

Radiopharmaceuticals – Handling and Packaging

Introduction to Radiopharmaceuticals

What are Radiopharmaceuticals?

- Radiopharmaceuticals are a group of medicinal formulations that contain radioactive isotopes (also called radionuclides).
- These compounds are used for diagnosis or therapy.
- They are unique in that they emit ionizing radiation, which can be detected externally (as in imaging) or used to destroy diseased tissues (as in cancer treatment).

Classification of Radiopharmaceuticals:

1. Diagnostic Radiopharmaceuticals:

- Used for imaging organs, tissues, or physiological functions.
- **Examples:** Technetium-99m (Tc-99m), Fluorine-18 (F-18), Iodine-123 (I-123)

2. Therapeutic Radiopharmaceuticals:

- Used for treatment, usually by delivering radiation directly to diseased tissues (e.g., tumors).
- **Examples:** Iodine-131 (I-131), Lutetium-177 (Lu-177), Yttrium-90 (Y-90)

Importance of Handling Radiopharmaceuticals in Hospital Pharmacy

- **Handling radiopharmaceuticals involves stringent protocols to ensure:**
 - Radiation safety for healthcare workers and patients.
 - Sterility and purity of the product.
 - Proper dosage and accurate labeling.
 - Waste disposal of radioactive materials.
- Hospital pharmacies that deal with radiopharmaceuticals often have a nuclear pharmacy unit or work closely with a radio pharmacy department.
- These departments are equipped and licensed to handle radioactive materials.

Handling of Radiopharmaceuticals

- Because radiopharmaceuticals emit ionizing radiation, they must be handled under strict **radiation protection guidelines** to protect:
 - Healthcare workers
 - Patients

- The environment

Handling radiopharmaceuticals involves several critical processes:

A. Receipt and Storage

- Upon arrival, radiopharmaceuticals are received in lead-shielded containers to minimize radiation exposure.
- The consignment is checked against the purchase order and radiation safety documents.
- Radiopharmaceuticals must be stored in designated areas, typically shielded refrigerators or lead-lined cabinets, depending on whether the radionuclide requires refrigeration and its half-life.
- Proper records of receipt, activity level, and batch number are maintained.

B. Radiation Safety Measures

- Hospital pharmacies must follow ALARA principles – "As Low As Reasonably Achievable" – to minimize radiation exposure.
- Use of Personal Protective Equipment (PPE): lead aprons, thyroid shields, leaded gloves.
- Radiation monitoring devices: staff are equipped with dosimeters (film badges, TLDs) to measure exposure.
- Shielding: Use of lead shields, syringe shields, vial shields, and remote handling tools.
- **Time, Distance, and Shielding principles:**
 - Minimize time spent near radioactive material.
 - Maximize distance from the source.
 - Use appropriate shielding materials.

C. Aseptic Handling

- Radiopharmaceuticals are mostly administered parenterally, hence must be sterile.
- Compounding and dispensing are done under laminar airflow hoods or isolators in a clean room classified as Class 100 (ISO 5).
- Strict aseptic techniques are used to avoid contamination.

D. Compounding and Dose Preparation

- The radioactive drug is typically combined with a ligand or pharmaceutical component (e.g., a carrier or targeting molecule).
- **Precise dosing is critical. Dosimetry calculations consider:**
 - Half-life of the radionuclide.
 - Time of administration.

- Decay corrections.
- Doses are drawn using shielded syringes or vials.
- Doses are verified using a dose calibrator (a specialized ionization chamber).

E. Labeling and Documentation

- **Radiopharmaceuticals must be clearly labeled with:**
 - Name of the compound.
 - Radioactive isotope.
 - Activity (in MBq or mCi) and date/time of calibration.
 - Expiry date/time (based on the half-life).
 - Route of administration.
- Documentation is crucial for tracking, accountability, and compliance.
- Records must comply with regulatory authorities such as:
 - Atomic Energy Regulatory Board (AERB – India).
 - Nuclear Regulatory Commission (NRC – USA).
 - European Medicines Agency (EMA – Europe).

Packaging of Radiopharmaceuticals

- Packaging is governed by radiation safety, transportation regulations, and pharmaceutical standards.
- It ensures the product remains stable, safe, and identifiable throughout its lifecycle.

Objectives of Packaging

- Protect handlers and public from radiation exposure.
- Prevent contamination or leakage.
- Ensure identification and traceability of the radioactive material.
- Comply with legal transport and labeling requirements.

Packaging Levels

Radiopharmaceuticals are packaged in **three layers** as per IAEA and WHO guidelines:

1. Primary Container (Primary Shielded Vial)

- Usually a glass vial containing the radioactive drug.
- Sealed with a rubber stopper and aluminum cap.
- Placed inside a lead or tungsten shielded container (called a pig).

2. Secondary Container

- The pig is then placed inside a shock-absorbent, sealed container, often made of plastic or metal.
- **May contain:**
 - Absorbent materials
 - Coolant (if temperature-sensitive)

3. Tertiary Container (Transport Package)

- The outermost layer used for transport.
- **Must be:**
 - Tamper-proof
 - Labeled with radiation warning signs
 - Compliant with UN transport codes (e.g., UN 2915 for Type A packages)

Types of Packaging Based on Activity Level

Depending on the **activity level** of the radioactive material, packaging is classified into:

1. Excepted Packages

- For very low levels of radioactivity.
- Minimal packaging, used for certain diagnostic agents.

2. Type A Packages

- For moderate levels of radiation.
- Must pass drop, compression, and water spray tests.

3. Type B Packages

- For high levels of radioactive materials (mainly used in therapy).
- Heavily shielded; must withstand severe accident conditions.

Labeling Requirements

- **Each package must have clearly visible labels including:**
 - Radiation symbol (trefoil)
 - “RADIOACTIVE” wording and classification (I, II, or III based on dose rate)
 - **UN number** (e.g., UN 2915)
 - Name of radionuclide (e.g., Tc-99m)
 - Activity level in Becquerels or Curies
 - Date and time of calibration



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