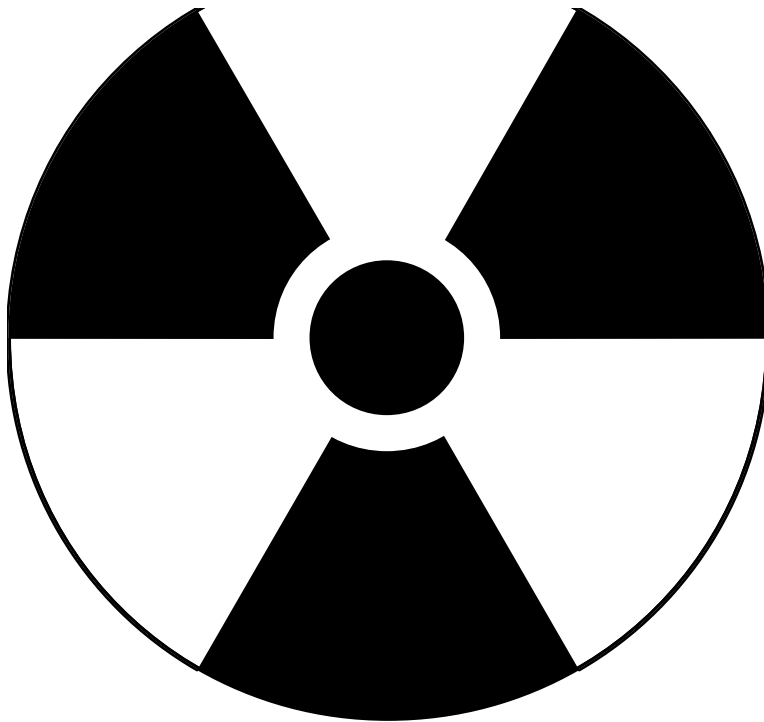


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RADIATION SAFETY USER'S GUIDE

NUCLEAR MEDICINE



A COPY OF THIS GUIDE SHOULD BE READILY AVAILABLE IN EACH FACILITY.

A handwritten signature in black ink, appearing to read "Ed M. J. K.", positioned above a horizontal line.

Reviewed by

May 24, 2024
Date

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Definitions of terms used in this guide:

- RAM - radioactive materials
- dosage - refers to activity (mCi) administered to the patient
- dose - refers to mrem received by patients or workers

PART I: SUMMARY OF ROUTINE REQUIREMENTS

1. Summary of Routine Requirements

A. Daily

- Dose calibrator constancy and other checks
- Well counter and thyroid probe constancies
- Survey meter functionality checks
- Package receipt records
- Generator QC Tests
- Personnel surveys
- Room/waste storage areas surveys for contamination/ambient exposure rates if applicable

B. Weekly

- Wipe test for removable contamination if applicable

C. As needed

- Written directives
- Thyroid bioassays
- Records of generator receipts/shipments and any other shipments
- Cold trash surveys
- Waste decay-in-storage surveys and log

PART II: CONTACTING EHRS AND EMERGENCY RESPONSE

2. Events Requiring EHRS Notification (EHRS contact information is on the cover of the User's Guide)

Workers are required to notify EHRS promptly in the event of any of the following:

- Emergencies involving RAM/Spills as explained in the next section
- Personnel contamination or a positive bioassay result
- Instrumentation failing constancy tests or otherwise malfunctioning
- Loss of radioactive material
- A generator elution failing QC tests
- Problems with an administration of a patient dosage/Medical Events
- Contaminated or damaged RAM shipments
- Patient Contamination
- Unapproved dose to embryo/fetus or nursing child

3. Spill Response

- #### **A.** Notify all persons in the area and limit access to the spill. No personnel in the spill area should leave the area until they have been surveyed and found to be free of contamination.

- B. Prevent the spread of contamination by covering the spill with absorbent pads (chux) or paper.
- C. A worker who was not in the room where the spill occurred should obtain a survey meter and monitor from the doorway of the room inward toward the spill area to identify the extent of the spill.
- D. Measure the exposure rate from the unshielded RAM. Use an ion chamber, if possible.
- E. Notify EHRS if any of the following occur:
 - the spill cannot be quickly controlled, or assistance is needed to complete clean-up
 - the exposure rate exceeds 2 mR/hr at 1 meter from the RAM
 - contamination is identified in an unrestricted area (outside of the department)
 - there is personnel contamination
 - there are any questions
- F. Decontamination
 - All workers in the spill area should wear booties, gloves, a lab coat, and appropriate eye protection.
 - Spills can usually be cleaned using paper towels, water, and commercially available cleansers.
 - Begin cleaning at the edge of the spill and work towards the center.
 - Survey the area after cleaning to evaluate the effectiveness of the decontamination.
 - Continue cleaning until survey results are below trigger levels for the area.
- G. Survey all personnel involved in the spill and clean up.
- H. Document what happened and survey results.

