

<825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging

Type of Posting	Revision Bulletin
Posting Date	22–Nov–2019
Official Date	01–Dec–2019
Expert Committee	Chemical Medicines Monographs 4
Reason for Revision	Compliance—Postponement

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, USP is postponing the official date of Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging <825> pending resolution of an appeal related to this chapter.

After publication of <825> on June 1, 2019, USP received an appeal related to the chapter. In accordance with [USP's Bylaws](#), the responsible Expert Committee (Chemical Medicines Monographs 4) worked with a sense of urgency to consider the information raised in the appeal and issued a decision on the appeal (see [Decision on Appeal to USP <825>](#)). In accordance with USP's [formal appeals process](#), the appellant has requested further review by an appointed Panel.

[USP's Bylaws](#) provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is postponing the official date of <825> until further notice.

USP's General Notices permit early adoption of revised standards in advance of their official date, as follows:

3.10 Applicability of Standards:

Early adoption of revised standards in advance of the official date is allowed by USP unless specified otherwise at the time of publication. Where revised standards for an existing article have been published as final approved “official text” (as approved in section [2.10 Official Text](#)) but have not yet reached the official date (6 months after publication, unless otherwise specified; see “official date”, section [2.20 Official Articles](#)), compliance with the revised standard shall not preclude a finding or indication of conformance with compendial standards, unless USP specifies otherwise by prohibiting early adoption in a particular standard.

It is the decision of individual entities regarding whether to implement <825> in advance of the official date. Regulatory authorities and enforcement bodies also may issue requirements or recommendations on this point. USP plays no role in enforcement.

Should you have any questions, please contact Ravi Ravichandran, Principal Scientific Liaison (301-816-8330 or rr@usp.org).

