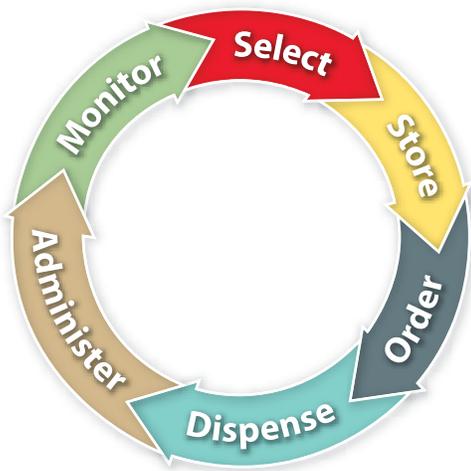


Frequently asked questions

Radiopharmaceuticals as medication

Formulary and FDA-approved radiopharmaceuticals

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 the role of hospital formulary, the use of FDA-approved radiopharmaceuticals, and use of adjunct pharmaceuticals in nuclear medicine.

Pharmacy director involvement

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

A Radiopharmaceuticals are now recognized by all accreditation organizations as medications. The pharmacy director is responsible for all aspects of drug use within the hospital based on specific standards established by accreditation organizations based on Centers for Medicare and Medicaid Services (CMS) Hospital Conditions of Participation (CoPs).

Q Which accreditation agency does this include?

A All CMS deemed accreditation organizations — 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: selection, storage, ordering, dispensing, administering and monitoring of drugs. In particular the pharmacy director may be interested in the formulary status of radiopharmaceuticals, review of clinical protocols, review of department policies, and the review of the contracted or outsourced nuclear pharmacy(s) to verify quality assurance.

Formulary and FDA-approved radiopharmaceuticals

Q What role does hospital formulary play?

A A formulary is a list of drugs that are reviewed and approved for use by the Pharmacy and Therapeutics (P&T) Committee and it is maintained by the pharmacy department. Medication management standard MM.02.01.01 requires that all medications used in the hospital are included on the hospital formulary.¹ Radiopharmaceuticals are medications and should be included on formulary.

Q What role does the radioactive materials (RAM) license play?

A Radiopharmaceuticals are radioactive materials regulated by the Nuclear Regulatory Commission and Agreement States. The RAM license lists the radioisotopes the hospital is approved to use and the quantities allowed. The hospital formulary should conform to the hospital RAM license.

Q What information would the pharmacy director need to initiate the formulary process for radiopharmaceuticals?

A The pharmacy director, in collaboration with the nuclear medicine staff, would identify all FDA-approved radiopharmaceuticals currently being used, their FDA-approved indications, their existing off-label uses, and submit them with appropriate clinical information for P&T Committee review. The nuclear medicine department should notify the pharmacy director if non-FDA approved radiopharmaceuticals are being compounded by the outsourced nuclear pharmacy. You can obtain a list of all commercially available FDA-approved radiopharmaceuticals, their generic and brand names, approved manufacturers, and approved indications from your local Cardinal Health nuclear pharmacy or on [cardinalhealth.com/nucmedcompliance](https://www.cardinalhealth.com/nucmedcompliance).

FDA-approved radiopharmaceuticals

Q Aren't all radiopharmaceuticals used in the nuclear medicine department FDA-approved?

A Using a licensed nuclear pharmacy does not always guarantee the use of FDA-approved radiopharmaceuticals. Some nuclear pharmacies dispense non-FDA approved radiopharmaceuticals in contravention of FDA Compounding Guidelines 460.200. The legitimate need to compound a modified version of a commercially available radiopharmaceutical for individual patient concerns or due to extended shortages is extremely rare in nuclear medicine.²

Q Are there risks associated with the use of compounded non-FDA approved radiopharmaceuticals?

A Yes, if the nuclear medicine department uses radiopharmaceuticals that originate from sources other than the FDA-approved manufacturer(s) then patient care and the hospital's accreditation may be at risk. Also, reimbursement may be impacted depending on how they are submitted for reimbursement.³

Q Are there resources available to identify FDA-approved radiopharmaceuticals and approved indications?

A Cardinal Health maintains a list of commercially available FDA-approved radiopharmaceuticals available at cardinalhealth.com/nucmedcompliance. The Orange Book, an online resource provided by the Food and Drug Administration, identifies FDA-approved medications and all manufacturers holding an approved New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Investigational New Drug Application (IND).⁴

Adjunct pharmaceuticals

Q Does medication management impact the use of adjunct pharmaceuticals used in nuclear medicine?

A Certain nuclear medicine procedures require the use of adjunct medications such as: adenosine, dipyridamole, regadenoson, dobutamine, furosemide, and captopril. The pharmacy director is responsible for the use of all medications in the hospital including adjunct pharmaceutical use in nuclear medicine. The pharmacy director may consult with nuclear medicine colleagues to identify which adjunct pharmaceuticals are being used and if they appear on the hospital formulary.

Q What if any issues may be involved with the use of adjunct pharmaceuticals in nuclear medicine?

A Hospitals prefer that the nuclear medicine department order these drugs through the hospital pharmacy rather than with the contracted nuclear pharmacy. However, the nuclear medicine team, working with the pharmacy director, should have a written and approved policy on file to help ensure compliance with medication management standards when ordering, storing, and administering adjunct pharmaceuticals supplied by a contracted nuclear pharmacy.

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 the medications used in nuclear medicine, both radiopharmaceuticals and adjunct pharmaceuticals. This may include verification from the contracted nuclear pharmacy that it dispenses commercially available FDA-approved radiopharmaceuticals. A review of the RAM license is necessary to ensure agreement between the hospital formulary and the approved possession limits for the nuclear medicine department.

For a current list of FDA-approved radiopharmaceuticals, easily accessible package inserts and material safety data sheets to help with the formulary process, visit cardinalhealth.com/nucmedcompliance or contact your local Cardinal Health nuclear pharmacy.

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