



Patient Focused. Community Driven.

PUTTING PATIENT SAFETY FIRST

Patient safety and the quality of radiopharmaceuticals compounded and dispensed by our pharmacies are top-line priorities for Triad Isotopes, Inc.

Our highly trained nuclear pharmacists and technicians prepare these specialized products based on a prescription order from the prescribing physician and with strict adherence to quality standards and aseptic technique. Supporting their efforts is our company's industry-leading quality management and internal safety audit program, which helps guarantee compliance with applicable regulations and standards.

In addition, Triad Isotopes has made significant capital investment in our nationwide network of pharmacies to ensure that they meet the standards for compounded sterile preparations as defined by the United States Pharmacopeia (USP <797>) and Board of Pharmacy regulations.

Our customers, and the patients they serve, can feel secure that every step is taken to assure the quality and integrity of radiopharmaceuticals dispensed by Triad Isotopes.

OUR QUALITY & SAFETY PLEDGE

As a customer of Triad Isotopes, Inc., you can rely on us to put the safety of your patients and the quality of your radiopharmaceuticals above all else. We pledge to take every step necessary to earn the confidence placed in us as your nuclear pharmacy provider and trusted advisor.



WHAT IS USP <797>?

The United States Pharmacopeia (USP) Chapter <797> - entitled "Pharmaceutical Compounding – Sterile Preparation" – outlines a comprehensive set of facility and personnel requirements designed to ensure the sterility of compounded sterile preparations administered to patients. The intent of USP <797> is to prevent patient harm from improperly compounded sterile preparations.

SAFE ENVIRONMENTS

- All Triad Isotopes pharmacies are licensed by the applicable Boards of Pharmacy and either the Nuclear Regulatory Commission (NRC) or the appropriate Agreement State RAM Agency, and have been approved for all required permits as required by state and federal law.
- Pharmacies are designed to ensure compliance with USP <797> required ISO specifications for ante-room, clean room, and segregated compounding areas within the pharmacy.
- Cleanrooms or segregated compounding areas are certified every six months at ISO <7> or ISO <8>, according to USP <797>.
- All biological safety cabinets and laminar flow hoods are certified every six months at ISO <5>.
- Certification is performed by a qualified vendor following Controlled Environment Testing Association (CETA) guidance CAG-003-2006 (updated 2012) to assure testing according to USP <797>.
- Adherence to rigorous daily, weekly, and monthly cleaning and disinfection procedures is required, according to USP <797> and Triad Isotopes policies and procedures. Specific validated procedures have been established for unit dose shield (pig) disinfection prior to reuse.
- Each pharmacy is subject to inspection by internal audit and external agencies at any time. The Agency Inspection success rate and internal audit scores are key metrics for evaluation of our pharmacy teams.

TRAINED PERSONNEL

- All Triad Isotopes pharmacists and technicians are licensed, registered and certified as specified by the Board of Pharmacy.
- Our dose drawing technicians are trained through an accredited Nuclear Pharmacist Technician instruction program, which is designed to assess competence in nuclear pharmacy practice. All are Certified Pharmacy Technicians (CPHT) or otherwise licensed or registered, as required by the state Board of Pharmacy.
- All compounding personnel undergo an initial Personnel Competency Assessment, which is repeated semi-annually. The assessment includes personnel media fill and gloved fingertip sampling, as well as other required training topics to demonstrate aseptic process competency.
- All pharmacy personnel receive specific training on aseptic technique, garbing, hand hygiene, and cleaning on an annual or more frequent basis.
- All pharmacy personnel receive specific training on Radiation Safety/ALARA, Pharmacy Quality and General Safety (OSHA) topics.
- Delivery employees are trained according to DOT requirements; HazMat and RAM Security are emphasized. Triad Isotopes drivers also receive specific training to assure compliance that meets Joint Commission survey requirements.
- Delivery employees undergo a rigorous background check upon hire, which is repeated every six months thereafter.
- Our pharmacies work closely with individual nuclear medicine departments to establish specific RAM delivery and security procedures that match institutional policy.

QUALITY PRODUCTS

- In accordance with Board of Pharmacy regulations, prescription orders are required for all radiopharmaceutical preparations compounded and dispensed by Triad Isotopes.
- Prior to delivery, a specially-trained Triad Isotopes team member performs radiopharmaceutical quality assurance testing (QC) on each lot of compounded radiopharmaceutical.
- Triad Isotopes procures and supplies FDA-approved radiopharmaceutical products exclusively from FDA-approved cGMP compliant manufacturers. Our company does not procure products from other compounding pharmacies or any gray market sources.
- Our company fully supports FDA guidelines outlined in the Food Drug and Cosmetic Act, including the recently enacted 2013 FDA Drug Quality & Security Act, including Title I – Compounding Quality Act and Title II – Drug Supply Chain Security Act, as well as other industry guidelines as provided by USP, SNMMI, ASHP, APhA, and others.

COMPREHENSIVE SAFETY PROGRAMS

- An industry leader in nuclear pharmacy, Triad Isotopes has established a comprehensive internal quality and safety audit program with structured corrective action plans for identified gaps.
- Triad Isotopes pharmacies report quality related events and incidents online. Following event investigation, a corrective and preventative action plan is developed for significant incidents.
- To ensure USP <797> compliance by Triad Isotopes pharmacies, a comprehensive set of Standard Policy and Procedures have been developed by our corporate Quality & Safety Department.

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