

- 1. **Purpose:** The following procedure describes general recommendations and steps for preparing a room for a patient who has been administered radioactive materials, including both radiopharmaceuticals and brachytherapy sources. The procedure also includes subsequent steps to release the room for unrestricted use.
- 2. Scope: Radiation Workers (RWs) who are involved in radiopharmaceutical administrations may follow this procedure when preparing a room for either a patient that is not immediately releasable per 10 CFR 35.75 or a patient who is immediately releasable but administration results in significant quantities of contamination during the procedure. RWs should also follow this procedure when decontaminating a room so that it may be released for unrestricted use. AUs may find this SOP useful when developing RAM permit-specific procedures such as door postings.

#### 3. Definitions:

- **3.1** Ambient Radiation Level Survey A survey of the immediate area where radioactive materials are used. Ambient surveys often refer to surveys performed with a handheld radiation detector such as a Geiger-Mueller (GM) detector and are in exposure units of mR/hr.
- 3.2 Chucks Medical chucks are absorbent pads used to minimize contamination.
- **3.3** Clean Zone The area, most often closest to the door, where no radioactive materials or contamination should be present.
- **3.4** Hot Zone The area that has protective coverings to minimize contamination. This is where the patient will stay throughout the procedure and stay time.
- **3.5** Inpatient An individual who has received a procedure involving radioactive materials and cannot be released per 10 CFR 35.75. To be immediately releasable, the dose to an individual from patient exposure must be less than 500 mrem. For purposes of this procedure, the term "patient" will also refer to inpatient or human research subject.
- **3.6** Restricted Area Any area to which access is controlled for the protection of individuals from exposure to radiation and radioactive materials.
- **3.7** Unrestricted Area An area in which a person could not be exposed to radiation levels in excess of 2 mrem in any one hour from external sources [10 CFR 20.1003].
- **3.8** Warm Zone The area designated for doffing PPE. Individuals will also survey themselves in this area prior to stepping into the clean zone to prevent contamination from spreading to unrestricted areas.

#### 4. Procedure Details:



- **4.1** Before administering radioactive materials, the Authorized User (AU) and their staff should evaluate if the individual will be releasable per 10 CFR 35.75. In the event the patient cannot be released, then individuals who may either provide patient care or be involved in the procedure should be identified so that the AU and the Radiation Safety Staff (RSS) can verify radiation safety training and RW requirements are met.
  - 4.1.1 Inpatients have typically received therapeutic dosages of radioactive materials. Therefore, safety instructions for RWs providing care or interacting with the inpatient should include information found in 10 CFR 35.310, 35.410, and 35.610 as well as any licensing guidance available for emerging technologies identified as part of 10 CFR 35.1000 or FDA protocols for clinical trials. These individuals should also be identified early on so that the RSS can evaluate if dosimetry is needed for the procedure.
  - 4.1.2 The RSS may also choose to incorporate these topics into the routine radiation safety training to better prepare current and future RWs for inpatients.
  - 4.1.3 Any instructions specific to a procedure should be included in the AUs permit application and are the responsibility of the AU to maintain and distribute.
- **4.2** General regulatory requirements for inpatients for both radiopharmaceutical and brachytherapy applications include [10 CFR 35.315, 10 CFR 35.415]:
  - 4.2.1 Inpatients must be placed in a room with a private sanitary facility. The patient can either be alone in the room or share the room with another inpatient who has received the same therapy. It is preferred that the inpatient room has an ensuite sanitary facility so that the patient does not have to leave the room and access the unrestricted hallway.
  - 4.2.2 The room must be visibly posted with a "Radioactive Materials" sign.
  - 4.2.3 Note on the door or in the patient's chart where and how long visitors may stay in the patient's room. Visitors are generally not allowed in inpatient rooms at MU since inpatients are not frequent and stay times would not be that long.
  - 4.2.4 For radiopharmaceuticals, any items being removed from the room must be surveyed, and contamination present must not be distinguished from background radiation levels with an appropriate radiation detector set on its most sensitive scale with no interposed shielding. If items do not meet this criterion, they must be handled as radioactive waste. Contaminated items can be held for Decay-In-Storage (DIS) based on the radionuclide's half-life. Before releasing an item back for unrestricted use, the RW must perform a survey as previously described to confirm



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no contamination is present that is distinguishable from the background. Release of these items should be documented in a DIS logbook.

