IREDELL MEMORIAL HOSPITAL

MOLECULAR IMAGING

Preparation and Handling Standard Operating Policy

Origination Date:	12/2025	**Approvals:**	**Department of Radiology** **Radiation Safety Committee** **P&T Committee**
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PURPOSE:

To ensure compounded radiopharmaceuticals and non-radioactive adjunctive Nuclear Medicine products used at our facility are prepared in accordance with accepted and proven guidelines established by the USP. Following these guidelines helps to ensure the quality and safety of the products we compound and use. These are responsibilities of the nuclear medicine technologists.

POLICY:

The Molecular Imaging Department at Iredell Memorial Hospital will use and compound radiopharmaceuticals and adjunctive drugs used in Nuclear Medicine in accordance with guidelines set forth by the United States Pharamceopeial Convention (USP). The USP chapters directly applicable to functions within Nuclear Medicine are USP 825, USP 797 and USP 795. This policy applies to all following pages and categories of use within Nuclear Medicine.

As approved by the Radiation Safety Officer, minimal compounding performed within Nuclear Medicine shall be performed by a nuclear medicine technologist under the supervision of an authorized user on the RAM License, and limited to the following:

1. Reconstituting “COLD” PYP vial with 3mL of Normal Saline for use in the “in vivo” tagging in red blood cell studies. (USP 797)
2. Reconstituting Kinevac vial with 5mL of Sterile Water for use in Gallbladder EF studies.(USP 797)
3. Reconstituting “ULTRATAG” RBC kits with the required components, 5mL of whole patient heparinized blood, syringe 1 & syringe 2 included in the kit, and the prescribed dose of 99mTc Pertechnetate. (USP 825) Kit to be compounded per manufacturer instructions.
4. Applies to all radiopharmaceutical processing activities.
5. DOES NOT APPLY to the administration of radiopharmaceuticals to patients.
6. DOES APPLY to any further processing and manipulation of the drug product after release.
7. Radiation regulatory agencies require limiting radiation exposure to personnel, which necessitates special provisions. Thus, it is necessary to balance aseptic handling practices (Patient Safety) with radiation protection practices (Worker Safety).
8. Access to the “Hot Lab” is restricted to trained personnel with specific responsibilities.

DEFINITIONS:

1. USP - The United States Pharmacopeia is a non-profit organization that establishes standards and guidelines to ensure the safety of medications used.

2. Immediate Use - Items compounded that meet several conditions and are not subject to the requirements of Category 1, 2 or 3 compounding. Compounding Immediate Use products does not require primary or secondary engineering controls (SEC).
   See Immediate Use Process in this Policy.
3. BUD - Beyond use Date. The date or hour and the date, after which a product must not be used, stored or transported.
4. 70% IPA - 70% Isopropyl Alcohol - Alcohol Wipes - Hand Sanitizer
5. Critical Site - A location that includes any component or fluid pathway surfaces or openings exposed and at risk of direct contact with air, moisture or touch contamination. Ex. vial septum, syringe tip, needle hub, and needle.
6. Preparation with minor deviations - "Deviation from the specified processes or methods of compounding, although not from the ingredients or proportions thereof, may occur provided that the finished preparation conforms to the relevant standards and to preparations produced by following the specified process."

PROCESS:
Preparation, Compounding, Dispensing and Repackaging:

Radiation Safety Considerations – Shall be followed by personnel during all radiopharmaceutical processing activities.

- ALARA - As Low As Reasonably Achievable
- Practice time, distance and shielding
- Minimize radioactive contaminations
- Wear dosimeter badges

Radiopharmaceuticals

- Shall be handled in a manner to avoid contaminating critical sites.
- Each critical site shall be cleaned with 70% IPA swabs prior to accessing.
- If vial shield top is closed, then septum must be disinfected again with 70% IPA.
- If septum is recessed in the vial shield, right angle forceps shall be used to hold a 70% IPA wipe to make contact with the septum for disinfecting.

