BOARD OF PHARMACY SPECIALTIES
NUCLEAR PHARMACY SPECIALIST CERTIFICATION
CONTENT OUTLINE/CLASSIFICATION SYSTEM
APPROVED SEPTEMBER 2018/FOR USE ON FALL 2019 EXAMINATION AND FORWARD

UNDERSTANDING THE CONTENT OUTLINE/CLASSIFICATION SYSTEM

The following domains, tasks and knowledge statements were delineated by the BPS Nuclear Pharmacy Practice Analysis Taskforce and validated through a role delineation study. The proportion of examination items allotted to each domain was determined through analysis and discussion of the results of the role delineation study by the BPS Nuclear Pharmacy Practice Analysis Taskforce and approved by the BPS Board of Directors.

Each of the major areas/domains of BPS Nuclear Pharmacy practice noted below will be tested. Questions will not be grouped by domain on the exam. Rather, items testing each domain are distributed throughout the total examination. Please note this examination will SAMPLE a candidate's knowledge rather than trying to test all of his/her knowledge. Examination items will address problems and situations reflective of the full range of practice.

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

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

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

Task 3: Assess acceptability of materials for use.

Knowledge of:

1. Product specifications (e.g., quantity, concentration, availability, calibration, expiration, manufacturer, contaminants, ingredients, and relative cost)
2. 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)
3. Inventory management of radiopharmaceuticals (e.g., anticipating adequate on-hand supply, possession limits)
4. Appropriate condition of materials upon receipt (e.g., temperature, light sensitivity, humidity)
5. Receipt requirements for radioactive and non-radioactive products, supplies, and other materials
6. Consequences of improper shipping (e.g., material stability, sterility, suitability for use, temperature excursions during shipping)
7. Required documentation and record retention to ensure traceability of all drugs and related components (e.g., certificates of analysis / compliance)
8. Storage requirements for radiopharmaceuticals, adjunct agents, components, and supplies, including the consequences of improper storage

9. Appropriate shielding requirements for radiopharmaceuticals and other radioactive materials
10. Knowledge of expirations and reasons for them.

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

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

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

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

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

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

Task 6: Perform appropriate end-product testing for radiopharmaceutical preparations.

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

Knowledge of:

1. Indications, dosage recommendations, route of administration, proper storage (pursuant to manufacturer's prescribing information) and use environment for radiopharmaceuticals and adjunct agents
2. Ingredients, components, and preparation techniques (such as heating or incubation times) of radiopharmaceuticals, including the purpose of each
3. Physical, chemical and kinetic properties, mechanisms of localization, and pharmacologic and therapeutic effects of radiopharmaceuticals and adjunct agents
4. Half-lives, modes of decay, and emission energies associated with radiopharmaceuticals
5. Appropriate documentation supplied by the vendor (e.g., prescribing information and operator guides)
6. Physical and chemical characteristics of available radionuclide generators (e.g., Mo-99 including HSA and LSA; Ge-68; Sr-82)
7. Radionuclide generator operation, kinetics, and elution techniques
8. Minimal acceptable release criteria for eluate
9. Factors that affect the stability and shelf-life of reagent kits and radiopharmaceuticals, including radionuclidic, radiochemical, and chemical contamination
10. Formulation factors that may adversely affect preparation and use
11. 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)
12. Blood labeling procedures and precautions for blood-borne pathogens
13. General chemistry and radiolabeling methods (e.g., redox reactions, chelation, substitution, radioiodination) as well as methods for optimizing yield of radiolabeled compounds

14. Containers, closures, and other packaging materials used in the compounding of radiopharmaceuticals
15. Physical and chemical incompatibilities that impact radiopharmaceutical preparation and use
16. Preparation verification methods and applications
17. USP standards for drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials
18. Methods and principles for performing appropriate and validated end-product testing
19. Release criteria for radiopharmaceuticals
20. Regulatory requirements for container labeling of radiopharmaceuticals and adjunct agents
21. Proper storage conditions of prepared radiopharmaceuticals pursuant to manufacturer's package insert
22. Applicable regulatory requirements pertaining to record keeping and traceability of radiopharmaceuticals and adjunct agents

Domain 3: Equipment and Environmental Requirements (16%)

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

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

Task 3: Maintain applicable quality assurance records to identify trends and document compliance.

