Unit Dose Dispensing
USP <825>

Jubilant Radiopharma. We are in the business of Improving Lives Through Nuclear Medicine™

Putting the safety of your patients and the quality of our radiopharmaceuticals above all else.

The practice standards of USP <825> clearly delineate requirements for single- or multiple-dose containers and for the preparation of sterile radiopharmaceuticals. Familiarity and compliance with these standards is particularly important for nuclear medicine customers who receive vials of multi-dose ("bulk") radiopharmaceutical preparations, or sodium pertechnetate Tc-99m to be used in the dispensing of multiple unit doses or in the preparation of kits intended for administration to multiple patients.

USP standards specify the following: Preparing kits and dispensing unit doses from multi-dose preparations must be done within a USP <825> compliant cleanroom/segregated radiopharmaceutical processing area (SRPA) inside a laminar airflow workbench (LAFW)or Primary Engineering Control(PEC) by appropriately garbed and trained individuals. Unless the institution's cleanroom facility or SRPA fully complies with the standards described above, Jubilant Radiopharma strongly recommends that nuclear medicine departments opt for unitdose radiopharmaceuticals whenever possible.

Unit dose dispensing is commonly considered the best practice in nuclear medicine.

The Centers for Disease Control and Prevention (CDC) and others, including The Joint Commission (TJC) and Institute for Safe Medication Practices (ISMP), encourage the use of single unit doses rather than multi-dose vials whenever possible. This guideline is included as part of CDC's Safe Injections Recommendation, which is designed to mitigate risk of transmission of infections and as a means of preventing administration errors.[1]

Hospitals also routinely opt to receive unit-dose radiopharmaceuticals because the administration of sterile unit-dose preparations to individual patients in a clinical setting is not considered as preparation/compounding under the practice standards of USP <825>.

Creating an investment in quality.

Jubilant Radiopharma continues to make significant capital investment in our nationwide network of pharmacies to ensure that they comply with the guidelines for sterile preparations as defined by the United States Pharmacopeia (USP <825>) and Board of Pharmacy regulations. Unit doses dispensed and delivered by Jubilant Radiopharma professionals conform to the highest standards of quality and safety.

For more information, please speak to your Radiopharmacies Division representative.

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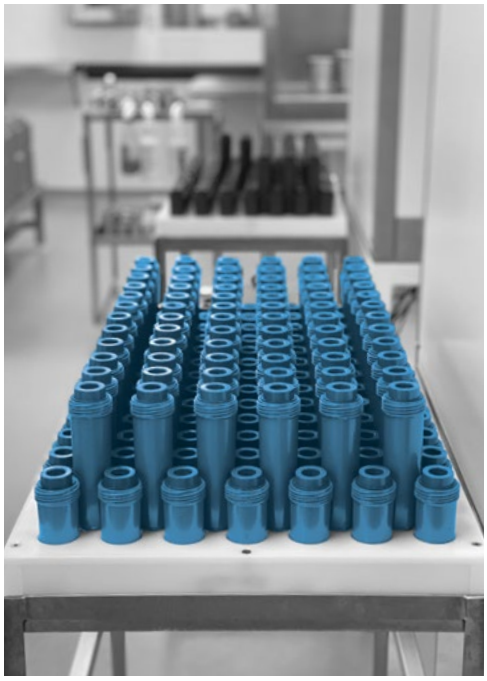
The following guidelines are applicable to unit-dose vs. multi-dose ("bulk") dispensing under Chapter USP <825>.[2]



Preparation Standards

Manipulation of a "bulk" preparation to withdraw unit doses for multiple patients and to prepare kits from a vial of "bulk" sodium pertechnetate are considered preparation, preparation with minor deviations and/or compounding. As such, all of the preparation standards contained within USP General Chapter <825> are applicable. These include, but are not limited to:

- facility design and environmental monitoring requirements
- patient administration area segregation and other facility requirements
- required training and competency assessments for hand hygiene, garbing, aseptic technique and media fills

Immediate Use Provisions

To be considered "immediate use", which signifies an emergency situation, a sterile preparation must be prepared for one patient and administered, using aseptic technique, within one hour of the first septum puncture or critical site exposure to ambient air. The remaining kit contents, as well as the remaining sodium pertechnetate Tc-99m, must be discarded, unless the preparation is performed in an ISO Class 5 PEC and subject to the facility, garbing and training provisions outlined in USP <825>.

Dispensing Guidelines

All facilities handling radiopharmaceuticals, whether or not they are preparing kits in house, should prioritize understanding of and compliance with the practice standards of USP <825>.

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While the Joint Commission does not directly enforce USP <825>, the Chapter is considered a professional practice standard. As such, compliance with USP <825> may be reviewed during a Joint Commission survey. Nuclear medicine departments are encouraged to work closely with their Director of Pharmacy, Quality Assurance, Risk Management or Joint Commission survey expert within the institution to review USP <825> compliance. A USP <825> gap analysis must be performed regularly within each compounding area, with results reviewed by the institution's Director of Pharmacy or other USP <825> or infection control compliance expert.

RAM Licensing

Some RAM licenses require receipt of unit-dosages only. If preparing kits in house, nuclear medicine departments are encouraged to review their RAM license commitments, as well as any scope of practice standards promulgated by their state, and to review physician or pharmacist oversight requirements.

Resources

1. CDC Safe Injections Recommendation: www.cdc.gov/injectionsafety/ip07_standardprecaution.html

2. USP General Chapter <825> Radiopharmaceuticals –Preparation, Compounding, Dispensing, and Repackaging: www.usp.org/chemical-medicines/general-chapter-825.

Additional Resource: US Pharmacopeia - FAQs on USP <825>: www.usp.org/frequently-asked-questions/radiopharmaceuticals

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