Immediate Use of Sterile Radiopharmaceuticals

- Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient
- Preparations components must be sterile, conventionally manufactured drug products
- Manipulations of unit doses (i.e. decreasing the dosage, needle changes) or dispensing for one patient (i.e. withdrawing a dose) is allowed
- Must be administered within 1 hour of the first container puncture or exposure of any critical site involved to ambient air, whichever is first
- All components involved must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first
- Adding saline – You can add saline to unit doses and/or vials as long as you follow guidelines for immediate use.
- DOSE POOLING (combining doses from two or more syringes to meet one patient's need) may be performed as immediate use. Any residual activity that remains must be immediately discarded and not utilized for any other patient

- Prior to initiating compounding, hand hygiene shall be performed as outline in section on Hand Hygiene.
- Labeling of product shall be performed with requirements listed in this policy.
- A designated area for sterile preparation and/or dispensing must be functionally separate from non-sterile compounding area (radiolabeling food) during time of use
- As per this policy and USP 825, immediate use DOES NOT require a segregated radiopharmaceutical processing area (SRPA), classified area, or other secondary control environment
- Number of steps or punctures is NOT LIMITED for immediate use.
- Compounding with a non-radioactive, sterile and commercially manufactured pharmaceutical (i.e. lidocaine) to unit dose IS ALLOWED for immediate use purposes as per requirements above.
- DOSE SPLITTING (splitting a unit dose for administration to more than one patient) MAY NOT be performed due to IMH not meeting the practices required.

Hand Hygiene and Garbing for Immediate Use Preparations

- Radiopharmaceuticals may be prepared and dispensed as immediate use, and the precautions related to personal hygiene to be followed must include the following:
- Secure hair back and apply hair covering, remove jewelry.

HAND HYGIENE - Wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub (teaspoon amount) until dry (approximately 10seconds), rubbing wrist for 30 seconds and between fingers.

GARBING - Immediately after hand hygiene, don a clean disposable gown that has not been exposed to a patient or patient care area, don sterile gloves or non-sterile gloves disinfected with 70% IPA. The gown used for preparation must be different than the gown worn for patient care. New PPE must be re-applied for each additional compound.

When performing the nonsterile radiopharmaceutical tagging of a gastric meal, the technologist should perform hand hygiene, don gown and gloves, but also don a hair covering.

Preparation of Radiolabeled Blood Components (WBCs)

- Due to the potential presence of microorganisms in the original blood sample, the preparation must be administered as soon as possible but no later than 6 hours after the blood sample is obtained from the patient
- Designated area for assaying of WBCs must be established and restricted for that use only.
- Designated area, equipment and supplies shall never be shared with other activities unless thoroughly cleaned and disinfected prior to and after assay of WBC dose.
- Use the designated blood product dipper and liner and the disposable sleeves to assay the dose or vial.

Radiolabeled Red Blood Cells for Immediate Use

Must be prepared with the following requirements (in addition to the above):

- A dedicated space for blood handling must be designated throughout the entirety of the blood radiolabeling process. This area must be free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection.
- Perform only one radiolabeling procedure at a time.
- Dedicated equipment must be used for blood radiolabeling procedure (L Block, syringe shield, vial shield, forceps, needle recapper). Use the designated blood product dipper and liner or the disposable sleeves to assay the dose.

- Cleaning and disinfecting with 70%IPA must be performed to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded.

Compounding Nonsterile Radiopharmaceuticals

- Compounding a non-sterile radiopharmaceutical is defined as combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a non-sterile radiopharmaceutical.
- Non-sterile radiopharmaceutical compounded include, but not limited to, radiolabeling of food (i.e. gastric emptying studies, changing and IV dose to an oral dosage form with the 99mTc Sulfur Colloid.
- Areas designated for nonsterile compounding must be free of clutter and separated from sterile radiopharmaceutical compounding area.
- Each compound, with minor deviations, must have a unique MFR (Master Formulation Record). An MFR compounding record must be maintained and include the following components:
  - Name of the radiopharmaceutical
  - Physical form (e.g., capsule or solution)
  - Name and quantity of ingredients including calibration time for radioactive ingredients
  - Total volume
  - Reference to the MFR
  - Any deviation from the MFR, if applicable
  - Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components
  - Name of the person who prepared and name of the supervising personnel (e.g., ANP or AU physician)
  - Date and time of preparation
  - Assigned internal identification number (e.g., lot number)
  - Unique reference [e.g., prescription, order number(s)]
  - Assigned BUD and storage requirements
  - Documentation of QC results

1. DEDIATED WORK AREA - When mixing radiolabeled meals for gastric exams, the area should not be used for other compounding or administration purposes until nonsterile compounding is complete and the area is cleaned and disinfected.
2. DON APPROPRIATE PPE - When performing the nonsterile radiopharmaceutical tagging of the gastric meal, the technologist should perform hand hygiene, don gown and gloves, but also don a hair covering.
3. MEAL TEMPERATURE - The meal should be checked for appropriate temperature of 165degrees with the digital food thermometer. (Not applicable to liquid meals) – Verified in Cafeteria, as we receive our eggs ready made from them.
4. CLEANING/DISINFECTING - The dedicated work area including the MICROWAVE, LBlock, dose calibrator, dose calibrator dipper/liner, forceps, etc. should be cleaned prior to and after nonsterile radioactive meal preparation.

