Nuclear Pharmacy
Content Outline

Definition and Target Audience

Nuclear Pharmacy seeks to improve and promote public health through the safe and effective use of radioactive drugs for diagnosis and therapy.

A nuclear pharmacist specializes in the procurement, preparation, compounding, dispensing, and distribution of Radiopharmaceuticals, as well as the regulatory aspects governing these processes. In addition, the nuclear pharmacist serves as the medication expert within the healthcare team regarding clinical aspects of radiopharmaceuticals and non-radioactive drugs used in patient care.

Domains

1. Procurement, Storage, and Handling (16% of examination)
2. Preparation, Compounding, Repackaging, End-product Testing, and Dispensing (40% of examination)
3. Personnel, Equipment and Environmental Requirements (16% of examination)
4. Licensing and Occupational Safety (16% of examination)
5. Drug Information and Professional Consultation (12% of examination)

Domain 1: Procurement, Storage, and Handling (16%)

Task 1. Define material specifications such as quantity, quality, concentration, availability, calibration, expiration, and manufacturer.

Knowledge of:
  a. Product specifications (e.g., quantity, concentration, availability, calibration, expiration, manufacturer, contaminants, ingredients, and relative cost)
  b. Inventory management of radiopharmaceuticals (e.g., anticipating adequate on-hand supply, possession limits)
  c. Knowledge of expirations and reasons for them

Task 2. Confirm appropriate shipping and storage conditions of materials.

Knowledge of:
  a. Appropriate condition of materials upon receipt (e.g., temperature, light sensitivity, humidity)
  b. Receipt requirements for radioactive and non-radioactive products, supplies, and other materials
  c. Consequences of improper shipping (e.g., material stability, sterility, suitability for use, temperature excursions during shipping)
  d. Storage requirements for radiopharmaceuticals, adjunct agents, components, and supplies, including the consequences of improper storage
  e. Appropriate shielding requirements for radiopharmaceuticals and other radioactive materials

Task 3. Assess acceptability of materials for use.

Knowledge of:
  a. USP standards, other regulations, and guidance documents governing products, supplies, and other materials needed for nuclear pharmacy practice (e.g., garbing material, media, disinfectant, solvents)
  b. Required documentation and record retention to ensure traceability of all drugs and related components (e.g.,
certificates of analysis / compliance)

Domain 2: Preparation, Compounding, Repackaging, End-product Testing, and Dispensing (40%)

Task 1. Review orders for radiopharmaceuticals, devices, and adjunct agents for appropriateness.

Knowledge of:
   a. Indications, dosage recommendations, route of administration (pursuant to manufacturer's prescribing information) and use environment for radiopharmaceuticals and adjunct agents
   b. Physical, chemical and kinetic properties, mechanisms of localization, and pharmacologic and therapeutic effects of radiopharmaceuticals and adjunct agents
   c. Half-lives, modes of decay, and emission energies associated with radiopharmaceuticals

Task 2. Select products, components, supplies, and equipment needed to prepare and compound prescription orders.

Knowledge of:
   a. Ingredients, components, and preparation techniques (such as heating or incubation times) of radiopharmaceuticals, including the purpose of each
   b. Formulation factors that may adversely affect preparation and use
   c. Containers, closures, and other packaging materials used in the compounding of radiopharmaceuticals
   d. Physical and chemical incompatibilities that impact radiopharmaceutical preparation and use

Task 3. Elute radionuclide generators, and end-product test the generator eluate.

Knowledge of:
   a. Physical and chemical characteristics of available radionuclide generators (e.g., Mo-99 including HSA and LSA; Ge-68; Sr-82)
   b. Radionuclide generator operation, kinetics, and elution techniques
   c. Minimal acceptable release criteria for eluate
   d. Factors that affect the stability and shelf-life of reagent kits and radiopharmaceuticals, including radionuclidic, radiochemical, and chemical contamination

Task 4. Prepare sterile and non-sterile medications and devices using appropriate aseptic and radiation control techniques.

