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Director of Pharmacy and Nuclear Medicine Oversight

An FAQ for the Nuclear Medicine Department

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> will include standards tailored to the needs of sterile and non-sterile radiopharmaceuticals which will impact nuclear pharmacy service providers, nuclear medicine department professionals and directors of pharmacy (DOP). The new chapter will become official on December 1, 2019.

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. **Historically my DOP has not been involved in nuclear medicine. What is prompting this involvement and how involved will he/she be in the department?**

   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 that require a prescription and fall under the purview of the DOP. 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 will the DOP be in activities that occur in the nuclear medicine department?**

   Nuclear medicine imaging and therapy protocols have historically been reviewed by the Director of Radiology. The DOP is likely to play a complementary role in reviewing the drug aspects of these same protocols. For example, the DOP may review the following: drug name, drug use, is the product FDA-approved, mechanism of ordering, receipt, storage and disposal, etc. The development of nuclear medicine protocols should be a collaborative effort between the DOP, Director of Radiology and the nuclear medicine staff.

3. **What is a formulary and how does it affect nuclear medicine?**

   A formulary is a list of drugs that has been approved for use in the medical facility and is maintained by the pharmacy department. All drugs used in nuclear medicine should be included on your hospital's formulary. Your DOP will probably want to know what medications are used within the nuclear medicine department and their approved uses to confirm whether they appear on the hospital's formulary.

All drugs used within the hospital should be commercially FDA-approved agents when available.[1] 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. You should also notify your DOP if any other radiopharmaceuticals are being used in your nuclear medicine department, which are not FDA-approved products.

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 FDA-approved commercially available radiopharmaceuticals on the Cardinal Health website at http://nps.cardinal.com/MSDSPI/Main.aspx.

5. Why would the DOP be concerned with how we order our radiopharmaceuticals and where we obtain them?

Radiopharmaceuticals, although radioactive, are also legend drugs requiring a prescription. The DOP most likely will be concerned about the sourcing, ordering process, delivery, etc. for these products to help ensure that only quality drugs are sourced from appropriately licensed providers.

6. Why may the DOP be concerned about where radiopharmaceuticals are stored?

The location and condition of drug storage are two of the medication management aspects of which the DOP has oversight under the accreditation standards. The nuclear medicine department should inform the DOP that most radiopharmaceuticals are stored in the nuclear medicine hot lab and share standard operating procedures (SOPs) regarding storage to make him/her aware of your department's policies and procedures.[2]

7. Radiopharmaceuticals are not narcotics, why is the DOP concerned about security?

Storage and security are other aspects of medication management for which the DOP has oversight under the accreditation standards. Although they are not narcotics, any loss may raise questions of drug diversion. In addition, since these products may be in a radioactive state, there may also be a safety issue associated with missing product.

8. How can I continue to get early morning deliveries so as to not adversely impact the work flow of my department?

To help ensure smooth workflow within the nuclear medicine department, a written SOP for deliveries should be created and kept on file. This SOP should delineate the various parties involved, their roles, responsibilities, etc. for the delivery of radiopharmaceuticals to the nuclear medicine department. This should allow deliveries to the hot lab to be made prior to the arrival of nuclear medicine staff.

9. I currently compound "cold kits" using a Mo-99 generator and/or bulk technetium. Is this included under the oversight of the DOP?

Yes, under accreditation standards, the DOP is responsible for helping to ensure that all compounding/preparing of medications within the hospital, including radiopharmaceuticals, meet USP <825> requirements.[3] A nuclear medicine department may receive non-patient specific isotopes and "cold kits" which may be prepared onsite under the immediate use provisions of USP <825>.[1] If these products are not prepared under the immediate use provisions or if the nuclear medicine department uses a Mo-99 generator for onsite compounding, then the DOP would need to ensure that full USP <825> requirements such as training, environmental controls, cleaning, garbing, personal validation, etc. are in place.

10. Why would the DOP require a statement from my outside radiopharmaceutical provider that says that the provider is compliant with USP <825> Radiopharmaceuticals — Preparation, Compounding, Dispensing, and Repackaging?

The DOP should discuss <825> with contracted nuclear pharmacy services provider to understand their activities to ensure compliance with USP <825> since compliance is another aspect of medication management for which the DOP is responsible. The contracted nuclear pharmacy services provider should be able to provide a written statement that they are compliant with USP <825>.

11. We have always had our imaging procedures approved by the Director of Radiology (DOR), why does the DOP need to be involved?

Protocol development is another aspect of medication management for which the DOP has oversight under the accreditation standards. In addition to the nuclear medicine department having their imaging and therapy protocols reviewed by the DOR, the DOP will play a complementary role in reviewing the drug aspects of these same protocols. For example, the DOP may review the following: drug name, drug use, is the product FDA-approved for that use, the mechanism of ordering, receipt, storage and disposal, etc. The development of nuclear medicine protocols should now become a more collaborative effort between the DOP, DOR, and nuclear medicine staff. The nuclear medicine department should inform the DOP of the approval of any new medications or new indications for use in nuclear medicine so that the DOP can review the new protocols and update the hospital formulary.

12. Why is our DOP concerned with how we dispose of our radiopharmaceuticals?

Disposal of medication is an aspect of medication management for which the DOP has oversight under the accreditation standards.[3] The DOP should be informed that when the radiopharmaceuticals are no longer usable, they are either returned to the contracted nuclear pharmacy services provider for disposal or they are segregated by half-life and held until the radiation has decayed to background levels. Once that decay is completed, those products are usually comingled with the medical waste disposal stream.[4] Also, the DOP should be provided with a copy of the department's written SOP on the disposal of radiopharmaceuticals.

13. Is there an issue with the use of non-radioactive stress agents (e.g. adenosine, dobutamine, furosemide, etc.) within nuclear medicine?

The DOP is responsible for all medications used within the hospital including ancillary drugs used in nuclear medicine. Some hospitals may prefer that these drugs be ordered by the nuclear medicine department through the hospital pharmacy rather than the nuclear pharmacy provider. You should have written SOPs in place that help ensure quality standards are maintained when ordering and using adjunct pharmaceuticals supplied by your contracted nuclear pharmacy provider. Share these SOPs with your DOP.

Sources

1 United States Pharmacopeia (USP). (July 27,2018). <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repacking [Glossary]. http://www.usp.org/sites/default/files/usp/document/our-work/chemicalmedicines/proposed-gc-825.pdf. Accessed 4.23.19.

2 10 Code of Federal Regulations (CFR) Part 20.1801

3 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

4 10 Code of Federal Regulations (CFR) 35.92(a) – Decay in Storage

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