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

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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 constancy and functionality checks
   - Package receipt records
   - Generator QC Tests
   - Personnel surveys
   - Room/waste storage areas surveys for contamination/ambient exposure rates

   B. Weekly
   - Wipe test of hot lab floors

   C. Monthly
   - Xenon trap test

   D. 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
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 (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 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

   New workers must complete Radiation Safety training before beginning unsupervised work with RAM. Training can be completed online at the EHRS website (http://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 online training on the EHRS website.

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 posted on the EHRS website under our personnel monitoring policy at http://www.ehrs.upenn.edu/programs/radiation/rad_policies.html.

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. Worker doses are summarized in a report that is stored at EHRS. A copy of the report is provided to the Nuclear Medicine or Radiology department.

3. Worker dose histories are available from EHRS upon request.

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., 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. Perform a baseline bioassay before the first time a worker handles activity requiring a bioassay.

2. For all Nuclear Medicine departments besides HUP:
   A thyroid bioassay will be performed 7 – 72 hours after handling of > 33 mCi of Iodine:
   • 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
3. Bioassays must be performed according to the bioassay procedure established in the department.

4. **EHRS must be immediately notified** if a bioassay result exceeds the posted trigger level.

5. 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 (EHRS) in writing of her pregnancy and estimated date of conception. This typically occurs during a counseling session with an EHRS physicist.

      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 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 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). Measuring an exposure rate from isotopes emitting lower energies (Cs-137 = 662 keV) 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 level is ok. Digital ion chambers typically have a Low Battery indicator.
   b. Verify the background level is within normal levels. If not, the meter may be contaminated or malfunctioning and should not be used.
   c. Check that the check source reading falls within the range indicated on the calibration sticker on the meter.

2. The front of the ion chamber should face the radiation source.

3. Digital ion chambers typically are self-scaling.

C. How to use GM survey meters (e.g., 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.
   c. Check that the check source reading falls within the range indicated on the calibration sticker on the meter.

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 cm\(^2\).
   - For area surveys, results should be per 100 cm\(^2\).

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. 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. 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.

G. EHRS performs annual calibrations of all these instruments.

PART V: CONTROL OF RAM, EXPOSURE, AND CONTAMINATION

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. 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 (i.e., 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. 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 be worn at all times 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 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. 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 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 or on paper logs.

   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 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 or on paper logs when the survey is finished. If there is a problem with the electronic records, record results on a handwritten 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. All volatile radiopharmaceuticals and radioactive gases should be stored in the shipper’s radiation shield and container in a fume hood until used.

B. Multi-dosage gas containers must be stored in a fume hood after drawing the first dosage from it.

C. 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 or before each use.

15. 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 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 breastfeeding, and treated accordingly.
17. Generators (10 CFR 35.204)

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 a limit.

**Elutions exceeding the following limits may not be administered:**

- Rb-82: 0.01 uCi Sr-82/mCi Rb-82, 0.1 uCi Sr-85/mCi Rb-82
- Mo-99: 0.15 uCi Mo-99/mCi Tc-99m

C. All values from QC measurements must be recorded, along with the date, time, and the name of the individual performing the test.

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/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. 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 is 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

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 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 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/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 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 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 33 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. 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 department’s established procedure. Record results on or with 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. In-house patient treatment

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. Out-patient treatment

If established in approved protocols, (i.e. Sr-89, Sm-153), patients may be treated on an out-patient basis without prior EHRS approval. If not, contact EHRS for approval of patient release as soon as possible prior to the date of treatment.

3. 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 \({\text{if the administered dosage is}} \geq 20\% \) 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

A Health Physicist at EHRS, not an HP technologist, must be immediately notified 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 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 (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)

<table>
<thead>
<tr>
<th>Package label</th>
<th>Exposure rate at surface</th>
<th>Exposure rate at 1 meter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited Quantity</td>
<td>≤ 0.5 mrem/hr</td>
<td>0</td>
</tr>
<tr>
<td>White I</td>
<td>≤ 0.5 mrem/hr</td>
<td>0</td>
</tr>
<tr>
<td>Yellow II</td>
<td>&gt; 0.5 to 50 mrem/hr</td>
<td>≤ 1</td>
</tr>
<tr>
<td>Yellow III</td>
<td>&gt; 50 to 200 mrem/hr</td>
<td>≤ 10</td>
</tr>
</tbody>
</table>

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 cm²
- alpha emitters: 660 DPM per 300 cm²

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 are 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:

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

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 (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.

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 cm$^2$. 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. Records

   1. Log each package, its 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. Otherwise contact EHRS for shipping.

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 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 C.

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/programs/radiation/rdrc/ for more information.

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 http://www.ehrs.upenn.edu/programs/radiation/licensing/.