Labeling

Each product must be labeled with the following:

INNER CONTAINER LABELING - (SYRINGES AND VIALS)

- Standard Radiation Symbol
-Words "Caution-Radioactive Material"
-For therapeutic and blood-products, the patient name/identifier
-Radionuclide and chemical form (generic name)
-Radioactivity at the date and time of calibration

OUTER CONTAINER LABELING - (SYRINGE SHIELDS AND VIAL SHIELDS) - Standard Radiation Symbol
-Words "Caution-Radioactive Material"
-For therapeutic and blood-products, the patient name/identifier
-Radionuclide and chemical form (generic name)
-Radioactivity at the date and time of calibration
-Volume or number of units dispensed (i.e. 2 capsules)
-Product expiration or BUD
-Special storage and handling instructions for non-immediate use (N/A to our depts.) -Route of Administration

KEY POINTS:

- DEDICATED AREA - For the mixing of the sulfur colloid meal for gastrics, the mixing of radiolabeled RBCs , and the assay of radiolabeled WBCs, you MUST HAVE a dedicated/ designated area used only for that purpose during the entirety of the process. Since we do not have separate dose calibrators and work areas for those processes, we will use the routine hot lab areas. When performing a dedicated/designated area task, i.e. gastric meal mixing, WBC assay, or RBC preparation, perform the steps for designated area below:
  -Hang the Designated Area Sign on the hot lab door
  -Clean the area, including dose calibrator, L Block, microwave, etc.
  -Cover the work area with absorbent paper
  -Use the dipper and chamber sleeve designated for blood products if doing WBC or RBC
  -Perform the task to completion and do not use the area for anything else during the task
  -Clean and disinfect the area, including the dose calibrator, L Block, syringe shields, microwave, etc.
  -Replace the absorbent paper with clean paper
- Environmental Controls & Monitoring – A thermometer with a standard calibration source and the ability to continuous monitor the environment and log deviations must be used in the hot lab refrigerator used for radiopharmaceutical storage when required. Temperature devices must be verified annually. Excursions must be documented with corrective actions.
- Designated Person(s) (DP) – Should be identified and supported by Department of Radiology Leadership and Radiation Safety Officer. DP shall be responsible and accountable for the performance of operation of the facility and personnel in the preparation and handling of radiopharmaceuticals and for performing functions as described in this SOP.
- Training and Personnel Qualifications – Personnel must be trained to work with radiopharmaceuticals. Personnel must demonstrate competency initially and annually thereafter. Competency per Immediate Use Preparation Policy shall be adhered to.
- Quality Control/Quality Assurance Program – The QA program is intended to provide mechanism for monitoring, evaluating, correcting and improving activities and processes involved in radiopharmaceutical preparation. Focus is placed on maintaining and improving the quality of systems and the provision of patient care. If problems are identified, a plan of action will include appropriate follow-up to make certain that effective corrective actions were performed. Elements of Quality Control include a description of specific training and adherence to policy, as well as equipment maintenance, detailed in the Molecular Imaging Policy and Procedure Manual.
- Cleaning and Disinfecting – The purpose of cleaning involves organic and inorganic residues from surfaces. Designated areas and equipment and supplies shall be cleaned and disinfected at a minimum daily and

recorded as such in the Nuclear Medicine tracking system. The surfaces, equipment and supplies are to be cleaned with 70% IPA and allow a dwell time of 1minute. All cleaning supplies must be low-lint and disposable. Reusable cleaning tools must be made of cleanable materials and must be cleaned and disinfected before and after each use.

- Spills – See Spills Policy in the Molecular Imaging Policy and Procedure Manual.
- Documentation – Applicable records must be maintained for all activities involved in preparing, compounding and dispensing radiopharmaceuticals.
- Patient Monitoring and AER – The pharmacy department and the Department of Radiology in conjunction with P&T Committee maintains a reporting program for significant ADR at IMH. Reports of AE and errors with radiopharmaceuticals will be reviewed by the P&T Committee and reported to FDA and USP as appropriate.

EXHIBITS:

USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging
USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations
USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations