FIELD PERSPECTIVE

Meeting the USP Chapter <825> Standards

In June 2019, USP published General Chapter <825> Radiopharmaceuticals – a new standard for the preparation, compounding, dispensing, and repackaging of radiopharmaceutical drugs. Following appeals to USP that delayed enforcement, the new standards became official on December 1, 2020.

Before USP <825> was officially enforced, we asked Tim Houston, PharmD, Nuclear Pharmacist at Northwestern Memorial Hospital (Chicago, IL) about how Chapter <825> may impact day-to-day operations in nuclear medicine departments, and how to best prepare.

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What are the most significant changes described in the USP Chapter <825>?

The unique qualities of radiopharmaceuticals (i.e. short half-lives, exposure concerns) were not adequately addressed in USP <797> and therefore numerous questions resulted and compliance was not easily implemented. Overall, the most significant change with USP <825> is the publication of specific standards relating to radiopharmaceuticals that eliminates interpretation, resulting in more standardized practices.

In addition, an important change is inclusion of radiation safety practices to protect staff preparing the radioactive products while maintaining patient safety through strict aseptic handling. The standards set forth in USP <825> reflect the unique properties of radioactive drugs, taking into consideration radiation safety practices while maintaining the sterility of the products prepared.

How will the new standards affect patient care?

The new standards will help to promote patient safety through consistency of product quality as a result of clearly defined standards. One notable specific scenario is the radiolabeling of red blood cells that is allowed under immediate use in USP <825>. Previously it was non-compliant with USP <797> secondary to requiring greater than two entries into a vial.

What part of the standards do you feel will present the biggest challenge to nuclear medicine departments?

The biggest challenge will depend on to what extent your specific nuclear medicine department prepares radiopharmaceutical products. If all of your products are outsourced and not manipulated after receipt, then you are not subject to the new standards. If you prepare products for immediate use, USP <825> outlines specific standards, but these should be relatively easy to comply with. The biggest challenge in this case may be for departments accustomed to getting a bulk vial of sodium pertechnetate and using it for more than one patient; USP <825> specifies immediate use is for single patient only. This can be easily complied with by changing backup sodium pertechnetate from one vial to multiple syringes.

If a department prepares radiopharmaceutical products beyond immediate use, then specific aseptic qualifications must be met by personnel. In addition, certain engineering controls must be in place. Depending on the specific manipulations and the environment in which they are performed, a corresponding beyond use date (BUD) is assigned. As the complexity level of the manipulation increases (i.e. immediate use, preparation, preparation with minor variation, sterile compounding, radiolabeling leukocytes) the engineering requirements become more stringent (i.e. primary engineering control within a classified area).

How do you expect the new standards will change your day-to-day practice of nuclear medicine?

Once again, changes to your day-to-day practices will depend on to what extent you manipulate sterile radiopharmaceuticals. Depending on the department some ordering patterns may need to be modified and operating procedures changed/implemented.

There is a section in USP <825> that provides guidance for compounding nonsterile radiopharmaceuticals, such as the addition of 99mTc-sulfur colloid in eggs. In this case a Master Formulation Record (MFR) is required detailing specific data (i.e. name of the radiopharmaceutical, detailed procedure, range of activity, equipment to be used, quality control tests, etc.).

One thing to keep in mind is that radiopharmaceuticals are medications, and as such, need to be stored in a secure area within certain specified temperature ranges.

What advice can you offer others who are preparing for <825> compliance? What should they focus on?

For nuclear medicine departments, my advice depends on the specific situation. To the extent staff prepare radiopharmaceutical products will direct my specific guidance. For example, if a department completely outsources their radiopharmaceuticals through a commercial nuclear pharmacy, then USP <825> will have little to no impact. However, if a department radiolabels RBC's or prepares a radiopharmaceutical kit after hours for immediate use, then certain USP <825> standards will apply.

My overall advice is to evaluate your current practices and identify those that fall under USP <825>. Then assess your current procedure versus the standard described in the chapter and create an action plan to become compliant. In general, focus should be on having the proper equipment/facilities for your practices and relevant staff training and competencies. Most staff in nuclear medicine departments are generally well-versed on ALARA principles but may be lacking on specific aseptic practices.

There are valuable resources online as well as potentially reaching out to your local Nuclear Pharmacy for additional support.

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