

Director of Pharmacy and Nuclear Medicine Oversight

An FAQ for the Director of Pharmacy (DOP)

Background: Nuclear medicine professionals have previously been held to the standards outlined in USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. In USP <797>, a small section was dedicated to sterile radiopharmaceuticals. Due to the uniqueness of radiopharmaceuticals and the lack of detail in <797>, it was decided that radiopharmaceuticals needed their own chapter: General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging. When published in June 2019, USP <825> included standards tailored to the needs of sterile and non-sterile radiopharmaceuticals which will impact nuclear pharmacy service providers, nuclear medicine department professionals and DOPs. The new chapter will become official on December 1, 2020.

Due to USP <825>, the DOP will become more actively involved in overseeing the management of medications in the nuclear medicine department. This includes oversight of diagnostic and therapeutic radiopharmaceuticals and collaboration with the nuclear medicine department to help ensure a compliant department. The following are frequently asked questions regarding potential areas of oversight by the DOP in nuclear medicine. The references to USP<825> apply to the current draft version of the chapter. These FAQs may be updated if necessary to reflect the final guidelines.

1. As the hospital DOP, historically, I have not been involved with the nuclear medicine department, this has been the responsibility of the Director of Radiology. What is prompting this change and how involved will I need to become?

All accrediting agencies require that the pharmacy department, specifically the DOP, maintain oversight of all aspects of drug use within the hospital as part of medication management. This includes: selection & procurement, storage, ordering & transcribing, preparing & dispensing, administration & monitoring. Radiopharmaceuticals are legend drugs and fall under the purview of the Director of Pharmacy. Accreditation agencies recognized by Centers for Medicare and Medicaid Services (CMS) include The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP), and National Integrated Accreditation for Healthcare Organizations (NIAHO) from Det Norske Veritas (DNV). Because of the implementation of <825>, these previously mentioned accrediting bodies are expected to actively require compliance with the new USP <825> standards.

2. How involved should I be in the activities that occur in the nuclear medicine department?

Historically, nuclear medicine department imaging and therapy protocols have been reviewed by the Director of Radiology (DOR). Based on new accreditation standards, the DOP is now likely to play a complementary role in reviewing the medication aspects of these same protocols. For example, the DOP would help ensure that the protocols include information such as the drug name, drug use, if the radiopharmaceutical is FDA-approved for that use, the mechanisms of ordering, receipt, storage and disposal, etc. The development of nuclear medicine protocols should be a collaborative effort between the DOP, DOR and the nuclear medicine staff.

3. What drugs will now have to be included on the hospital formulary?

As legend drugs, all radiopharmaceuticals should be on the hospital formulary.¹ The DOP should consult with the nuclear medicine department to understand which drugs are currently being used and which are or are not on formulary. The DOP should also understand whether or not the radiopharmaceutical

being used are commercially available FDA-approved drug products or unapproved copies of those radiopharmaceuticals. All drugs used within the hospital should be commercially FDA-approved agents when available.² This includes radiopharmaceuticals in the nuclear medicine department as well. You can find the list of FDA-approved radiopharmaceuticals at bit.ly/FDAradiopharmaceuticals. This list includes information such as the brand and generic names and manufacturers' names.

4. Where can I find the package inserts for FDA-approved radiopharmaceuticals?

You can find current package inserts and safety data sheets (SDS) for all of these FDA-approved radiopharmaceuticals on the Cardinal Health website at <http://nps.cardinal.com/MSDSPI/Main.aspx>.

5. How and from where are radiopharmaceuticals generally ordered?

In addition to being prescription medications, these drugs are radioactive. The hospital should possess a radioactive materials (RAM) license issued by the Nuclear Regulatory Commission (NRC) and/or the local agreement state. The RAM license specifies which isotopes may be possessed and the quantities for each isotope. It also specifies where the isotopes are to be used and how they should be stored. Your nuclear medicine department most likely has a contractual relationship with an outside nuclear pharmacy services provider which has a copy of the hospital's RAM license on file. The nuclear pharmacy services provider dispenses patient-specific unit dose radiopharmaceuticals per physician prescriptions and as authorized by the RAM license.

6. Where are radiopharmaceuticals stored?

Any radiopharmaceuticals should be stored in the nuclear medicine hot lab.³

7. What measures are taken to secure these medications?

All radiopharmaceuticals should be stored in the nuclear medicine hot lab which is a limited access area.² Because these medications are radioactive, they are stored in lead or tungsten shielded containers to protect the nuclear medicine staff from radiological hazards.

