(825) Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised General Chapter (825) Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. The purpose of this revision is to remove the text regarding compendial applicability, added as part of the Revision Bulletin which became official on December 1, 2020.

The text regarding compendial applicability, added as part of the Revision Bulletin which became official on December 1, 2020, is being deleted from General Chapter (825). General Chapter (825) is now compendially applicable because it is referenced in both (795) and (797), which are applicable general chapters numbered below 1000 and became official on November 1, 2023. This means that regulatory bodies with jurisdiction over compounded radiopharmaceuticals may also require compliance with the requirements in (825).

The (825) Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging Revision Bulletin supersedes the currently official general chapter.

Should you have any questions, please contact Gerald J. Hsu, Principal Scientist (240-221-2097 or gdh@usp.org).