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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**

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B. Weekly

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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 (p.2)
- Personnel contamination (p.9) or a positive bioassay result (p.5)
- Instrumentation failing constancy tests or otherwise malfunctioning (p.6)
- Loss of radioactive material (p.8)
- a Molybdenum breakthrough result exceeding the limit (p.11)
- problems with an administration of a patient dosage/Medical Events (p.14)
- Contaminated or damaged RAM shipments (p.18)

3. Spill Response

- A. Notify all persons in the area and limit access to the spill.
- 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 spill 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 federal and state regulations, the University's licenses issued by the Nuclear Regulatory Commission (NRC) and the State of Pennsylvania, as well as good work practices. Regulations and the University's licenses 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 NRC and the State of Pennsylvania provide Notices to Employees with instructions to workers on these matters. These notices are posted in all Nuclear Medicine facilities.
- C. Workers' occupational doses are maintained (see below), and are available for review, at EHRS. 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
- 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

New workers must complete Radiation Safety training before beginning unsupervised work with RAM. Training can be completed on-line at the EHRS website (www.ehrs.upenn.edu).

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

6. ALARA Policy, Occupational Doses, and Personnel Monitoring Policies

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." 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. The following table summarizes ALARA trigger levels, as well as annual occupational dose limits. The ALARA levels are a fraction of the annual dose limits.

Exposure type	Quarterly ALARA trigger (mrem)	Annual Dose limit (mrem)
Whole body	250	5,000
Lens of eye	250	15,000

Extremity	1,875	50,000
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3. Worker doses are summarized in a report that is stored at EHRS. A copy of the report is provided to the Nuclear Medicine department for posting.
4. Worker dose histories are available from EHRS upon request.

C. External Exposure Monitoring Policy

1. All Nuclear Medicine personnel who handle licensed material must wear both whole body and extremity dosimeters and exchange them on a monthly basis.
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 (rings) 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 (ie, finger tip side of the index finger).
3. Dosimeters should be stored in a low background area to prevent inaccurate exposure readings.

D. Internal Exposure Monitoring Policy

1. Bioassays must be performed following handling of > 1 mCi of unsealed iodine or > 30 mCi of iodine in capsule form.
2. Bioassays must be performed according to the procedure posted by the uptake probe.
3. Immediately notify EHRS if a bioassay result exceeds the posted trigger level.
4. Bioassay results should be recorded on the written directive form.

7. Pregnant Worker Policy (10 CFR 20.1003)

A. Declaring pregnancy

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

It is entirely the choice of the worker whether or not to declare a pregnancy. A worker may also choose to rescind her written pregnancy declaration at any time.

If a pregnancy is declared, the NRC and 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 EHRS. 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 NRC/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 measuring 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), use an ionization chamber whenever possible.

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). Measuring an exposure rate from isotopes emitting lower energies (Cs-137 = 662 keV) with a GM meter will result in a reading that is greater than the actual exposure rate.

B. How to use an ionization chamber

1. Each day, before the first use:
 - a. Verify the battery level is ok. Digital ion chambers typically have a Low Battery indicator.
 - b. Check that the check source reading falls within range indicated on the sticker on the meter.
 - c. In a low background area, verify the background level is within normal levels. If not, the meter may be contaminated or malfunctioning and should not be used.
2. If the ion chamber has white dots on the side, they should face the radiation source.
3. Digital ion chambers typically are self-scaling.

C. How to use GM survey meters (eg, pancake probes)

1. Each day, before the first use:
 - a. Verify the battery level is ok.
 - b. Check that the check source reading falls within range indicated on the sticker on the meter.

- c. In a low background area, verify the background level is within normal levels. If not, the meter may be contaminated or malfunctioning and should not be used.
 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 of the contamination that is present)
1. Put on gloves.
 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)
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. Verify the background is < 5 μ Ci. If not, adjust the background to approximately 0 μ Ci.
 - 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. Enter readings in the well computer or log.
2. Notify EHRS if the constancy reading exceeds +/- 5% of the expected value or if the instrument is suspected to not be functioning properly in any way.
 3. EHRS performs annual calibrations of the 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 20.1902-3, 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. NRC form 3, “*Notice to Employees*” and Pennsylvania Department of Environmental Protection Form ER-BRP-3, “*Notice to Employees.*” must 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 and information necessary for workers in the area to take appropriate precautions, such as nuclide, activity, radiation levels, and kind of materials.
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. "Flange syringe shields" should be used for withdrawals of large activities (eg, making kits).