Knowledge of:
   a. Concepts, techniques, and parameters required for optimal or essential preparation of radiopharmaceuticals (e.g., prescribing information recommended volumes, activities, pH, temperature, order of mixing, excipients, specific activity)
   b. Approved blood labeling procedures and precautions for blood-borne pathogens
   c. Appropriate documentation supplied by the vendor (e.g., prescribing information and operator guides)
   d. General chemistry and radiolabeling preparation methods (e.g., redox reactions, chelation, substitution, radioiodination) as well as methods for optimizing yield of radiolabeled compounds

Task 5. Compound sterile and non-sterile preparations according to professional standards and regulations.

Knowledge of:
   a. Concepts, techniques, and parameters required for optimal or essential custom compounding of radiopharmaceuticals (e.g., prescribing information recommended volumes, activities, pH, temperature, order of mixing, excipients, specific activity)
   b. Custom compounding blood labeling procedures and precautions for blood-borne pathogens
   c. Documentation supplied by the vendor(s) supporting compounding (e.g., clinical research, peer-reviewed published literature)
   d. General chemistry and radiolabeling compounding methods (e.g., redox reactions, chelation, substitution, radioiodination) as well as methods for optimizing yield of radiolabeled compounds
Task 6. Perform appropriate end-product testing for radiopharmaceutical preparations.

Knowledge of:
   a. Methods and principles for performing appropriate and validated end-product testing
   b. Release criteria for radiopharmaceuticals
   c. Factors that affect the stability and shelf-life of reagent kits and radiopharmaceuticals, including radionuclidic, radiochemical, and chemical contamination
   d. USP standards for drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials

Task 7. Verify the identity, integrity, concentration, container labeling, and proper storage of preparations.

Knowledge of:
   a. Regulatory requirements for container labeling of radiopharmaceuticals and adjunct agents
   b. Proper storage conditions of prepared radiopharmaceuticals pursuant to manufacturer’s package insert
   c. Applicable regulatory requirements pertaining to record keeping and traceability of radiopharmaceuticals and adjunct agents
   d. Preparation verification methods and applications

Domain 3: Personnel, Equipment and Environmental Requirements (16%)

Task 1. Perform appropriate quality assurance procedures for nuclear pharmacy personnel, instrumentation, equipment, and environment.

Knowledge of:
   a. Regulatory requirements regarding the possession, use, and quality assurance testing of radiologic instruments, equipment, and devices (e.g., dosimeter, dose calibrator, survey meter, scintillation detector)
   b. Appropriate dose calibrator testing procedures
   c. The reasons for use and mechanics of use for the quality assurance testing of radiologic instruments, equipment, and devices used (e.g., dosimeter, dose calibrator, survey meter, scintillation detector)
   d. Regulatory requirements and standards regarding personnel aseptic performance (e.g., media fill testing, gloved fingertip sampling, hand hygiene, garbing assessment)

Task 2. Ensure appropriate processes are in place for maintenance of sterility of aseptic preparations.

Knowledge of:
   a. Appropriate cleaning and maintenance of primary and secondary engineering controls


Knowledge of:
   a. Evaluation of equipment documentation (e.g., anomalous testing results, testing result trending, documentation of appropriate response)
   b. Evaluation of environmental documentation (e.g., microbial identification and susceptibility paired with disinfecting agent selection and identifying potential routes of incursion)
   c. Evaluation of equipment documentation (e.g., anomalous testing results, testing result trending, documentation of appropriate response)

Task 4. Ensure facility compliance with applicable USP standards.

Knowledge of:
   a. Regulatory requirements and standards regarding primary and secondary engineering controls (e.g., testing, certification, and equipment specifications)
   b. Regulatory requirements and standards regarding the use, maintenance, and testing of environmental controls (e.g., pressure gradients, air changes per hour, viable / non-viable testing)
Domain 4: Licensing and Occupational Safety (16%)

Task 1. Ensure compliance with radioactive materials regulations and license requirements for radiation and radiopharmaceuticals.

Knowledge of:
   a. Radiation protection principles, techniques, and standards (e.g., NRC)
   b. Regulatory requirements related to the receipt, storage, handling, and medical use of radioactive materials
   c. Regulatory requirements governing the storage, possession, testing, and use of sealed sources
   d. Radioactive material license designation and scope of practice in both clinical and investigational radiopharmaceutical settings
   e. Regulatory requirements for effluent release and derived air concentration (e.g., NRC, EPA)

Task 2. Ensure compliance with regulatory requirements concerning handling, packaging, labeling, and transporting radioactive, biohazardous, and chemical substances and waste.

