

USP Compliance Chapters <795> & <797>

We are confident in our ability to maintain material compliance with USP Chapters <795> and <797> as they pertain to the practice of nuclear pharmacy and are enforced by the various state Boards of Pharmacy. We remain committed to ensuring that Cardinal Health's nuclear pharmacies provide safe, accurate and efficacious prepared pharmaceuticals.

Cardinal Health Nuclear Pharmacy Services (NPS) is an active advocate for positive change in the Practice of pharmacy and we embrace improvements that result in enhanced quality patient care.

Most radiopharmaceuticals are short-lived, compounded, sterile products. Patient administration typically occurs the same day of preparation (generally within a few hours after preparation) with an absolute beyond-use time of between 12 and 24 hours. Because the drugs are radioactive, by regulation the caregiver must be an authorized user physician or his / her designee, a must be a nuclear medicine technologist. A member of the lay public will never directly receive our radiopharmaceuticals or be the caregiver. The sterile injectable radiopharmaceuticals dispensed by Cardinal Health Nuclear pharmacies are defined by USP <797> as low-risk. These radiopharmaceuticals are received from the manufacturer ready to use or they are compounded on site from commercially manufactured sterile lyophilized drug vials and sterile radioactive solutions in a certified ISO Class 5 PEC.

Multiple policies and procedures are included in Cardinal Health's Quality Assurance program to assure the sterile compounding environment and personnel meet pre-established criteria necessary for preparing sterile drugs. Some of these include: The adoption of a standardized format and nomenclature, certification of engineering controls, robust cleaning procedures with specific products and validation of cleaning personnel, appropriate gowning and hand hygiene, routine disinfection of shielded unit-dose containers and objects entering the buffer area and PEC, on-going environmental monitoring of viable particles and total particles. Training and qualification of personnel includes, but is not limited to didactic testing, aseptic media challenge testing and aseptic technique validation. Regular periodic re-assessment validates and monitors performance and demonstrates that the essential pre-defined standards are being met.

The health and safety of patients and employees are our top priorities. There are unique circumstances and requirements for radiopharmaceutical preparations that necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. In addition to nuclear pharmacy's unique practice setting, there are required NRC and Agreement State regulations for nuclear pharmacies that result in required variation in certain details and facility design. Cardinal Health NPS Q&R is carefully evaluating satisfying both NRC and Agreement state regulations and USP Chapter <797> requirements. An example of one distinct difference is the fact that visual inspection of compounded radiopharmaceutical products would pose a severe risk and occupational exposure to our staff.