PART III: WORKER ISSUES

4. Regulations and Workers' Rights and Responsibilities

- A. EHRS requirements are based on regulations, the University's license issued by the State of Pennsylvania, and good work practices. Regulations and the University's license are available for review at EHRS.
- B. Workers have both the right and the responsibility to report unsafe work conditions, without fear of penalty. EHRS is always available to evaluate such concerns. Additionally, the State of Pennsylvania provides a Notice to Employees with instructions to workers on these matters. This notice is posted in all Nuclear Medicine facilities.

- C. Workers' occupational doses are maintained, and are available for review, online and at EHRS. See Section 6.B. for details. Bioassay results are maintained, and are available for review, in the Nuclear Medicine Department.
- D. EHRS must be notified when there is a new employee. Before he/she begins work, the following are required:
 - training must be completed as explained in the next section
 - the worker must have whole body and extremity dosimeters as appropriate for their job
- E. Notify EHRS when an employee ceases working in the department. If requested, EHRS will provide a dose history.

5. Radiation Worker Training

A. New workers

Any new workers/students handling radioactive material must complete Radiation Safety training before beginning unsupervised work with RAM. Training can be completed online at the EHRS website.

Workers/students should also receive training from Nuclear Medicine personnel concerning department procedures and potential hazards associated with RAM the employee will work with or around.

B. Annual Radiation Safety Review

All workers/students must complete annual radiation safety training. This will be provided as an in-service conducted by EHRS and/or by online training on the EHRS website.

C. NM Technologist Limited DOT Training

All workers/students must complete initial NM Technologist Limited DOT Training. This will be provided as an in-service conducted by EHRS and/or by online training on the EHRS website. Retraining is required every three years.

6. ALARA Policy, Occupational Doses, and Personnel Monitoring Policies (10 CFR 20)

A. ALARA

1. The acronym ALARA, "As Low as Reasonably Achievable," means that persons using sources of ionizing radiation should make every reasonable effort to keep radiation exposures to individuals and releases of RAM to unrestricted areas as far below regulatory limits as is practicable.
2. Supervisors and workers should periodically review work habits and available safety equipment for adherence to the ALARA principle.

B. Occupational doses, ALARA trigger levels, and Annual Limits

1. EHRS reviews occupational doses on a monthly basis. Doses are summed for each calendar quarter and compared to trigger levels that are referred to as "ALARA levels." ALARA levels are in our Personnel Monitoring policy, posted on the EHRS website under Radiation Safety Policies.
If a dose exceeds an ALARA level, EHRS will investigate and suggest appropriate corrective actions to reduce the worker's future doses. ALARA doses and investigation results are reported to the Radiation Safety Committee.
2. Badged employees can review their doses online via the dosimetry company's websites or by contacting EHRS. Instructions to access doses online have been distributed to department managers and are also available on the EHRS website under Personnel Monitoring. The name of the company (Landauer or Mirion) that processes the dosimeter readings is stated on the front of the whole-body dosimeter.

C. External Exposure Monitoring Policy

1. Nuclear Medicine technologists who handle licensed material must wear both whole body and extremity dosimeters (ring badges) and exchange them on a monthly basis. Physicians should wear whole body dosimeters and extremity dosimeters if applicable to their work.
2. Proper wearing of dosimeters
 - a. Whole body dosimeters must be worn between the collar and the waist. The side of the dosimeter with information printed on it should face away from the worker's body.
 - b. The whole-body dosimeter also estimates the worker's dose to the lens of the eye, so workers may wish to wear it closer to the collar than the waist.
 - c. Extremity dosimeters should be worn whenever handling RAM. The face of the ring with information printed on it should be positioned to measure the highest exposure that fingers will receive (i.e. palm side on the index finger).
3. Dosimeters should be stored in a low background area to prevent inaccurate exposure readings and exchanged at the required frequency.

D. Internal Exposure Monitoring Policy

1. For all Nuclear Medicine departments besides HUP:
A thyroid bioassay will be performed 7 – 72 hours after handling of > 33 mCi of Iodine-131:
 - in liquid form
 - in a capsule if there are any signs the capsule has leaked, including contamination of the work area

For HUP Nuclear Medicine only:

Routine bioassays are not required. Confirmatory bioassay monitoring will be performed:

- within 72 hours after handling of > 600 mCi of volatile I-131 in liquid form handled in an open vial outside a fume hood, or
- in the event of contamination or unusual events, including signs that a capsule has leaked

2. Bioassays must be performed according to the bioassay procedure established in the department.
3. **EHR** must be immediately notified if a bioassay result exceeds the posted trigger level.
4. Bioassay results should be documented on or with the written directive form.

7. Pregnant Worker Policy (10 CFR 20.1003, 20.1208)

A. Declaring pregnancy

A declared pregnancy is when an employee voluntarily informs the licensee (EHR) in writing of her pregnancy and estimated date of conception. This typically occurs during a counseling session with an EHR physicist.

It is entirely the choice of the worker whether to declare a pregnancy. A worker may also choose to rescind her written pregnancy declaration at any time.

If a pregnancy is declared, the PA State dose limit to the embryo/fetus is 500 mrem for the entire pregnancy (10% of the annual occupational dose limits for adults). If a worker chooses to not declare her pregnancy, the lower dose limit does not apply.

B. If you are pregnant or have questions concerning working with or around radiation during pregnancy, please contact EHR. All inquiries will be kept in confidence. We will take the following steps:

- Provide an opportunity to declare your pregnancy.
- Evaluate your dose history and exposure potential.
- Provide you with information concerning risk.
- Provide suggestions for reducing exposure.
- Monitor your radiation dose with respect to the State limits.

PART IV: INSTRUMENTATION AND MONITORING

8. Use of Instrumentation and How to Monitor

A. How to monitor with a meter: Using ionization chambers vs. GM meters

1. For monitoring for contamination, use a GM meter and never an ionization chamber.

GM meters are designed to detect small amounts of contamination. Ion chambers are not sensitive enough to use for contamination monitoring.

2. For measuring exposure rates (mR/hr) an ionization chamber is more accurate than a GM meter.

Ionization chambers are designed to measure radiation fields, so they are more accurate for measuring exposure rates. When measuring exposure rates, GM meters are only accurate for

the isotope they are calibrated with (usually Cs-137 = 662 keV). GM meters can be used to measure an approximate dose rate but measuring an exposure rate from isotopes emitting lower energies with a GM meter can result in a reading that is significantly greater than the actual exposure rate.

B. How to use an ionization chamber

1. Each day, before the first use in a low background area:
 - a. Verify the battery levels are ok. Digital ion chambers typically have two Low Battery indicators. If you see LO, please contact EHRS about service from vendor. If you see LOW BAT, please replace the nine (9) volt batteries.
 - b. Verify the background level is within normal levels. If not, the meter may be contaminated or malfunctioning and should not be used.
 - c. Verify that the meter responds properly to the check source.
2. Digital ion chambers typically are self-scaling.

C. How to use GM survey meters (i.e. pancake probes)

1. Each day, before the first use in a low background area:
 - a. Verify the battery level is ok.
 - b. Verify the background level is within normal levels. If not, the meter may be contaminated or malfunctioning and should not be used.
 - d. Verify that the meter responds properly to the check source.
2. Use the meter's lowest scale (typically "x 0.1").
3. The "F/S" switch should be in the Fast position.
4. Hold the face of the probe parallel to the surface being scanned and as close to the surface as possible without touching it (to avoid contaminating the meter).
5. Move the probe slowly when surveying - approximately the width of the probe face per second.
6. Compare readings to the applicable trigger levels (see section 13).

D. How to monitor: wipe tests (wipe tests are used to determine the amount of removable contamination, but will likely not detect all the contamination that is present)

1. Put on gloves and a lab coat.
2. Applying moderate pressure, drag a filter paper or swab across the area being surveyed. Use of dry wipes is preferable.
3. Count a background sample along with the test samples in the well counter.

4. Compare readings to the applicable trigger levels (see sections 13 and 23-25).

- For package surveys, results should be per 300 cm².
- For area surveys, results should be per 100 cm².

E. Dose calibrators (10 CFR 35.60, AAPM 181)

1. Unless a special potentiometer setting is posted at the dose calibrator by EHRS, use the preset isotope buttons or potentiometer settings provided by the manufacturer.
2. Each day, before the first use:
 - a. Perform dose calibrator “daily checks”. These typically include electronic zero, background, and system voltage checks. Verify the background is < 5 µCi. If not, adjust the background to approximately 0 µCi.
 - b. Verify the Cs-137 check source falls within +/- 5% for all settings indicated in the hot lab computer. To ensure correct results, the check source should be vertical and should be positioned in the "cut-out circle" of the dipper.
 - c. Enter the check source readings into the hot lab computer.
3. Immediately notify EHRS if the dose calibrator fails any daily test or is suspected to not be functioning properly in any way.
4. EHRS performs the geometry, accuracy, and linearity tests. Test results are available at EHRS.

F. Well counters and thyroid uptake probes

1. Each day, before the first use:
 - a. Perform a constancy test. To ensure correct results, the source must be positioned in the correct geometry.
 - b. Verify the background readings are within the normal range.
 - c. Document readings.
2. Notify EHRS if the constancy reading exceeds +/- 5% of the expected value or falls outside of the prescribed range or if the instrument is suspected to not be functioning properly in any way.

G. EHRS performs annual calibrations of all these instruments.

PART V: CONTROL OF RAM, EXPOSURE, AND CONTAMINATION

9. Security of RAM (10 CFR 20.1801-2)

When in storage, RAM must be secured from unauthorized removal or access. When not in storage, RAM must be maintained under constant surveillance or secured from unauthorized removal or access.

10. Posting and Labeling

A. Posting Requirements (10 CFR 20.1003, 20.1902-3, 35.75)

1. Areas or rooms where RAM is used or stored must be posted with a “*CAUTION RADIOACTIVE MATERIALS*” sign, except for rooms or other areas in hospitals that are occupied by patients which are not required to be posted with caution signs provided that the patient could be released from confinement pursuant to 10 CFR 35.75.
2. Areas, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates, must be posted with a “CAUTION, RADIATION AREA” sign.
3. Pennsylvania or New Jersey Department of Environmental Protection Form “*Notice to Employees*” should be posted in the Nuclear Medicine department.

B. Labeling Requirements (10 CFR 20.1904, 35.69)

1. All RAM containers must be labeled with a “Caution, Radioactive Materials” label.
2. Radiopharmaceutical vials, syringes, must be conspicuously labeled to identify the radioactive drug. Syringe and vial shields must also be labeled unless the label on the syringe or vial is visible when shielded.

11. External Exposure Control

- A. Vial shields must be used whenever handling vials of RAM.
- B. Appropriate syringe shields (gamma, beta, PET) should be used unless use is contraindicated.
- C. RAM, storage containers, waste containers, and sealed sources must be shielded to keep exposure levels below trigger levels stated on the daily area monitoring list.
- D. To minimize exposure, maximize distance from exposure sources. From point sources, the exposure rate is proportional to the square of the distance from the source.
- E. To minimize exposure, minimize time spent in proximity to the source.

12. Personnel Contamination Control and Monitoring

A. Contamination Control

1. Clothing to prevent personnel contamination must be worn when in the department near sources of RAM, such as in the hot lab or around patients being administered activity. This includes a lab coat, long pants, and closed toed shoes. Shorts, skirts, and sandals are not permitted.
2. A lab coat and disposable gloves must always be worn when handling RAM. Disposable sleeves can also help reduce the risk of skin contamination. Face protection, such as an L-block, should be used as needed.
3. Eating, drinking, storing food, smoking, or applying cosmetics are prohibited in any area where RAM is used or stored.

B. Monitoring

1. Hands, shoes, and clothing should be monitored for contamination throughout the day (especially when exiting the Hot Lab) and before leaving the department.
2. In the event of personnel contamination, immediately wash with soap and lukewarm water and contact EHRS. Record contamination readings.

13. Facility Contamination Control and Monitoring

A. Contamination Control

1. The dosage preparation areas in the hot labs should be lined with absorbent pads. Preparation areas and areas adjacent to them should be assumed to be contaminated unless they have been surveyed and found to be free of contamination.
2. Contamination precautions such as absorbent pads should be placed on surfaces beneath administration sites.
3. Special care should be paid to administrations for patients on treadmills, as patients sometimes unexpectedly move as the administration is attempted.

B. Monitoring (10 CFR 35.70, 35.2070, 20.1501)

1. All licensed areas where RAM has been used should be surveyed at the end of each day for contamination and ambient exposure rates. Areas used only for storage should be surveyed at the end of each day for ambient exposure rates. Rooms in which material was administered under a written directive must be surveyed.
 - a. Trigger levels are listed in mR/hr in the hot lab computer or on paper logs. Departmental trigger levels will not exceed 5 mR/hr in the Hot Lab and 0.05 mR/hr in all other areas.

- b. A pancake probe may be used to simultaneously survey for both contamination and exposure rates, if the survey results are recorded in mR/hr. If an exposure rate exceeds a trigger level, resurvey with an ionization chamber to obtain a more accurate reading.
2. The floor of the hot lab must be wipe tested weekly if the background is routinely elevated. Trigger levels are listed in DPM in the hot lab computer or on paper logs.
3. If any results exceed the trigger level:
 - a. Decontaminate and resurvey until the measurement is below the trigger level.
 - b. If levels cannot be reduced below the trigger level, notify EHRS.
 - c. Document the initial and final survey results and explanatory notes.
4. All survey results should be recorded in the hot lab computer or on paper logs when the survey is finished.

Survey records must include the following:

- a. the date of the survey
- b. the survey results
- c. the survey instrument used
- d. the name of the individual who performed the survey

14. Inventory and Leak Testing of Sealed Sources (10 CFR 35.67)

- A. Notify EHRS before ordering sealed sources. EHRS must be notified before sealed sources are disposed or transferred from the department. New sources will be leak tested by manufacturer or EHRS before first use.
- B. Inventory and leak testing of sealed sources will be performed at least semi-annually by EHRS. Procedures for performing inventory and leak testing, along with results, are available at EHRS.

PART VI: ASSAY AND ADMINISTRATION OF RADIOPHARMACEUTICALS

15. Pregnant or Breast-Feeding Patient Policy

Female patients of childbearing age should be screened in accordance with the Nuclear Medicine Department's policies to determine if they are pregnant or breastfeeding and treated accordingly.

16. Generators (10 CFR 35.204, 35.2204, 35.3204)

- A. Generators must pass all established QC tests each day of use before generator-produced dosages may be administered to patients.
- B. Elutions from generators must be tested before the first use of the day to ensure they do not exceed established limits. Immediately notify EHRS if an elution exceeds limit.

Elutions exceeding the following limits may not be administered:

- Rb-82: 0.01 μCi Sr-82/mCi Rb-82, 0.1 μCi Sr-85/mCi Rb-82
- C. All values from QC measurements must be recorded in units of $\mu\text{Ci}/\text{mCi}$, along with the date and time of the measurements and the name of the individual performing the test.
- D. Within 7 days after discovery that the elution exceeded limits (0.02 μCi Sr-82/mCi Rb-82, 0.2 μCi Sr-85/mCi Rb-82), EHRS will notify the PA DEP and the generator distributor. Within 30 days, EHRS will submit a written report to the PA DEP.

17. Determination and Administration of Dosages (10 CFR 35.63, 35.2063)

- A. Prior to administration of the dosage, the Nuclear Medicine technologist should verify the patient's identity.
- B. The activity of all dosages must be determined and recorded before administration. Unless specific approval is given prior to the administration by an Authorized User who is approved for that type of administration, a dosage may not be administered if:
 - it falls out of the prescribed dosage range, **or**
 - it differs by more than 20% from the prescribed dosage.

This approval should be documented in the administration records.

- C. Refer to the department's clinical procedures manual for specific information concerning studies. All administrations must be in accordance with the department's clinical procedures manual.
- D. Dosage determination - photon emitters
 - 1. For most dosages, the activity is determined by direct measurement in the dose calibrator.
 - For most radiopharmaceuticals, use the preset button or manufacturer potentiometer setting.

- For some radiopharmaceuticals, a special potentiometer setting may be posted at or programmed into the dose calibrator.
2. Dosages may also be determined by:
 - a combination of measurement of radioactivity and calculations, or
 - a combination of volumetric measurements and calculations based on the measurement of a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements.
- E. Dosage determination – alpha and beta emitters
1. Alpha and beta emitting dosages may not be measured in the dose calibrator unless a special potentiometer setting is established and posted at or programmed into the dose calibrator.
 2. If an alpha or beta emitter arrives as a unit dosage, the activity may be determined by:
 - a decay correction of the activity or activity concentration determined by either a manufacturer or preparer licensed under 10 CFR 32.72 or Agreement State requirements (or an NRC or Agreement State licensee for use in research in accordance with a RDRC-approved protocol or an IND protocol accepted by the FDA).

A unit dosage is a dosage that is prepared by the manufacturer as a single dosage to a patient or human research subject without any further manipulation after it is initially prepared.
 3. Alpha and beta emitting dosages may also be determined as explained in #2 under photon emitters.
- F. Records of all dosage administrations must include the following (10 CFR 35.2063):
- Radiopharmaceutical
 - patient's or human research subject's name or ID number, if assigned
 - prescribed dosage (activity)
 - determined dosage (activity)
 - date and time of the dosage determination
 - name of person who determined the dosage

18. Procedures for Administrations Requiring a Written Directive (10 CFR 35.40, 35.41)

- A. Prior to administration of the dosage, a written directive must be completed, and signed and dated by an Authorized User, who is approved for that type of therapy, for the following procedures:
 - Any therapeutic procedure
 - I-131 sodium iodide in quantities greater than 30 microCuries (μCi)
- B. The written directive must include the following information (10 CFR 35.40(b)):

- Patient's or human research subject's name
 - Radiopharmaceutical
 - Route of administration
 - Dosage (activity)
 - Dated signature of the Authorized User
- C. Prior to administration of the dosage, the administering Nuclear Medicine technologist or Authorized User must verify all aspects of the administration are in accordance with the completed written directive.
1. Verify the patient's identity.
 2. After determining the dosage, directly verify with an Authorized User that the dosage, radiopharmaceutical, and route of administration are in accordance with the written directive.
 3. If there are any questions concerning either the written directive or the procedure being performed, the procedure must be stopped until all questions are resolved.
- D. Exceptions
1. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user prior to the administration.
 2. If, because of the patient's medical condition, a delay in the order to provide a written directive (or a written revision to an existing written directive), would jeopardize the patient's health, an oral directive (or oral revision to an existing directive) is acceptable provided the following are performed:
 - a. The oral revision is immediately documented, and
 - b. The authorized user must sign and date a revised written directive within 48 hours of the oral revision.
- E. The individual administering the dosage must document the administration in the standard dosage administration records.

19. Therapy Procedures

- A. Notifications
1. For treatments involving EHRS staff, such as inpatient treatments and Y-90 TheraSpheres/SIR-Spheres, notify EHRS by sending an email to the EHRS therapy account (RADIATIONTHERAPY@lists.upenn.edu) as soon as a therapy date is scheduled.
 2. An email must also be sent to notify EHRS of schedule changes and cancellations.

3. Notify EHRS of any unusual situations that are expected during the treatment. Examples include the patient being on a respirator, needing dialysis, and other medical complications.

B. Inpatient Treatments

1. On the day of administration, page the EHRS therapy technician as soon as the time of administration is known.
2. Patients are released from the hospital based on measurements performed by EHRS.
3. Written instructions with actions recommended to maintain doses to other individuals as low as reasonably achievable are provided to the patient or the patient’s parent or guardian.

C. Outpatient Treatments

1. The treatments listed in the table below may be performed on an outpatient basis without prior EHRS approval if the administered activity does not exceed the value listed.

For administered activities that exceed the release limit, EHRS must individually approve the administration prior to the treatment being performed.

For any therapies not included in the table, EHRS must be contacted and give approval, before the treatment may be performed.

Treatment	Release limit (mCi)	Written instructions required (mCi)
I-131 hyperthyroidism	40	7
I-131 NaI/MIBG cancer treatments	175	7
Ra-223 Dichloride Xofigo	65	13
Sm-153 EDTMP	700	140
Lu-177 Lutathera	475	95
Y-90 SIR-Spheres	Not applicable	Not applicable
Y-90 Theraspheres	Not applicable	Not applicable
Y-90 Zevalin	Not applicable	Not applicable
Ac-225 Lintuzimab	Not applicable	Not applicable

2. Written instructions with actions recommended to maintain doses to other individuals as low as reasonably achievable must be provided to the patient or the patient’s parent or guardian if the administered activity exceeds the value listed in the above table. Written instructions may also be provided to patients receiving these treatments when the administered activity does not exceed the listed activities.
3. The referring physician and Authorized User will consult with the patient or patient’s parent or guardian to determine appropriateness of out-patient treatment. If it is determined that the patient is not capable of complying with the written instructions, outpatient treatment will not be performed.

4. The Authorized Users should consider delaying treatment if a patient shows any signs of illness, especially nausea. Following administration, the patient should stay in the department for an enough time to ensure the patient can be released without complications.

20. Medical Events (10 CFR 35.3045)

A. A Medical Event occurs when either 1 or 2 happens:

1. When, except from patient intervention, a patient or human research subject receives a dose:

a. > 5 rem whole body or 50 rem to an organ, tissue, or the skin from administration:

- of the wrong radiopharmaceutical, or
- by the wrong route of administration, or
- of a dosage to the wrong patient, or
- of a dosage delivered by the wrong mode of treatment

b. \geq the dose that would have resulted from the prescribed dosage by 5 rem whole body or 50 rem to an organ, tissue, or the skin **if** the administered dosage is $\geq 20\%$ from prescribed dosage or falls outside the prescribed dosage range.

2. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

- a. 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and
- b. 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

3. An event resulting from patient intervention in which administration results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Medical events reporting

A Physicist at EHRS, not an HP technician, must be immediately notified if there is any problem with administration of a dosage. The physicist in consultation with the authorized user will determine if a medical event has occurred and notify the required personnel.

PART VII: WASTE

21. Waste Disposal (10 CFR 35.92)

A. Non-radioactive waste

1. All items that may be contaminated must be monitored with a pancake probe and the result found to be indistinguishable from background before being put into non-radioactive trash. This includes RAM shipment boxes, gloves, chux, and items in the hot lab.
 2. Contaminated items may be decontaminated and treated as non-radioactive, if monitoring shows that the decontamination was effective.
- B. "Cold Trash" containers
1. All "cold trash" must be monitored with a pancake probe and the result found to be indistinguishable from background before it may be released as non-radioactive.
 2. If the survey level of the trash is greater than the background radiation level, it must be treated as radioactive waste.
- C. Radiation labels must be removed or defaced before being placed into radioactive and non-radioactive waste, unless they are within containers which will be managed as biomedical waste after they have been released from the licensee.
- D. Radioactive waste with half-lives of less than 120 days may be held for decay-in-storage according to the following procedure:
1. Separate waste according to half-life categories.
 2. When the container is full:
 - a. close and mark the container with the isotope, date, and initials of the worker.
 - b. Record the required information in department records.
 - c. Transfer the container to storage area in hot lab.
 3. Store the container for 10 half-lives of the longest-lived isotope in the container or until it meets the criteria listed under item 4.
 4. Prior to disposal as normal trash, each container must be monitored as follows:
 - a. Survey the package in a low-level area with a GM meter.
 - b. Survey all surfaces of each container.
 - c. Discard as normal waste only if the exposure level does not exceed the background level.
 - d. Remove or obliterate any radiation labels before disposal in normal waste.
 - e. Complete all the required information in department records.
- E. All radioactive waste with half-lives greater than 120 days must be transferred to EHRS. Waste with shorter half-lives may also be transferred to EHRS. Transfers should be documented in department records.

PART VIII: SHIPMENTS OF RAM

22. DOT/NRC Requirements

A. Terminology

1. DOT Class and Proper Shipping Name - The DOT has nine classes and hundreds of specific "Proper Shipping Names" for hazardous material shipments. RAM shipments are always Class 7, but there are with several different Proper Shipping Names possible. The Proper Shipping Name includes the UN identification number, such as UN 2910.
2. Package Type - Refers to the activity being shipped. Packages are either Limited Quantity, Type A, or Type B. It is extremely likely that all nuclear medicine packages are Type A or Limited Quantity. Package types are discussed in more detail in section E.
3. Marking - Wording required to be on or in a RAM package (e.g., Type 7A, Radioactive).
4. Labeling - Required to be on Type A and B packages. Labels are White I, Yellow II, or Yellow III.
5. Transport Index (TI) - The dimensionless number equal to the package's exposure rate in mrem/hr at 1 meter, rounded to one decimal place. If the exposure rate does not exceed 0.05 mR/hr, the TI = 0.

B. Exposure Level limits (49 CFR 173.441)

<u>Package label</u>	<u>Exposure rate at surface</u>	<u>Exposure rate at 1 meter</u>
Limited Quantity	≤ 0.5 mrem/hr	0
White I	≤ 0.5 mrem/hr	0
Yellow II	> 0.5 to 50 mrem/hr	≤ 1
Yellow III	> 50 to 200 mrem/hr	≤ 10

C. Contamination Limits (49 CFR 173.443)

Packages may not exceed the following limits of removable contamination:

beta and gamma emitters	7,200 DPM per 300 cm ²
alpha emitters	720 DPM per 300 cm ²

D. Notifications (10 CFR 20.1906 (d))

If a received package is found to have removable contamination or radiation levels in excess of the limits listed in sections [B](#) and [C](#), EHRS, the final delivery carrier, and the PA DEP or NJ DEP must be immediately notified.

E. Types of packages

1. Normal form RAM shipments / Type A Packages
 - a. Definition

Nuclear Medicine RAM shipments are normal form, Type A packages unless they meet the requirements to be shipped as Limited Quantity.

b. Labeling and marking

Type A packages must be labeled with a labeled White I, Yellow II, or Yellow III label on two, opposite sides of the container (not the bottom). The label type is determined by the package's exposure levels, as listed in section B. The blanks on the label must be completed with legible, durable weather resistant printing.

Type A packages must be marked on the outside of the package with the Proper Shipping Name, and "Type A" in letters at least 0.5 inches high. It must also be marked with the package's gross mass in kg if it exceeds 50 kg (110 pounds).

c. Packaging

Containers used for Type A shipments must be DOT certified. Type A packages must pass a rigorous series of tests designed to measure their durability during shipping, such as water spray and crush tests. These tests consider the packaging within the container, such as molded Styrofoam that surrounds generators and syringe pigs.

Typically, the only containers used for Type A shipments from Nuclear Medicine are generator boxes. EHRS must be contacted if there any other Type A shipments to ensure that any container and packaging used for Type A shipments has been DOT certified.

d. Shipping papers

Shipping papers must be completed for all Type A shipments.

2. Limited Quantity (LQ) Shipments (49 CFR 173.421, .422, .425)

a. Definition

Packages may be shipped as an Excepted package, Limited Quantity (LQ) of radioactive material if they meet the exposure level and contamination limits listed in sections [B](#) and [C](#) and contain less than the following quantities:

<u>Isotope</u>	<u>Max. Act. - Liquid form</u> (mCi)	<u>Max. Act. - Solid form</u> (mCi)
Mo-99 (for domestic use)	2.0	20
Tc-99m	11.0	110
I-131	1.9	19
I-123	8.1	81
I-125	8.1	81
In-111	8.1	81
Ga-67	8.1	81
Tl-201	11.0	110
Co-57	27.0	270
Gd-153	N/A	240

b. Exemptions

Limited Quantity packages are excepted from packaging, labeling, shipping paper, and certification requirements of normal form RAM shipments, but must be marked as follows:

- The UN identification number must be marked on the outside of the packaging. It is UN2910 for Limited Quantity Radioactive Materials.
- The outside of the packaging or the inner packaging must be marked "Radioactive".

c. Container requirements

Containers used for Limited Quantity shipments must be able to withstand normal conditions encountered during shipment, such as surviving intact after being dropped from 3 feet. Ammo boxes are acceptable for Limited Quantity shipments.

3. "Non-radioactive shipments"

It is possible for a shipment (i.e. blood sample) to have an activity that is low enough that it may be shipped as non-radioactive. Permission to ship this way must be given by EHRS on a case-by-case basis.

23. Procedure for Receipt of Incoming Packages (10 CFR20.1906)

- A. Put on gloves.
- B. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damaged, stop the procedure and notify EHRS.
- C. Measure the exposure rate at 1 meter and then at the surface. If exposure rates are substantially different from the Transport Index on the shipping label, or exceed the limits listed above, stop and contact EHRS. If possible, use an ion chamber. A pancake probe will over-respond for most isotopes.
- D. Wipe test the outside of the package over an area of 300 cm². If the result is greater than the posted trigger level, contact EHRS. Packages containing only RAM in gaseous form are not required to be wipe tested.
- E. Remove the packing slip.
- F. Open the package according to the manufacturer's instructions, if provided.
- G. Open the inner package and verify that the contents agree with the packing slip.
- H. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
- I. If anything is other than expected, stop and contact EHRS.
- J. Prepare packaging for return as described below. If packaging will not be reused, monitor the packing material and the empty packages for contamination with a survey meter before discarding them.

- a. If contaminated, treat as radioactive waste.
- b. If not contaminated, remove or obliterate the radiation labels before discarding in normal trash.

K. Records

1. Log each package, its contents, and survey results into the hot lab computer.
2. Place associated generator and sealed sources records in the appropriate files. For sealed sources, provide a copy of the sealed source certificate to EHRS.

24. Outgoing Shipments

A. **Nuclear Medicine staff may not ship radioactive materials unless they are current in DOT training for the type of shipment being performed.** A copy of the DOT training certificate is available upon request from EHRS. Otherwise, contact EHRS for shipping.

B. Packages that do not contain syringes or radioactive materials:

1. The package will be shipped as an EMPTY package or Limited Quantity package, depending on the return markings provided by the individual pharmacy for returning the container.
2. Place the empty lead shields in the shipping container.
3. Close and secure the container.
4. Verify there is no likelihood of the external surface of the container having become contaminated since the incoming package survey was performed.
 - a. If there are no indications that contamination is likely a wipe test is not required.
 - b. If there is evidence of possible contamination of the container, such as a spill in the area the container has been in, wipe test the outside of the package over an area of 300 cm². If the result is greater than the limits listed above in 23. C. the package may not be shipped. Contact EHRS.
5. Verify the exposure rate on the external surface of the container does not exceed 0.5 mR/hr.
 - a. If the exposure rate measurement during the incoming package survey did not exceed this limit a survey is not required, unless your department has a procedure to perform this measurement for all returned packages.
 - b. A new exposure rate measurement is required if the measurement during the incoming survey exceeded 0.5 mR/hr. If the package still exceeds 0.5 mR/hr it may not be shipped. Contact EHRS.
6. Flip the pharmacy labels on the outside of the container, so that either the UN2910 Limited Quantity radioactive material markings or UN2908 Empty Package labels are visible on the outside of the container.
7. Place the container in the designated location for the pharmacy to pick it up.

C. Packages that contain spent (used) or unused decayed syringes with radioactive materials:

1. The package will be shipped as a Limited Quantity package.
2. Place the spent (used) or unused decayed syringes in the lead shields in the shipping container.
3. Close and secure the container.
4. Verify the activity does not exceed the limits for a Limited Quantity package (see 23. E. 2). If the package contains more than one isotope, calculate the ratio of the activity divided by the LQ limit for each isotope; the sum of all these ratios must not exceed 1.0. If the limit, or the sum of ratios limit, is exceeded, the package may not be shipped until the contained activity has decayed enough that these limits are not exceeded.
5. Wipe test the outside of the package over an area of 300 cm². If the result is greater than the limits listed above in 23. C. the package may not be shipped. Contact EHRS.
6. Measure the exposure rate on the external surface of the container. If it exceeds 0.5 mR/hr the package may not be shipped. Contact EHRS.
7. Make a record of the package shipment, including the package's wipe test and exposure rate measurements, in the department's records.
8. Flip the pharmacy labels on the outside of the container, so that the UN2910 Limited Quantity radioactive material marking is visible on the outside of the container.
8. Place the container in the designated location for the pharmacy to pick it up.

D. Packages that contain radioactive materials or exposure rates exceeding Limited Quantity limits

1. These packages must be shipped as a Type A package with appropriate labeling. Notify EHRS if any Type A shipments must be made. Only personnel who have received specific training may perform these shipments. A copy of the DOT training certificate must be available upon request. Otherwise, contact EHRS for shipping.
2. Classify the package as either Limited Quantity or one of the three types of labeled package types (White I, Yellow II, or Yellow III), based on the isotope, physical form of the RAM, and activity being shipped.
 - a. Measure and record the exposure rate at 1 m and at the package's surface. If the exposure rate exceeds the limit for the package type, the package must be reclassified.
 - b. Wipe test the outside of the package over an area of 300 cm². If the result is greater than the limits listed above in 23. C. the package may not be shipped. Contact EHRS.
3. Marking and labeling

Prepare the package as appropriate for the shipment type as described above.
4. Records

- a. Record all measurements and information in the hot lab computer.
- b. Complete the shipping paper. A copy must be maintained at Nuclear Medicine.

PART IX: RESEARCH USES OF RAM

25. Human-use and Non-human use Research

A. Human use research

1. Before conducting any research administration of RAM to a human subject, an Institutional Research Board (IRB) protocol must be approved. For more information, see <https://ehrs.upenn.edu/radiation-safety/topics/research/human-research-involving-use-ionizing-radiation>
2. Special training may be necessary for certain research protocols.

B. Non-human use research

Research must take place under a research lab license issued by EHRS. For more information, see <https://ehrs.upenn.edu/radiation-safety/topics/research/radioactive-material-licensing>