Triad Isotopes®
patient focused. community driven.

USP <797> Best Practices

UNIT DOSE DISPENSING

Triad Isotopes puts the safety of your patients and the quality of our radiopharmaceuticals above all else.

The practice standards of USP <797> clearly delineate requirements for single- or multiple-dose containers and for the compounding of sterile preparations. Familiarity and compliance with these standards is particularly important for nuclear medicine customers who receive vials of multi-dose ("bulk") compounded radiopharmaceutical preparations, or sodium pertechnetate Tc-99m to be used in preparation of unit doses or in kits intended for administration to multiple patients.

USP standards specify the following: Compounding kits and dispensing doses from multi-dose preparations must be done within a USP <797> compliant cleanroom/segregated compounding area by appropriately garbed and trained individuals.

Unless the institution's cleanroom facility or segregated compounding area fully complies with the standards described above, **Triad Isotopes strongly recommends that nuclear medicine departments opt for unit-dose 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 dose 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 compounded unit-dose preparations to individual patients in a clinical setting is not considered to be sterile compounding under the practice standards of USP <797>.

Triad Isotopes has made significant capital investment in our nationwide network of pharmacies to ensure that they comply with the standards for compounded sterile preparations as defined by the United States Pharmacopeia (USP <797>) and Board of Pharmacy regulations. Unit doses dispensed and delivered by Triad professionals conform to the highest standards of quality and safety.

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DISPENSING GUIDELINES

The following guidelines are applicable to unit-dose vs. multi-dose ("bulk") dispensing under Chapter USP<797>.[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 is considered "compounding." As such, all of the preparation standards contained within USP General Chapter <797> are applicable. These include, but are not limited to:

- facility and equipment requirements
- segregation and other facility requirements
- required training and competency assessments for hand hygiene, garbing, aseptic technique and media fill

Immediate Use Provisions

To be considered "immediate use", which signifies an emergency situation, a compounded sterile preparation must be prepared for one patient and administered, using aseptic technique, within one hour of preparation. The remaining kit contents, as well as the remaining sodium pertechnetate Tc-99m, must be discarded, unless the preparation is performed using a multi-dose product or preparation in an ISO <5> hood and subject to the facility, garbing and training provisions outlined in USP <797>.

Note: There are also specific requirements regarding the number and type of manipulations that can be considered under the immediate use provisions.

COMPLIANCE CONSIDERATIONS

All facilities handling radiopharmaceuticals, whether or not they are compounding kits in house, should prioritize understanding of and compliance with the practice standards of USP <797>.

USP <797>

While the Joint Commission does not directly enforce USP <797>, the Chapter is considered a professional practice standard. As such, compliance with USP <797> may be reviewed during a Joint Commission survey.[3] Nuclear medicine departments are encouraged to work closely with their Director of Pharmacy, USP <797> expert or Joint Commission survey expert within the institution to review USP <797> compliance. A USP <797> gap analysis must be performed regularly within each compounding area, with results reviewed by the institution's Director of Pharmacy or other USP <797> or infection control compliance expert.[4]

RAM Licensing

Some RAM licenses require receipt of unit-dosages only. If compounding 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: http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html, http://blogs.cdc.gov/safehealthcare/?p=2802

[2] U.S. Pharmacopeia Convention - USP <797> Standards for Pharmaceutical Compounding Sterile Preparations: http://www.usp.org/usp-healthcare-professionals/compounding/compounding-general-chapters/download-usp-nf-general-chapter-pharmaceutical-compounding

[3] Journal of Nuclear Medicine Technology - Review of Joint Commission Medication Management Standards Applicable in Nuclear Medicine: http://tech.snmjournals.org/content/early/2012/.../jnmt.111.094268.full.pdf

[4] Critical IQ & Critical Point - Gap Analysis for Nuclear Medicine: http://797study.criticalpoint.info/

Additional Resource: Society of Nuclear Medicine - FAQs on USP <797>: http://interactive.snm.org/index.cfm?PageID=7906

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