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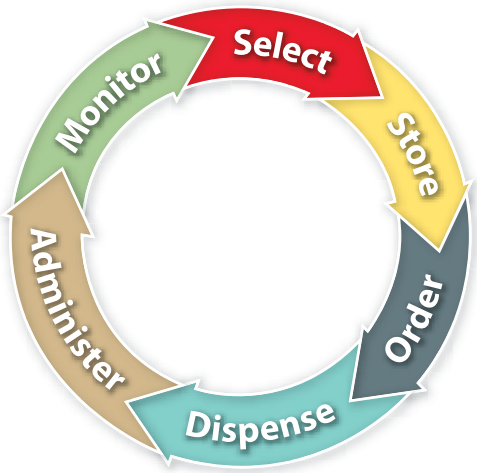
Frequently asked questions

Medication management in nuclear medicine

Medication Management



All regulatory agencies and accreditation organizations define radiopharmaceuticals as medications.

The pharmacy director has oversight responsibility for their use which must comply with applicable medication management standards. These standards encompass all aspects of drug use from selection to monitoring to ensure patient safety.

These questions and answers focus on aspects of the medication use cycle in nuclear medicine that includes storing, ordering, dispensing, administering, and monitoring.

Pharmacy director involvement

Q **Historically, radiopharmaceuticals were managed by the radiology director or the nuclear medicine physician, why has this changed?**

A *All Centers for Medicare and Medicaid Services (CMS) deemed accreditation organizations define radiopharmaceuticals as medications. The pharmacy director is responsible for drug use within the hospital due to specific standards established by accreditation organizations based on CMS Hospital Conditions of Participation (CoPs). These organizations include The Joint Commission (TJC), DNV Healthcare, and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP).*

Q **What are some of the possible areas the pharmacy director may be involved with in the nuclear medicine department?**

A *Under medication management standards, typical areas of interest for the pharmacy director include: select, store, administer, dispense, order, and monitor.*

Store and secure

Q **Why would the pharmacy director be concerned with radiopharmaceutical storage?**

A *The location and condition of drug storage are aspects of medication management that are the oversight responsibilities of the pharmacy director. The pharmacy director would likely review with the nuclear medicine staff the RAM license storage requirements and any written policies to ensure compliance with applicable medication management and other standards.*

Q **How would unit dose radiopharmaceutical storage differ from other pharmaceuticals?**

A *The majority of hospitals use a contracted nuclear pharmacy to provide unit or multi-dose radiopharmaceuticals. Unit dose radiopharmaceuticals are delivered to the hot lab in individually shielded syringes, appropriately labeled, ready for patient administration. Multi-dose radiopharmaceuticals are delivered in vials. Both are secured and stored in the hot lab as specified in the RAM license. Most unit dose radiopharmaceuticals have a beyond-use-date (BUD) of less than 24 hours.*

Q **What measures should be taken to secure radiopharmaceuticals to comply with medication management standards?**

A *All radiopharmaceuticals should be appropriately labeled and stored in the hot lab which is a secured limited access area. Since they are radioactive, they are stored in lead or tungsten shielded containers to protect the nuclear medicine staff from radiation hazards.*

Q **Since radiopharmaceuticals are generally not narcotics, why would the pharmacy director be concerned with their security?**

A *Radiopharmaceuticals are legend drugs that require a prescription and any loss may raise questions of drug diversion or questions about safety. The only commercially available radiopharmaceutical that is a Schedule 2 substance is DaTScan™ (I-123 ioflupane) that requires a DEA permit for its handling or administration. The pharmacy and nuclear medicine departments should collaborate on policies and procedures for the purchase, storage, disposal and use of DaTScan™ (I-123 ioflupane).*

USP<795> and USP<797>

Q **Why would the pharmacy director be concerned with USP<797> compliance in the nuclear medicine department?**

A *The safe preparation of all medications used in the hospital is the responsibility of the pharmacy director under medication management standards. Pharmacy directors should be aware of the unique USP<797> requirements for both radiopharmaceutical compounding in the hospital and in commercial nuclear pharmacies.*

Q **How does USP<797> impact how radiopharmaceuticals are prepared in the nuclear medicine department?**

A *Most nuclear medicine departments contract with a nuclear pharmacy to receive patient-specific unit dose radiopharmaceuticals. The contracted nuclear pharmacy must be compliant with USP<797> requirements in terms of preparing radiopharmaceuticals. The nuclear medicine department should have on file written statements of compliance from all the nuclear pharmacies they currently use. The hospital must have a process to review and approve the use of contracted services, such as that of an external nuclear pharmacy.*

Q **Why is it necessary to have a written statement of compliance with USP<795> (non-sterile pharmaceuticals) and USP<797> (sterile pharmaceuticals) requirements from outsourced nuclear pharmacies?**

A *All outsourced compounders, including nuclear pharmacies, must comply with USP<795> and <797> and should provide written documentation verifying compliance. This documentation should be kept on file in the nuclear medicine department and as directed by the director of pharmacy. If the pharmacy director does a site inspection of the contracted nuclear pharmacy, he/she should be aware of unique USP<797> requirements for the preparation of radiopharmaceuticals by commercial nuclear pharmacies.*

Q **If a nuclear medicine department uses a molybdenum-99 generator and/or bulk technetium to prepare 'cold kits', is this activity under the oversight of the pharmacy director?**

A *Yes. The pharmacy director is responsible to help ensure that all medications compounded or prepared in the hospital meet USP<795> and <797> requirements, including radiopharmaceuticals. CMS and accreditation organizations consider this "in house compounding" of radiopharmaceuticals, and specific information is required to comply with regulatory and accreditation requirements.*

USP<795> and USP<797> ***continued on the next page ...***

Q **How is the on-site after-hours preparation of radiopharmaceuticals impacted by USP<797> requirements?**

A *Nuclear medicine departments may receive non-patient specific isotopes and 'cold kits' for onsite after-hours preparation of unit dose radiopharmaceuticals under the USP<797> immediate use provisions. Immediate use permits the nuclear medicine technologist to prepare a kit on the countertop if there are fewer than two punctures into a septum outside an ISO 5 air environment and the preparation is used for only one patient within one hour of compounding and the remainder is discarded.*

Q **How is the routine on-site preparation of radiopharmaceuticals impacted by USP<797> requirements?**

A *The nuclear medicine department may use non-patient specific isotopes, bulk technetium-99m, or a molybdenum-99 generator for the routine onsite compounding of unit doses using 'cold kits.' If these unit doses are not prepared under the USP<797> immediate use provisions then the pharmacy director must ensure that full training, environment controls, cleaning, garbing, personal validation, etc. are in place to be compliant with USP<797> and medication management standards.*

Order and deliver

Q **Why would the pharmacy director be concerned with the ordering and delivery of radiopharmaceuticals?**

A *Radiopharmaceuticals are medications subject to medication management standards that fall under the purview of the pharmacy director. The ordering and delivery of medications are aspects of medication management.*

Q **How does radiopharmaceutical ordering differ from other pharmaceuticals?**

A *Radiopharmaceuticals are prescription drugs but they are also radioactive. Their use must also comply with Nuclear Regulatory Commission (NRC) or local agreement state regulations. The NRC or local agreement state issues a radioactive materials (RAM) license to the nuclear medicine department that specifies which isotopes may be possessed, the quantity limits for each, storage requirements, and use. The ordering of isotopes or radiopharmaceuticals must be in conformity with RAM license specifications.*

Q **How would the pharmacy director oversee the radiopharmaceutical ordering process?**

A *The majority of nuclear medicine departments have a contractual relationship with a licensed nuclear pharmacy. The nuclear pharmacy would have a copy of the RAM license of the nuclear medicine department on file and would dispense radiopharmaceuticals per physician prescriptions or orders in compliance with the RAM license. The pharmacy director may consult with the nuclear medicine team to review existing contracts with nuclear pharmacies and may conduct a site inspection of the nuclear pharmacy to verify quality assurance is provided as is expected from other sterile compounders.*