- 4.2.5 For brachytherapy sources, emergency response equipment shall be available near each treatment room to respond to a source that could either be dislodged from the patient or lodged within the patient following removal of the source applicators.
- **4.3** To prepare a room for an inpatient, adequate measures should be taken to minimize the amount of contamination and exposure to the public.
  - 4.3.1 The AU should verify the inpatient room to be used is approved for use. This should be listed in the AU's RAM permit. Prior to approval, inpatient rooms are typically evaluated for dose rates in adjacent unrestricted areas by performing a dose assessment. This ensures that members of the public will not exceed the annual limit of 100 mrem. The RSS may also find it useful to record dose rates in adjacent unrestricted spaces to confirm manual calculations performed during evaluation are correct.
  - 4.3.2 In addition to the Radioactive Materials sign that must be temporarily posted, the RSS recommends posting additional information that includes items such as the type of therapy administered, telephone numbers of responsible persons, and radiation safety instructions for nursing staff and other patient care staff. The template for these instructions should be submitted as part of the AU's RAM permit application.
  - 4.3.3 It is recommended to minimize the amount of furniture in the room so that fewer items may be contaminated. Always verify with nursing staff prior to rearranging a room.
  - 4.3.4 Absorbent pads, tarps, chucks, or a similar protective covering should be applied to the following locations:
    - 4.3.4.1 The floor underneath or near where the patient will sit or lay.
    - 4.3.4.2 The floor where the patient may walk. A pathway could also be created towards the room entrance.
    - 4.3.4.3 Any surface that could be touched by the patient's hands including a personal cabinet, emergency assistance pull-cords or buttons, head and footboard of bed, TV remote, phone, food table, and more.
    - 4.3.4.4 The infusion chair where the patient sits during the administration.
    - 4.3.4.5 The bathroom floor.



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4.3.4.6 The bathroom walls surrounding the toilet.

- 4.3.4.7 Toilet paper dispensers, handrails, toilet flush handles, sink handles, door handles, and other bathroom areas where patients may frequently touch.
- 4.3.4.8 The toilet lid and other parts of the toilet if feasible.
- 4.3.4.9 The sink basin and walls surrounding the sink including the mirror.
- 4.3.5 Block off the use of any built-in trash cans in the room or bathroom.
- 4.3.6 If the suite has a shower, restrict the use. This can be achieved by placing caution tape and/or signage over the shower area.
- 4.3.7 At the entrance of the room, designate an area for donning and doffing PPE as well as surveying individuals and items prior to leaving the room. This can be deemed the warm zone. Once an individual confirms they are contamination-free, they can then step into the designated clean zone.
- 4.3.8 Place waste containers in the hot zone and the warm zone.
- 4.3.9 Examples of room preparation can be found in Appendix A.
- 4.3.10 Room preparation like this is most likely only applicable to radiopharmaceutical inpatients and not brachytherapy inpatients.
- 4.4 Once the room has been prepared and an inpatient is present:
  - 4.4.1 Anyone entering the hot zone must wear shoe covers at a minimum.
  - 4.4.2 When interacting with the dose or the patient, individuals must also wear a protective gown and gloves. Depending on the task being performed, double gloves might be necessary.
  - 4.4.3 Nursing staff may not always need to be RWs depending on the procedure and their level of involvement. This should be determined prior to the initial approval of any new RAM procedure. If nurses do not need to be RWs, they should receive ancillary training and document the training in the AU's records.
  - 4.4.4 Instructions defined in 10 CFR 35.310, 35.410, 35.610, and any other licensing guidance should be posted on the door next to the Caution Radioactive Materials temporary signage. An example of instructions and temporary door signage can be found in Appendix B.
  - 4.4.5 Pregnant and nursing individuals who may not feel comfortable providing patient care should discuss options with their supervisor, the AU, and/or the RSO.



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Depending on the procedure, these individuals may not be allowed to provide patient care.

- 4.4.6 Depending on the procedure, patients should not be in their street clothes. Upon arrival, they can be given patient gowns, and their street clothes can be returned after release.
- 4.4.7 Instruct patients to sit when using the toilet; standing when using the toilet creates significant contamination in the surrounding area.
- 4.4.8 When individuals leave the room, they must survey, at minimum, their hands and feet.
- **4.5** Once the patient is released, the room should be decontaminated and returned for unrestricted use.
  - 4.5.1 When patients are not immediately releasable, documentation and justification for release must be recorded when they are eventually released. Patient release is normally documented on the written directive since inpatients are not common. However, a template for documenting inpatient release can be found in Appendix C. AUs do not have to use this exact template and can choose to develop their own methods for documenting release. See EHS-SOP-RAD-400.01 Release of Radioactive Human Patients for more information on patient release.
  - 4.5.2 Remove all coverings and place them in the radioactive waste containers. Make sure to wear proper PPE when performing this task.
  - 4.5.3 Remove any bedding and place in a waste container for Decay In Storage (DIS).
  - 4.5.4 Bag items that are too contaminated or difficult to clean and place them in DIS until they can be released back for unrestricted use. Make sure to follow DIS procedures when releasing items, and place waste tags as necessary on contaminated items.
  - 4.5.5 Log any waste moved to the DIS area in the DIS log.
  - 4.5.6 Record the background count rate of the room on the survey map before surveying the room. Survey maps of rooms should be developed during the initial application to use the radiopharmaceutical or radioactive materials source.
  - 4.5.7 Using a GM or other appropriate handheld detector, survey the room for any contaminated areas. It is recommended to start from areas of low to high contamination (i.e. start at the entrance of the room and work towards the bathroom which will have the most contamination). GMs are most often used for surveying, however, a NaI may be useful.