8. How are deliveries made to the nuclear medicine department?

To help ensure the smooth workflow within the nuclear medicine department, radiopharmaceutical deliveries are made directly to the hot lab by the nuclear pharmacy service provider. The first delivery of the day is made prior to the arrival of the nuclear medicine staff to allow them to begin patient imaging as soon as possible. A written standard operating procedure (SOP) for deliveries should be in place that delineates the various parties,

their roles, responsibilities, etc. Throughout the course of the work day additional deliveries to the hot lab may be made depending upon patient demand.

9. How are radiopharmaceuticals prepared/compounded within the nuclear medicine department and how does this impact USP <825> standards?

USP <825> requirements do not apply to administration of radiopharmaceuticals to patients. So nuclear medicine departments that receive patient-specific unit-dosed radiopharmaceuticals delivered to the hot lab in individually shielded syringes, appropriately labeled, and ready for patient administration are able to sidestep most of USP <825>.⁴ There are unique requirements in USP <825> for in-house radiopharmaceutical preparation.⁴ Occasionally a nuclear medicine department may receive nonpatient-specific isotopes and "cold kits" intended for use onsite for after hour preparation of radiopharmaceuticals. The immediate use provisions of USP <825> address nonpatient-specific isotopes and cold kits.² If these radiopharmaceuticals are not prepared under the immediate use provisions or if the nuclear medicine department receives a Mo-99 generator to prepare doses using "cold kits, then full USP <825> applies, including applicable provisions related to training, environmental controls, cleaning, garbing, personal validation, etc.

10. If the nuclear medicine department uses a contracted nuclear pharmacy services provider how can I be assured that the provider is compliant with USP <825> for sterile and non-sterile radiopharmaceuticals?

Discuss <825> with your nuclear medicine department's contracted nuclear pharmacy services provider to understand their activities to ensure compliance with USP <825>. They should be able to provide a written statement that they are compliant with USP <825>.

11. How would the DOP become involved in the drug use procedure review process in the nuclear medicine department?

One suggested approach would be for the DOP to introduce himself or herself to the DOR or Chief of Nuclear Medicine since the DOP will need to collaborate with them in this protocol review. The DOR has historically reviewed the imaging and therapy protocols used in the nuclear medicine department. They will be able to provide these protocols to the DOP for the DOP's review of the medication management aspects of the protocols that include: drug name, drug use, is the radiopharmaceutical FDA-approved for that use, mechanism of ordering, receipt, storage, disposal, etc. The nuclear medicine department should also inform the DOP of the approval of any new medications or new indications for existing drugs used in nuclear medicine so that the DOP will be able to review the new protocols and update the formulary.

12. What is the disposal procedure for radiopharmaceuticals?

When the radiopharmaceuticals are no longer usable, they are either returned to the nuclear pharmacy services provider for disposal or they are segregated by half-life and stored within the hot lab until the radiation has decayed to background levels. Once that decay is completed, they are usually comingled with the hospital's medical waste disposal stream.⁶

13. Besides radiopharmaceuticals, are any other drugs used in the nuclear medicine department, and if so, what are they?

Some nuclear medicine procedures require the use of ancillary drugs in conjunction with the radiopharmaceuticals. Some examples are stress agents: adenosine, dipyridamole, dobutamine, etc. Confer with your nuclear medicine colleagues to identify what adjunct pharmaceuticals are used in the department. Some hospitals may prefer that these drugs be ordered by the nuclear medicine department through the hospital pharmacy rather than the nuclear pharmacy provider. The nuclear medicine department should have written SOPs on file that help ensure quality standards are maintained when ordering and using adjunct pharmaceuticals supplied by a contracted pharmacy provider.

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Sources:

- 1 42CFR482.25, pages 488–489, conditions of participation for hospitals. Available at: http://edocket.access.gpo.gov/cfr_2004/octqtr/42cfr482.25.htm. Updated October 1, 2004. Accessed 5.3.2019
- 2 United States Pharmacopeia (USP). (July 27, 2018). <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging [Glossary]. <http://www.usp.org/sites/default/files/usp/document/our-work/chemicalmedicines/proposed-gc-825.pdf>. Accessed 4.23.19.
- 3 10 Code of Federal Regulations (CFR) Part 20.1801
- 4 United States Pharmacopeia (USP). (July 27, 2018). <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging [Introduction]. <http://www.usp.org/sites/default/files/usp/document/our-work/chemicalmedicines/proposed-gc-825.pdf>. Accessed 4.23.19.
- 5 United States Pharmacopeia (USP). (July 27, 2018). <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging [Preparation]. <http://www.usp.org/sites/default/files/usp/document/our-work/chemicalmedicines/proposed-gc-825.pdf>. Accessed 4.23.19.
- 6 10 Code of Federal Regulations (CFR) 35.92(a) – Decay in Storage