Q **How does the delivery of radiopharmaceuticals differ from other pharmaceuticals?**

A *In general, radiopharmaceutical deliveries are made directly to the nuclear medicine department hot lab by the contracted nuclear pharmacy delivery person. The first delivery of the day is usually prior to the arrival of the nuclear medicine staff and secured properly. This allows the staff to begin patient imaging as soon as possible, to help ensure an efficient department workflow.*

Q **What radiopharmaceutical delivery procedures would be of interest to the pharmacy director?**

A *The pharmacy director may review the written policy on file in the nuclear medicine department for the delivery of radiopharmaceuticals to ensure compliance with medication management standards. The policy may define: 1) security of the medications, 2) authorized personnel with access to the hot lab, 3) their roles and their responsibilities, and 4) processes to ensure the safe handling, delivery and storage of the radiopharmaceuticals.*

Q **Is it necessary to have security personnel escort the nuclear pharmacy delivery person?**

A *In general, accreditation standards do not specifically require that hospital staff escort the nuclear pharmacy delivery person. Standards do specify that the hospital should minimize risks associated with the delivery of radiopharmaceuticals. In addition, NRC and agreement states do not specifically require escorted deliveries. Instead, hospitals should have a written plan that defines how the hospital will ensure constant supervision of the radiopharmaceuticals to a secured area. NRC and agreement states require that the nuclear pharmacy delivery person must have specific training to ensure the safe handling of radiopharmaceuticals. The pharmacy director may wish to verify this training process with the contracted nuclear pharmacy. To escort or not is the decision of the hospital and is not specifically required by the NRC, agreement states, or accreditation organizations.*[1]

Disposal of radiopharmaceuticals

Q **Why would the pharmacy director be concerned with radiopharmaceutical disposal?**

A *Medication disposal is part of medication management under the purview of the pharmacy director. The pharmacy director may likely review the written procedures in the nuclear medicine department for the disposal of radiopharmaceuticals.*

Q **How does the disposal of radiopharmaceuticals differ from pharmaceuticals?**

A *Radiopharmaceuticals are radioactive and their disposal must comply with NRC and local agreement state regulations. If a contracted nuclear pharmacy is used, radiopharmaceuticals that are not usable may be returned to the nuclear pharmacy for disposal in compliance with all NRC and Department of Transportation (DOT) regulations.*

Q **What other processes may be used for the disposal of radiopharmaceuticals?**

A *In some cases, the nuclear medicine department may segregate radiopharmaceuticals by half-life, store them in the hot lab until the radiation has decayed to background levels, and once the decay is complete, the spent radiopharmaceuticals are usually comingled with the hospital medical waste disposal stream.*

Summary

The oversight responsibility of the pharmacy director includes the safe use of radiopharmaceuticals. Collaboration between the pharmacy and nuclear medicine departments is the most effective way to ensure compliance with applicable accreditation standards and other regulatory requirements.

A recommended first step is to initiate a formal P&T Committee review of medications, both radiopharmaceuticals and adjunct pharmaceuticals, used in nuclear medicine. This review should ensure that only FDA-approved radiopharmaceuticals are used.

Additional collaboration between the pharmacy and nuclear medicine departments may include a review of the drug aspects of clinical protocols, review of existing policies and procedures to identify and resolve any process gaps, and a review of existing agreements with all outsourced nuclear pharmacy providers.

Visit cardinalhealth.com/nucmedcompliance for additional resources to assist with medication management compliance in nuclear medicine or contact your local Cardinal Health nuclear pharmacy.

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References:

1. Joint Commission Perspectives®, "Ensuring the Safety and Security of Radioactive Materials", July 2012, Volume 32, Issue 7, pp 8-10.

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