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- 4.5.8 When areas are identified as contaminated, the amount of removable contamination per 100 cm<sup>2</sup> of surface area should be determined by wiping that area with a filter or soft absorbent paper (i.e. swipe or wipe), applying moderate pressure, and assessing the amount of contamination on the wipe with an appropriate instrument of known efficiency. GMs are best suited for this.
- 4.5.9 If the swipe appears to have contamination, decontaminate the area. Once decontamination is complete, reswipe the area and count the swipe on the GM. Repeat this process until the count rate is within acceptable levels.
  - 4.5.9.1 As a rule of thumb, two times the background can be considered contaminated and is worth further investigation.
  - 4.5.9.2 NUREG 1556, Volume 9, Revision 3 lists acceptable surface contamination levels in unrestricted areas. This can be used as a guide when developing room release criteria for each procedure.

Table 1. Acceptable Surface Contamination Levels in Unrestricted Areas per NUREG 1556, Volume 9, Revision 3. CPM calculations assume a 10% efficiency.

	Average Maxim contamination contami		Average Maximum contamination		verage Maximum Removable amination contamination contamination		vable ination
Radionuclide	DPM/100 cm <sup>2</sup>	CPM/100 cm <sup>2</sup>	DPM/100 cm <sup>2</sup>	CPM/100 cm <sup>2</sup>	(DPM/100 cm <sup>2</sup>	CPM/100 cm <sup>2</sup>	
U-nat, U-235, U-238, and associated decay products	5000	500	15000	1500	1000	100	
Transuranics, I-125, I-129, Ra-226, Ra-228, Pa-231, Ac-227, Th-230	100	10	300	30	20	2	
I-126, I-131, I-133, Ra-223, Ra-224, Sr-90, U-232, Th- nat, Th-232	1000	100	3000	300	200	20	
Other alpha emitters	500	50	1500	150	100	10	
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission except those noted above)	5000	500	15000	1500	1000	100	

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- 4.5.10 To use Table 1, assume a GM has a 10% efficiency for unknowns. If an efficiency is known for the radionuclides being measured, then the CPM/100 cm<sup>2</sup> columns can be adjusted.
  - 4.5.10.1 The values in Table 1 should be the net count rate (i.e. background has been subtracted).
  - 4.5.10.2 The removable contamination column can be used to define release criteria for the patient room. When swiping the area and counting it on a GM, the count rate should be below the removable contamination column.
  - 4.5.10.3 For areas where the contamination cannot be removed and/or swipes cannot be taken, such as the inside of the toilet, both the average and maximum columns can be used to release the item or area for unrestricted use. The item or area should have an average count rate matching the average column, and any higher count rates should not exceed the maximum count rate listed.
  - 4.5.10.4 Alternative criteria other than that listed in Table 1 can be used as long as the reason for the criteria is justified.
- 4.5.11 Ambient radiation level surveys can also be performed if a meter is calibrated to read in exposure units of mR/hr. Refer to the Radiation Safety Manual for recommended ambient dose rates for unrestricted areas.
- 4.5.12 As swipes are taken, make sure to document the locations of the swipes on the survey map. Save the final swipes (after any decontamination has been performed) for later so they can be counted on benchtop equipment such as a well counter or liquid scintillation counter.
- 4.5.13 In addition to documenting the swipe results on the survey map, the AU may wish to use another form to officially record the room release. A template for documenting room release can be found in Appendix D; the AU is not required to use this.
- **4.6** If a room cannot be released, notify the RSO and the AU. The nursing supervisor for the inpatient room should also be notified. The RSO can determine how long the room will be removed for non-radioactive patient use.
- **4.7** In the event an inpatient has a medical emergency or dies, the RSO or delegate must be notified [10 CFR 35.315, 10 CFR 35.415].

#### 5. References:



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- 5.1 NUREG 1556, Volume 9, Revision 3
- 5.2 Regulatory Guide 8.39
- 5.3 10 CFR 20
- 5.4 10 CFR 35

#### 6. Revisions

**6.1** Rev 01 – 2023-11-1 – New SOP. Incorporated content from older archived SOPs including RSIP-M-14 I-131 Therapy Inpatient Care and Release and RSIP-M-18 I-131 Therapy Patient Room Set Up and Take Down for EFCC PT8223.

