall include information regarding [G.36(b)]:
- Procedures for patient/human research subject and visitor control;
 - Contamination control;
 - Waste control;
 - Procedures for notifying the RSO or AU if the patient/human research subject dies or has a medical emergency; and
 - The information listed in COMAR Part J (see Procedure 1.7, *Radiation Safety Training*).

4.0 Records and Reports:

4.1 Records

- 4.1.1 "Nursing Instructions," "Patient Instructions," "Radiation Safety Checklist for Iodine Therapy over 30 Millicuries," and the final room survey shall be filed. These documents and the bioassay results for personnel involved in the patient's dosing shall be retained for a period of at least three years [G.36(c)].
- 4.1.2 Radiation safety records shall be created and maintained consistent with the requirements of Procedure 1.2, *Radiation Safety Records*.

4.2 Reports

Radiation safety reports shall be created and filed consistent with the requirements of Procedure 1.3, *Radiation Safety Reports*.

5.0 References:

COMAR 26.12.01.01
Maryland License MD-07-014-01
UMB Radiation Safety Program

USNRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs"