

<825> Compounding—Radiopharmaceuticals

Type of Posting: General Announcement

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Expert Committee: Chemical Medicines Monographs 4

Expert Panel: Radiopharmaceutical Compounding Panel

Input Deadline: August 31, 2017

Suggested audience: Nuclear medicine professionals, nuclear pharmacists, nuclear pharmacies, radiopharmaceutical manufacturers, and regulatory professionals.

Estimated proposal PF: *Pharmacopeial Forum* 44(6) [Nov.-Dec. 2018]

Background and objective(s): Radiopharmaceuticals represent a unique class of drug products where compounding activities include the use of radionuclide generators, the preparation of commercially-manufactured radiopharmaceutical kits, the dilution of FDA-approved multi-dose vials, the labeling of human blood products with radionuclides, the preparation of patient-specific doses, etc. These activities occur in an environment where individualized patient needs and the safe handling of radioactive materials demand a high level of professional care and clearly-defined standards that support these activities.

Since 2004, General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations* has described standards for the entire spectrum of compounded sterile preparations. Standards for radiopharmaceuticals have been addressed at various levels within <797>, but it has been difficult to develop and maintain standards for radiopharmaceuticals in this manner due to the scope of <797> and the unique characteristics of radiopharmaceuticals.

On February 1, 2017, the USP hosted a roundtable discussion on compounding standards for radiopharmaceuticals. The roundtable was attended by stakeholders from the nuclear medicine community, regulatory agencies, and USP staff. During this day-long session, participants discussed potential approaches to address the challenges associated with this class of products. Based on this discussion, the stakeholders from the nuclear medicine community strongly favored the development of a new general chapter for radiopharmaceutical compounding. After considering these stakeholder inputs, the USP staff and Compounding Expert Committee agreed with the development of a separate chapter to effectively address these needs.

The objective of the new General Chapter <825> *Compounding—Radiopharmaceuticals* is to provide clear and effective USP public standards that meet patient and practitioner needs for compounded sterile radiopharmaceuticals today and in the future. The proposed new general chapter will delineate compounding activities for radiopharmaceuticals and provide standards associated with these activities. When complete, General Chapter <825> will contain standards for this class of products.

Description of scope and application: The Chemical Medicines Monographs 4 Expert Committee will form a new Expert Panel, which will be charged with drafting <825> *Compounding—Radiopharmaceuticals*. The Expert Panel will prepare a draft for review by the appropriate Expert Committees within the USP. Upon approval by these Expert Committees, the proposal will be published in *Pharmacopeial Forum* for public comments.

Anticipated proposed design phase activities: The background and concepts in this new general chapter are included in a white paper that was written by the Committee on Radiopharmaceuticals, which is a standing committee within the Society of Nuclear Medicine and Molecular Imaging. The white paper was shared with USP leadership and is also available at the following link: http://snmmi.files.cms-plus.com/SNMMI-USP-Recommendations-Final_2016.pdf. The proposed new general chapter will be published for comment in *Pharmacopeial Forum* 44(6) [Nov.–Dec. 2018].

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