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# Appendix A – Example Pictures of Room Preparation

## Blocking off showers:





Covering area near toilet:

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## Covering sink area:







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Appendix B – Example of Temporary Door Signage

# **NO ENTRY – SEE NURSE**

## RADIATION SAFETY INSTRUCTIONS FOR RADIOPHAMACEUTICAL THERAPY PATIENT CARE

- 1. Patient to be placed in private room with both pages of this document on the door.
- 2. Radiation Safety Staff or Nuclear Medicine Technologists shall prepare the room prior to administration of the radiopharmaceutical.
- 3. Patient is to be confined to the room and no visitors are to be allowed in the room unless specifically permitted by the Radiation Safety Staff.
- 4. Pregnant or nursing women are not to enter the room.
- 5. Nurses are required to wear a badge that monitors radiation exposure while caring for the patient.
- 6. Nursing personnel are to wear disposable gloves when caring for patient and when handling articles used by the patient. Disposable gowns are to be worn if the patient has to be lifted.
- 7. Nursing personnel are to wear disposable shoe covers upon entering the patient room and remove and dispose of the shoe covers when leaving the room.
- 8. Patients are to be provided disposable slippers and hospital gowns to be used when up in the room. Gowns and slippers should be discarded when patient is discharged.
- 9. Disposable isolation trays are to be used for meals.
- 10. Disposable items are to be used in patient care, i.e., stethoscope and substitutes for thermometers.
- 11. All disposable items are to be placed in the radioactive waste receptacle in the room.
- 12. Laundry is to be placed in a laundry hamper in the room.
- 13. All items used in the room must be monitored by Radiation Safety or Nuclear Medicine prior to leaving the room.
- 14. Patient is to use lavatory and toilet facilities in the room. Patient should flush the toilet two (2) times after each use. Males shall sit whenever using the lavatory.
- 15. Bathroom and lavatory shall not be used by any other person during the treatment and until the room has been released by Radiation Safety or Nuclear Medicine Staff.
- 16. Patient cannot be released until approved by the Radiation Safety or Nuclear Medicine Staff.
- 17. Patient room cannot be used until released by the Radiation Safety or Nuclear Medicine Staff.
- 18. All personnel leaving the room must survey hands and feet and remove shoe covers first.

## UNIVERSITY OF MISSOURI INSTRUCTIONS FOR CARE OF PATIENT RECEIVING RADIONUCLIDE THERAPY

Patients who have been administered therapeutic quantities of radioactive material require special attention so needless exposure may be avoided. Attendant personnel are urged to follow these instructions carefully and to ask the Physician, Nuclear Medicine Staff, or the Radiation Safety Staff whenever unsure of radiation safety instructions.

Room:					
					_

Radionuclide Administered: \_\_\_\_\_

Physician: \_\_\_\_\_

Activity Administered: \_\_\_\_\_

Date Administered: \_\_\_\_\_

PERMISSIBLE DAILY TIMES OF STAY FOR ATTENDANT PERSONNEL AND VISITORS:

-No visitors without specific approval of Radiation Safety

RULES FOR OTHER PATIENTS:

-Patients who have been administered therapeutic quantities of radioactive material are to be placed in a private room.

# CAUTION: RADIOACTIVE MATERIAL RADIATION AREA

#### IN CASE OF EMERGENCY CALL:

Authorized User Physician	Office	Service
Radiation Safety	Office	Home
Nuclear Medicine	Office	Home

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## Appendix C – Template for Documenting Inpatient Release

### Send To:

- Nursing Station
- Nuclear Medicine
- □ EHS Radiation Safety

Patient Name:		
Patient Room:		
Patient Release Date:	Time:	

Final release of the patient and patient belongings by Radiation Safety or Nuclear Medicine has been performed. Exposure rates indicated that the residual [insert radiopharmaceutical] activity of the patient will result in less than 500 mrem to any member of the public (10 CFR 35.75). The patient may be removed from radiation isolation and allowed the use of hospital facilities in accordance with any written instructions provided by the physician. The patient can be released from the hospital upon authorization of the attending physician.

Signed,

Date: \_\_\_\_

Radiation Safety, Nuclear Medicine, or Authorized User

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## Appendix D – Template for Documenting Room Release

#### Send To:

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- Nursing Station
- Nuclear Medicine
- □ EHS Radiation Safety

Patient Name:		
Patient Room:		
Patient Release Date:	Time:	

A radiation survey was performed in the above room and the room contents following radiation treatment with [insert radiopharmaceutical]. Radiation levels in the room and the contents are within acceptable levels. The room may be returned to normal use, and any remaining equipment or laundry in the room may be returned to service. Any exceptions or special instructions are noted below.

Signed,

Date: \_\_\_\_\_

Radiation Safety, Nuclear Medicine, or Authorized User

Notes:\_\_\_\_\_