Knowledge of:
   a. Regulatory requirements (e.g., IATA/ICAO and DOT) concerning packaging, labeling, and transportation of dangerous goods, (e.g., radioactive material, biohazardous material, compressed gas)
   b. Regulatory requirements governing the storage and disposal of waste materials

Task 3. Assure adequate development and application of policies and procedures for a safe working environment.

Knowledge of:
   a. Regulatory requirements for providing a safe working environment (e.g., NRC, CDC, OSHA, NFPA)
   b. Allowable personal exposure limits in normal and special populations (including units of measurement, TEDE, general public, etc.)
   c. Evaluation of shielding effectiveness using attenuation coefficients and HVLs

Task 4. Assure adequate development and application of policies and procedures in regulatory situations and medical events.

Knowledge of:
   a. Regulatory requirements governing the handling and reporting of radiation incidents (e.g., medical events, spills, dispensing errors, overexposures)
   b. Procedures used in response to radiation incidents
   c. Scientific basis for the operation of equipment or devices used to measure radioactivity and radiation exposure rates

Task 5. Assure adequate development and application of policies and procedures for security of the facility, radioactive materials, medications, and supplies.

Knowledge of:
   a. Regulatory requirements and standards governing the security of the facility, radioactive materials, medications, and supplies (e.g., NRC)

Domain 5: Drug Information and Professional Consultation (12%)

Task 1. Evaluate factors affecting patient outcomes in nuclear medicine procedures.

Knowledge of:
   a. Radiopharmaceutical kinetics, biodistribution, and image acquisition or therapy application
   b. Clinical significance of factors that alter radiopharmaceutical kinetics, biodistribution, and image acquisition or therapy (e.g., radiopharmaceutical impurities, concomitant medication use, and disease or pathology)
   c. Requirements and techniques for the administration of radiopharmaceuticals and adjunct agents
Task 2. Consult with practitioners to ensure optimal utilization of radiopharmaceuticals and adjunct agents in patient care.

Knowledge of:

a. Role of nuclear medicine procedures relative to other modalities in the diagnosis or management of specific disorders (e.g., acceptable use criteria, relative cost, accessibility, radiopharmaceutical reimbursement)
b. Nuclear medicine procedures used to monitor the safety, efficacy, and toxicity of therapeutic drug regimens or other therapeutic, surgical, or interventional procedures
c. Mechanisms by which selected medications can enhance the utility, safety, or efficacy of specific radiopharmaceuticals
d. Patient preparation to improve the safety or efficacy of the nuclear medicine procedure (e.g., fasting, hydration, sedation, thyroid blockade)
e. Education of patients and other health-care professionals

Task 3. Provide information on the prevention, recognition, treatment, reporting, and analysis of adverse drug events.

Knowledge of:

a. Mechanisms, symptoms, incidence, and management of reported adverse drug events to radiopharmaceuticals and adjunct agents

Task 4. Report information regarding drug defects or clinical issues associated with the use of radiopharmaceuticals and adjunct agents.

Knowledge of:

a. Drug defects, and resulting clinical issues, (e.g., identification, investigation, reporting systems)

Task 5. Provide information about health physics and radiation safety compliance.

Knowledge of:

a. Patient release criteria post-radiopharmaceutical administration (e.g., caregivers, members of public)
b. Concepts of radiation safety (e.g., dose, exposure, time, pharmacokinetics, routes of excretion)
c. Radiation biology, nuclear physics, instrumentation, and radiation safety to provide education to the public (e.g., patients, employees, administrative staff, families, and community organizations)

Task 6. Determine proper dose of radiopharmaceuticals and adjunct pharmaceuticals based on patient-specific parameters.

Knowledge of:

a. Procedure selection factors such as patient-specific parameters and study sequencing
b. Pregnancy and nursing mother guidelines for nuclear medicine procedures
c. Organ systems and pathophysiologic disorders in patients administered radiopharmaceuticals and adjunct agents