

<b>Name of Policy:</b>	<u>USP 797 &amp; USP 825</u>	
<b>Policy Number:</b>	3364-135-125	
<b>Department:</b>	Radiology	
<b>Approving Officer:</b>	Chief Operating Officer - UTMC	
<b>Responsible Agent:</b>	Chairman & Professor, Radiology	
<b>Scope:</b>	Radiology	
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Minor/technical revision of existing policy		<b>Effective Date:</b> 6/1/2023 Initial Effective Date: 7/31/2008
<input checked="" type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy		

**(A) Policy Statement**

It is the objective of the Nuclear Medicine Department that all Technologists familiarize themselves, and comply with, applicable standards contained in USP 797 and USP 825.

**(B) Purpose of Policy**

To comply with USP standards for aseptic control and maintaining the sterility of medications prepared in the department and radiopharmaceutical (RP) unit doses supplied by contracted radiopharmacies. Proper housekeeping, personal hygiene, and garbing will be enforced to reduce the risk of microbial contamination and to maintain the cleanest environment possible to prepare these medications for administration, while minimizing the risk of radioactive material (RAM) contamination and radiation exposure.

**(C) Procedure**

The hot labs (rooms 1230 in the UTMC main hospital and 1070 D in the Dana Cancer Center) are designated areas for the preparation of medications and RPs for immediate use. These restricted areas are limited to personnel traffic, are to be clean, free of clutter, and functionally separate from patient care areas. All medication and RP preparation will be conducted in the designated preparation areas.

**1. Preparation of Radiolabeled Red Blood Cells (RBCs) for Immediate Use**

Staff will adhere to the departmental procedure standards for the preparation and administration of radiolabeled blood products to patients. These standards maintain the sterility of the products and ensure safety measures are implemented to mitigate the risk of administering blood products to the wrong patient, or mixing blood products with other sterile preparations.

Instructions for the cleaning, disinfecting, and proper RBC labeling are posted in the hot lab for reference.

**2. Beyond Use Dates (BUD)**

For immediate use preparations, the BUD will be one (1) hour from the time a vial is first punctured, or a syringe/needle/hub is exposed to ambient room air.

Unless otherwise authorized by Pharmacy, prepared adjunct medications must be labeled with the date/time of preparation and used within one (1) hour after first puncture.

All vial tops must be properly disinfected with an alcohol prep pad and allowed to completely dry prior to puncture.

No RP unit dose will be administered past the labeled expiration date/time by the manufacturer.

### **3. Cleaning and Disinfecting**

Appropriate cleaning and disinfection procedures will be completed and documented daily prior to any medication preparation or manipulation. This process involves:

- Cleaning and disinfecting all countertops and “high touch” surfaces.
- Cleaning and disinfecting areas surrounding the L-block, dose calibrator, syringe shields, forceps, and dose trays.
- Dry mopping and wet mopping the floors with disinfectant.
- Placing new absorbent pads behind the L-block and dose trays; visibly soiled pads or pads contaminated with RAM will be replaced immediately.

Cleaning and disinfecting practices will be conducted throughout the workday as needed, and as necessary, such as when alternating between non-sterile and sterile dose preparations.

### **4. Personal hygiene**

Technologists working in the RP processing area must be appropriately garbed and must maintain proper personal hygiene to minimize the risk of contamination to the preparation area and/or prepared products.

Staff with a condition that poses a high risk of microbial contamination (e.g., rashes, sunburns, open sores, recent tattoos, conjunctivitis, or active respiratory infection) must report these conditions to their supervisor to determine if they should be excluded from working in the processing area.

All lab coats are to be clean and not visibly soiled. A clean coat/gown that has not been exposed to a patient or patient care area should be worn during preparation of immediate use products. Separate lab coats/gowns should be worn to care for a patient than one used for RP dose preparation.

Proper handwashing with soap and water up to the wrists, or with a suitable alcohol-based hand sanitizer must be completed prior to and after donning gloves and/or preparing medications.

Nails should be kept clean and neatly trimmed to minimize particle shedding and to avoid glove puncturing; nail products (e.g., artificial nails, polish, and extenders) must not be worn.

Personal items and garments (e.g., bandanas, coats, jackets, sweaters, hats, electronic ear buds, bracelets, hanging jewelry, etc.) must not be worn in the processing area.