- 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. A lab coat and disposable gloves must be worn at all times when handling RAM. Disposable sleeves can also help reduce the risk of skin contamination.
- 2. 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 and before leaving the department.
- 2. In the event of personnel contamination, immediately wash with soap and luke-warm 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. Absorbent pads should be placed on surfaces being used for injection.
- 3. Contamination precautions, such as lining the floor with absorbent pads, should be used when radioactive drugs are not administered by a syringe (ie, microspheres, non-bolus IV administrations).
- 4. 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 areas where RAM is routinely used or stored must be surveyed at the end of each day for contamination and ambient exposure rates. Rooms used only for waste storage may be surveyed only for exposure rates outside of the room.
 - a. Trigger levels are listed in mR/hr in the hot lab computer and on the "hand written" log.

- 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 hot labs must be wipe tested weekly. Trigger levels are posted at the well counter.
3. If any results exceed the trigger level:
 - a. Decontaminate and resurvey until the measurement is below the trigger level.
 - b. If levels can not 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 when the survey is finished. If there is a problem with the computer, record results on a hand-written log.

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. Control of Airborne Radioactivity

- A. Radioactive gases must only be administered in rooms that have been posted by EHRS as being at negative pressure compared to surrounding rooms and which vent to the atmosphere.
- B. All volatile radiopharmaceuticals and radioactive gases must be stored in the shipper's radiation shield and container in a fume hood until used.
- C. Contact EHRS before using multi-dosage containers. Multi-dosage containers must be stored in a fume hood after drawing the first dosage from it.
- D. Radioactive aerosols and gases must be used with a system designed to minimize the airborne concentrations in the room. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container. Reusable gas collection systems must be checked for proper operation each month.

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

- A. EHRS must be notified before sealed sources are ordered, disposed, or transferred from the department. New sources will be leak tested before being used.
- B. Inventory and leak testing of sealed sources will be performed 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

16. 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 breast feeding, and treated accordingly.

17. Molybdenum Concentration (10 CFR 35.204, 35.2204)

- A. Radiopharmaceuticals containing more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m may not be administered.
- B. Each time the generator is eluted, the Molybdenum concentration must be measured and the following recorded:
 - measured Tc-99m activity in mCi
 - measured Mo-99 activity in μ Ci
 - ratio of the measurements expressed as μ Ci Mo-99 per mCi of Tc-99m
 - date and time of measurement
 - the name of the individual making the measurement
- C. Immediately notify EHRS if a breakthrough ratio exceeds 0.07 μ Ci Mo-99/mCi Tc-99m.

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

- A. Prior to administration of the dosage, the Nuclear Medicine technologist must verify the patient's identity by at least two methods. These may include:
 - asking the patient to state his or her name, social security number, birth date, or address; and
 - checking the patient's ID bracelet, medical insurance card, or hospital ID card.
- B. The activity of all dosages must be determined and recorded before administration. Unless specific approval is given by an Authorized User prior to the 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.
- C. If any dosage is not determined by direct measurement in a dose calibrator (explained below), the decay correction of the manufacturer's activity should be determined by two independent methods: calculation by the hot lab computer, decay chart, use of a hand held calculator, or calculation by two technologists.
- 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 is posted at 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 - beta emitters

1. Beta emitting dosages may not be measured in the dose calibrator unless a special potentiometer setting is posted at the dose calibrator.
2. If a 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. Beta emitting dosages may also be determined as explained in #2 under photon emitters.

F. Records of all dosage administrations must include the following:

- isotope and pharmaceutical
- 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

19. 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 for the following procedures:

- Any therapeutic procedure
- I-131 or I-125 sodium iodide in quantities greater than 30 microcuries

B. The written directive must include the following information:

- Patient's or human research subject's name
- Isotope and pharmaceutical name

- Route of administration
 - Dosage (activity)
 - Dated signature of an Authorized User
- C. Prior to administration of the dosage, the Nuclear Medicine technologist or Authorized User must verify all aspects of the administration are in accordance with the completed written directive.
1. At least two methods must be used to verify the patient's identity. These may include:
 - asking the patient to state his or her name, social security number, birth date, or address; and
 - checking the patient's ID bracelet, medical insurance card, or hospital ID card.
 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.

20. Therapy Procedures

- A. I-131 NaI Therapies
1. In-house patient treatment
 - a. EHRS staff should be notified as far in advance as possible to schedule the room setup.
 - b. Nuclear Medicine staff should page the EHRS therapy technologist as soon as the time of treatment is known.
 2. Out-patient treatment
 - a. Contact EHRS for approval prior to performing out-patient treatments with dosages greater than 175 mCi.

- b. Patients who receive more than 7 mCi of I-131 NaI must receive written directions to help minimize dose to members of the public, including members of his or her family. Directions will be provided by the Authorized User.
 - c. Patients who receive more than 30 mCi are to stay in a private residence, and not in a hotel, for the first two to three days following administration. The referring physician and Authorized User will consult with the patient to determine appropriateness of out-patient treatment.
 - d. If a patient shows any signs of illness, especially which may lead to vomiting, the Authorized User should consider if treatment should be delayed. If treatment is given, the patient should stay in the department for a sufficient time to ensure the patient can be released without complications.
 - e. For treatment of hyperthyroidism, the patient must remain in the department for observation for at least 1/2 hour following administration.
 - f. For dosages greater than 30 mCi, the patient must remain in an isolated room during the administration and for at least 1 hour following administration for observation.
 - g. Exposure rates in unrestricted areas may not exceed 2 mR in an hour. (10 CFR 20.1301)
3. Bioassays must be performed according to the procedure posted by the uptake probe. Record results on the written directive.

B. Microspheres

Specialized training must be completed prior to being authorized to administer microspheres and to act as an Authorized User for microspheres procedures.

C. Other therapies

- 1. Notify EHRS as soon as it is known that an in-patient therapy will be performed. Radiation safety requirements for these patients are addressed on a case by case basis.
- 2. For established therapy protocols, patients may be treated on an out-patient basis with pure beta emitting isotopes such as Sr-89, Sm-153, and Y-90 without prior EHRS approval. New therapy protocols must be approved by EHRS prior to being implemented.

21. 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. 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

Immediately notify EHRS if there is any problem with administration of a dosage. EHRS will determine if a medical event has occurred and notify the required personnel.

PART VII: WASTE

22. 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. These surveys must be documented, and records must include: date, meter used, background reading, waste reading, and name of individual performing survey.
3. 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.
2. When the container is full:
 - a. close it and mark the container with the isotope, exposure rate, date, and initials of the worker.

- b. Record the required information in the decay-in-storage log.
 - 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.
 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 on the decay-in-storage form.
- 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 the decay-in-storage logs.

PART VIII: SHIPMENTS OF RAM

23. 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 (eg, 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>
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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	6,600 DPM per 300 cm ²	(2,200 DPM per 100 cm ²)
alpha emitters	600 DPM per 300 cm ²	(200 DPM per 100 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 NRC 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 take into account 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 Shipments (49 CFR 173.421, .422, .425)

a. Definition

Packages may be shipped as Limited Quantity 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, marking, 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 (ie. 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.

24. 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 than 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. 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.
 - c. Ammo boxes and Generator boxes should be handled for return shipment as described below.
- K. Inventory Records
 - 1. Log each package, it's contents, and survey results into the hot lab computer.
 - 2. Generators must also be logged into the Generator Log.

25. Outgoing Shipments

- A. Nuclear Medicine staff may not ship radioactive materials unless they are current in DOT training. A copy of the DOT training certificate must be available upon request.
- B. Packages that **may be** contaminated or contain contaminated items
 - 1. Survey the package and items to determine if anything is contaminated.
 - 2. If nothing is contaminated and no RAM is contained within the package, the package is not a RAM shipment. Remove the Radiation Label from the side of the box and place it within the box before shipping.
 - 3. If anything is contaminated, use a survey meter and wipe test to determine the isotope and amount of activity and ship as described in B.
- C. Packages that contain RAM or contamination

1. Notify EHRS if any Type A shipments must be made other than generator return shipments.
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 package over 300 cm². If the wipe test result exceeds three times background, the packaging should be treated as radioactive and not used for shipment and the RAM should be repackaged.
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 appropriate log.
 - b. Complete the shipping paper. A copy must be maintained at Nuclear Medicine.

PART IX: RESEARCH USES OF RAM

26. 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. See <http://www.ehrs.upenn.edu/protocols/radiohuman.html> for more information.
2. Protocols will be licensed under the nuclear medicine department, not the individual physician.
3. Special training may be necessary for certain research protocols.

B. Non-human use research

Research must take place under a research license issued by EHRS. For more information, see the Radiation Safety link on the EHRS web site.