



The Council on Radionuclides and Radiopharmaceuticals, Inc.



July 27, 2022

BY EMAIL: execoffice@nabp.pharmacy

Caroline D. Juran, BSPharm, DPh, Chairperson
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Re: USP General Chapter <825>

Dear Ms. Juran:

We are writing jointly on behalf of the American Pharmacists Association, the Council on Radionuclides and Radiopharmaceuticals, Inc., the National Association of Nuclear Pharmacies, and the Society of Nuclear Medicine and Molecular Imaging to request NABP's assistance in urging state boards of pharmacy to adopt USP General Chapter <825>, "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging."¹ Our four industry and professional organizations together represent the major stakeholders in radiopharmaceutical manufacturing, nuclear pharmacy practice, and nuclear medicine practice in the U.S.

As you may know, General Chapter <825> is the first nationally applicable compendial standard for radiopharmaceutical preparation and compounding. This chapter was necessary to remedy the failure of General Chapter <797> (Pharmaceutical Compounding – Sterile Preparations) to address the unique challenges presented by radiopharmaceuticals, which require not only aseptic handling, but also radiation safety practices and attention to the abbreviated shelf-lives of these products. The chapter became official on December 1, 2020. However, it is considered merely informational until the finalization of USP General Chapters <795> and <797>, on pharmaceutical compounding of non-sterile and sterile preparations, respectively, both of which contain references to General Chapter <825>. When General Chapters <795> and <797> become official, General Chapter <825> will then also become compendial. General Chapters <795> and <797> are expected to be published in July or August of this year, and will most likely have a six-month implementation period before they become official. Of course, states are free to adopt General Chapter <825> early,

¹ A copy of General Chapter <825> can be downloaded from the USP web site [here](#).

as USP has encouraged them to do. To date, seven states and the District of Columbia have adopted General Chapter <825>.²

We strongly recommend that state boards of pharmacy adopt General Chapter <825> at the earliest possible time – before it becomes compendial if possible, but if not, as soon as practicable afterward. As you know, pharmacies play a much larger role in the preparation of radiopharmaceuticals than conventional drugs. Unlike conventional drugs, radiopharmaceuticals must, at the very least, be dispensed as sterile, patient-ready doses at the nuclear pharmacy, and usually the pharmacy also plays a major role in preparing and radiolabeling the drug so that it is in usable form. All of this must be done in a manner that protects nuclear pharmacy personnel and health care workers from radiation exposure. The outsized role of pharmacies in the preparation of usable radiopharmaceuticals gives General Chapter <825> unusual importance among pharmacy standards. The General Chapter ensures the safety, efficacy, integrity, and quality of radiopharmaceuticals by establishing facility and engineering controls, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals. It also sets forth radiation safety standards to protect the nuclear pharmacy personnel engaged in these activities. For sterile preparations, which comprise the great majority of radiopharmaceuticals, the standards also ensure aseptic handling practices to protect the safety of patients. General Chapter <825> is state of the art. The sooner it is implemented by states, the better and more consistent will be nuclear pharmacy practice, and the safer will be nuclear pharmacy personnel.

Another reason for our urgency in requesting your help is that state standards for nuclear pharmacy practice, and for inspection of nuclear pharmacies, have become not only inconsistent among states, but also confusing within a particular state. In certain states, nuclear pharmacy inspectors are unsure whether to enforce the old General Chapter <797>, new General Chapter <797>, new General Chapter <825>, or state-specific standards that are different from all of these. As a result, within a single state, different nuclear pharmacies are being held to different standards by different inspectors. The problem of inconsistent standards is magnified for nuclear pharmacy providers that operate in multiple states.

We recognize that states will need time to incorporate General Chapter <825> into their pharmacy regulations and/or policies, which is all the more reason to urge them to start the process now. We are requesting your help in communicating to state boards of pharmacy (other than the eight jurisdictions listed in footnote 2), in a manner you deem most effective, the necessity of implementing General Chapter <825>. For your convenience, we have attached a simple model regulation that states could use to incorporate General Chapter <825> into their pharmacy regulations. Please let us know if NABP is willing to communicate the importance of General Chapter <825> to its members, and if so, whether there is anything further we can do to assist you in that process.

We appreciate your consideration of our request for your assistance and we are available to collaborate with you in this effort. If you would like to meet to discuss this issue, please contact Michael Guastella at michael.guastella@corar.org and Michael Baxter at mbaxter@aphanet.org. We look forward to hearing from you.

² The states are Connecticut, Iowa, Kentucky, Mississippi, New Mexico, Ohio, Washington, and the District of Columbia. In addition, 10 states are currently discussing adoption of General Chapter <825>: California, Idaho, Louisiana, Maine, New Jersey, New Mexico, South Dakota, Utah, Vermont, and Wyoming.

Sincerely,



David Barnes, RPh
Coordinator
Nuclear Pharmacy Practice Special Interest Group
The American Pharmacists Association



Michael J. Guastella, MS, MBA
Executive Director
Council on Radionuclides and Radiopharmaceuticals, Inc.



Jeffrey P. Norenberg, PharmD, PhD
Executive Director and Chairman
National Association of Nuclear Pharmacies



Munir Ghesani, MD, FACNM, FACR
President
Society of Nuclear Medicine and Molecular Imaging

cc: Dr. Al Carter, MS, PharmD, RPh, Executive Director/Secretary, NABP

Model Pharmacy Regulation

- (x) A nuclear pharmacy engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals for human or veterinary use shall comply with United States Pharmacopeia (USP) General Chapter <825>, entitled “Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging”.