

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

Type of Posting	Revision Bulletin
Posting Date	June 1, 2020
Official Date	December 1, 2020
Expert Committee	Chemical Medicines Monographs 4
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Chemical Medicines Monographs 4 (CHM4) Expert Committee is reinstating the official date of General Chapter <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*, following the resolution of an appeal related to the chapter.

After publication of General Chapter <825> on June 1, 2019, with an anticipated official date of December 1, 2019, USP received an appeal related to the chapter, necessitating the postponement of the original official date pending appeal resolution.

In accordance with the formal appeals process set forth in [USP's Bylaws](#), the responsible Expert Committee (CHM4) worked with a sense of urgency to consider the information raised in the appeal and issued a decision denying the appeal (see [Decision](#) on Appeal to USP <825>).

The appellant requested further review of the appeal by an appointed Panel, and the Panel ultimately denied the appeal (see [Appeals Panel Decisions on <795>, <797>, and <825>](#)). Based on the final decision of the Appeals Panel, the CHM4 Expert Committee has decided to lift the postponement and to establish a new official date of December 1, 2020.

When General Chapter <825> becomes official, it will be informational unless otherwise required by a regulatory body. This is because revisions to General Chapters <795> and <797>, published on June 1, 2019, which contained cross-references that would have made <825> compendially applicable, have been postponed until further notice (see [Role and Applicability of USP General Chapter <825> Related to Radiopharmaceuticals](#)). USP continues to encourage early adoption and implementation of the chapter to help ensure a safe environment and protection of healthcare practitioners and others when handling radiopharmaceuticals.

Should you have any questions, please contact Ravi Ravichandran, Principal Scientific Liaison (301–816–8330 or GC825SL@usp.org).