Task 4: Ensure facility compliance with applicable USP standards.

Knowledge of:

1. 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)
2. Regulatory requirements and standards regarding primary and secondary engineering controls (e.g., testing, certification, and equipment specifications)
3. 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)
4. Appropriate cleaning and maintenance of primary and secondary engineering controls
5. Regulatory requirements and standards regarding personnel aseptic performance (e.g., media fill testing, gloved fingertip sampling, hand hygiene, garbing assessment)
6. Evaluation of equipment documentation (e.g., anomalous testing results, testing result trending, documentation of appropriate response)
7. Evaluation of environmental documentation (e.g., microbial identification and susceptibility paired with disinfecting agent selection and identifying potential routes of incursion)
8. Appropriate dose calibrator testing procedures, (e.g., survey meter daily checks)
9. 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)

Domain 4: Licensing and Occupational Safety (16%)

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

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

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

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

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

Knowledge of:

1. Radiation protection principles, techniques, and standards (e.g., NRC)
2. Evaluation of shielding effectiveness using attenuation coefficients and HVLs
3. Regulatory requirements related to the receipt, storage, handling, and medical use of radioactive materials
4. Regulatory requirements governing the storage, possession, testing, and use of sealed sources
5. Scientific basis for the operation of equipment or devices used to measure radioactivity and radiation exposure rates
6. Regulatory requirements (e.g., FAA and DOT) concerning packaging, labeling, and transportation of dangerous goods, (e.g., radioactive material, biohazardous material, compressed gas)
7. Regulatory requirements governing the storage and disposal of waste materials
8. Regulatory requirements for providing a safe working environment (e.g., NRC, CDC, OSHA, NFPA)
9. Regulatory requirements for effluent release and derived air concentration (e.g., NRC, EPA)
10. Regulatory requirements governing the handling and reporting of radiation incidents (e.g., medical events, spills, dispensing errors, overexposures)
11. Procedures used in response to radiation incidents
12. Regulatory requirements and standards governing the security of the facility, radioactive materials, medications, and supplies (e.g., NRC)
13. Knowledge of radioactive material license designation and scope of practice in both clinical and investigational radiopharmaceutical settings.
14. Knowledge of allowable personal exposure limits in normal and special populations (including units of measurement, TEDE, general public, etc.)

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

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

Task 2: Consult with practitioners to ensure optimal utilization of radiopharmaceuticals and adjunct agents in patient care.

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

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

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

Task6: Determine proper dose of radiopharmaceuticals and adjunct pharmaceuticals based on patient-specific parameters.

Knowledge of:

1. Radiopharmaceutical kinetics, biodistribution, and image acquisition or therapy application
2. 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)
3. Procedure selection factors such as patient-specific parameters and study sequencing
4. Requirements and techniques for the administration of radiopharmaceuticals and adjunct agents
5. Organ systems and pathophysiologic disorders in patients administered radiopharmaceuticals and adjunct agents
6. 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)
7. Nuclear medicine procedures used to monitor the safety, efficacy, and toxicity of therapeutic drug regimens or other therapeutic, surgical, or interventional procedures
8. Mechanisms by which selected medications can enhance the utility, safety, or efficacy of specific radiopharmaceuticals
9. Patient preparation to improve the safety or efficacy of the nuclear medicine procedure (e.g., fasting, hydration, sedation, thyroid blockade)
10. Pregnancy and nursing mother guidelines for nuclear medicine procedures
11. Mechanisms, symptoms, incidence, and management of reported adverse drug events to radiopharmaceuticals and adjunct agents
12. Adverse drug events, drug defects, and resulting clinical issues, (e.g., identification, investigation, reporting systems)
13. Patient release criteria post-radiopharmaceutical administration (e.g., nursing mother, caregivers, members of public)
14. Concepts of radiation safety (e.g., dose, exposure, time, pharmacokinetics, routes of excretion, pregnancy, nursing mother)
15. Radiation biology, nuclear physics, instrumentation, and radiation safety to provide education to the public (e.g., patients, employees, administrative staff, families, and community organizations)
16. Education of patients and other health-care professionals