

BOARD OF PHARMACY SPECIALITIES

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Content Outline for the NUCLEAR PHARMACY SPECIALTY CERTIFICATION EXAMINATION March 2007

The following domains, subdomains, tasks and knowledge statements were identified by the BPS Specialty Council on Nuclear Pharmacy and validated through a role delineation study, most recently updated in 2007. 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 Specialty Council.

Each of the major areas/domains of Nuclear Pharmacy practice noted below will be tested. Questions will not be grouped by domain. Items testing each domain are distributed throughout the total examination. Please note that this examination will **SAMPLE** a candidate's knowledge rather than trying to test all of his/her knowledge.

Domain 1: Drug Order Provision: (66% of the examination)

Subdomain A. Procurement (8% of the examination)

Task:

1. Determine product specifications and inventory (such as quantity, concentration, date and time of delivery, calibration time, and specific delivery instructions) for both radioactive and nonradioactive materials

Knowledge of:

- 01 Cost, source, and availability/delivery of radiopharmaceuticals, ancillary medications, and related products and services
- 02 Specifications and requirements related to placement of product orders, including manufacturer or regulatory requirements
- 03 USP standards for pharmaceutical ingredients, precursors, reagents, tests and assays, vendor certificates of purity or physical/chemical means of identification and other materials
- 04 Radiopharmaceutical class, including regulatory status, vendors, availability/delivery, formulation, components (e.g., antioxidants, stabilizing agents, buffers), expiration, storage
- 05 Analytical supplies and other materials needed for radiopharmaceuticals quality control procedures (e.g., solvents, chromatography strip/columns, sterility test media, endotoxin test media)
- 06 Supplies needed to practice nuclear pharmacy including needles and syringes, disinfectants, gloves, sharps containers, and other disposable/consumable supplies

- 07 Use patterns (e.g., amounts/rate of use) of radioactive and nonradioactive drugs, components and supplies

Task:

2. Store and maintain both radioactive and nonradioactive material to maintain drug integrity and security of material using safe handling procedures

Knowledge of:

- 01 Storage requirements for radioactive and nonradioactive drugs, components, and supplies (e.g., light, temperature, and humidity)
02 Consequences of improper storage conditions on the physical and/or chemical integrity of the material
03 Shielding requirements for radioactive materials
04 Federal regulations and standards regarding inspections of drug storage areas (e.g., Joint Commissions, JCAHO, ASHP, USP, APhA)

Subdomain B. Compounding (26% of the examination)

Task:

1. Review prescription orders for radiopharmaceuticals and interventional agents

Knowledge of:

- 01 Indications and dosage recommendations for radiopharmaceuticals and interventional agents based on patient specific characteristics

Task:

2. Select products, components, supplies, and equipment for compounding prescription orders

Knowledge of:

- 01 Ingredients/components of reagent kits and radiopharmaceuticals, including the purpose of each
02 Record-keeping procedures to ensure traceability of all drugs and related components for manufacturer or FDA recall procedures
03 Physiochemical and kinetic properties, mechanisms of localization, pharmacologic and/or therapeutic effects of radiopharmaceuticals and ancillary medications
04 Half-lives, modes of decay, gamma ray, etc., constants associated with clinically-used radionuclides
05 Factors that affect the stability and shelf life of reagent kits and radiopharmaceuticals, including radionuclidic contamination
06 Formulation factors that might adversely affect product performance
07 Compounding concepts, techniques and parameters required for optimal preparation of radiopharmaceuticals (e.g., volumes activities, pH, temperature, order of mixing, excipients, specific activity)
08 General synthetic radiolabeling methods (e.g. redox reactions, chelation, substitution, radioiodination, template synthesis) as well as methods for optimizing yield of radiolabeled product

Task:

3. Compound sterile and non-sterile preparations using appropriate aseptic, biological, and radiation safety techniques

Knowledge of:

- 01 Appropriate aseptic and ALARA techniques
- 02 Professional standards for compounding sterile and non-sterile products
- 03 Blood labeling procedures and universal precautions for blood borne pathogens
- 04 Containers, closures, and other packaging materials used in the compounding and dispensing of radiopharmaceuticals

Task:

4. Elute radionuclide generators for use in radiopharmaceutical preparations

Knowledge of:

- 01 Physical and chemical characteristics of available generators
- 02 Generator kinetics, elution techniques, and quality assurance techniques

Task:

5. Produce accelerator-based radionuclides

Knowledge of:

- 01 USP or other standard and regulations regarding the proper compounding of radiopharmaceuticals
- 02 Physical and chemical characteristics of components including incompatibilities
- 03 Product verification methods and applications
- 04 Components including precursors, reagents, target solutions and gases, containers and closures, transfer lines and membrane filters
- 05 Production methods, including parameters of nuclear reactions

Task:

6. Verify the identity, integrity, concentration, labeling, and proper storage of the final product

Knowledge of:

- 01 USP standards for drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials

Subdomain C. Quality Assurance (9% of the examination)**Task:**

1. Implement and follow procedures and maintains records for radionuclidic purity, radiochemical purity, chemical purity, pH, pharmaceutical integrity (e.g., particle size, isotonicity, sterility, apyrogenicity), biological integrity (e.g., leukocytes, platelets, antibodies), and other characteristics (e.g., specific activity, isomeric purity)

Knowledge of:

- 01 Principles of chemical, radiochemical, and radionuclidic purity and the maximum permissible limits

- 02 Analytical methods used to assess the chemical, radiochemical, and radionuclidic purity of radiopharmaceuticals
- 03 Pharmaceutical integrity (e.g., analytical methods for estimating particle size and number, calculations and analytical methods for determining isotonicity)
- 04 Analytical methods for the determination of biological integrity, including USP tests for sterility and apyrogenicity and the impact on the patient
- 05 Proper storage of quality control materials
- 06 Acceptable results ranges/action levels and reporting protocols

Task:

- 2. Check the function of instruments, equipment, and devices and maintain records as appropriate

Knowledge of:

- 01 Principles of operation and procedures for quality control of the nuclear pharmacy instruments, equipment, and devices
- 02 NRC regulations and standards regarding the possession, use, calibration, and quality control of the instruments, equipment, and devices used in the nuclear pharmacy

Subdomain D. Dispensing (23% of the examination)

Task:

- 1. Determine dosage levels based on patient history, age, weight, body surface area, and/or other factors

Knowledge of:

- 01 Indications and dosage recommendations for radiopharmaceuticals
- 02 Situations when pharmacologic interventions are clinically indicated
- 03 Factors that affect dosage selection as well as methods used to calculate/determine dosages of radiopharmaceuticals for specific patients, including breastfeeding and pregnant patients
- 04 Proper sequencing when multiple imaging procedures or modalities are required as part of a patient's diagnostic workup
- 05 Mechanisms by which selected interventions can enhance the utility, safety, or efficacy of specific nuclear medicine procedures

Task:

- 2. Dispense prescriptions and maintains appropriate records

Knowledge of:

- 01 Applicable rules and regulations pertaining to radiopharmaceutical recordkeeping and traceability
- 02 Healthcare Health Insurance Portability and Accountability Act (HIPAA)

Task:

- 3. Supervise and review the activities of nonpharmacist personnel under the pharmacist's supervision

Knowledge of:

- 01 Current pharmacy law pertaining to supervisory tasks and ancillary staff

Domain 2: Health and Safety: (24% of the examination)

Task:

- 1. Comply with applicable rules and license requirements regarding radiation and radiopharmaceuticals (e.g., ALARA)

Knowledge of:

- 01 Radiation protection principles, techniques, and standards (e.g., those issued by NRC, NCRP, ICRP, OSHA, EPA, or DOT)
- 02 Appropriate shielding techniques as well as attenuation coefficients, half-value layers
- 03 Applicable regulations and standards related to the receipt, storage, handling, clinical application and disposal of radioactive materials used in medical and pharmacy practice
- 04 USP standards for sterility and apyrogenicity, drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials

Task:

- 2. Comply with all applicable regulations concerning packaging, labeling, and transportation of radioactive, biohazardous and hazardous substances

Knowledge of:

- 01 Regulations concerning packaging, labeling, and transportation of radioactive and biohazardous materials from own facility or from other facilities
- 02 Proper procedures and use of equipment necessary to verify that package meets DOT requirements
- 03 OSHA and CDC standards for providing a safe working environment
- 04 Radioactive and biohazardous waste disposal policies and methods

Task:

- 3. Implement and maintain policies and procedures to provide a safe working environment with respect to health risks other than radiation (e.g., chemical or biohazard risks)

Knowledge of:

- 01 Types of risk involved and accepted techniques for minimizing such risks
- 02 OSHA and CED standards for providing a safe working environment

Task:

- 4. Implement and maintain policies and procedures for equipment and sealed sources and maintain appropriate records

Knowledge of:

- 01 Principles of operation, storage, possession, transfer, use, calibration, and quality control procedures for nuclear pharmacy equipment and devices

- 02 Operation, calibration, and quality control of instrumentation used to measure radioactivity and radiation exposure rates
- 03 Federal regulations governing the storage, possession, testing, and use of sealed sources

Task:

- 5. Implement and maintain policies and procedures to ensure proper storage, disposal, and transport of waste material and maintain appropriate records

Knowledge of:

- 01 Rules and regulations governing the storage, disposal, and transport of waste materials
- 02 Radioactive and biohazardous waste disposal policies and methods

Task:

- 6. Implement and maintain policies and procedures concerning recognition and investigation of regulatory and medical events, corrective/preventative actions, notification of proper authorities, and maintenance of appropriate records

Knowledge of:

- 01 Regulations governing medical events and notification of proper authorities
- 02 Procedures used in response to spills or other accidents involving radioactive material

Domain 3: Drug Information Provision: (10% of the examination)

Task:

- 1. Provide information and consultation on all aspects of nuclear pharmacy

Knowledge of:

- 01 Significance of quality control procedures and the interpretation of test results as they relate to product
- 02 Mechanisms by which medications can alter the kinetics of radiopharmaceuticals, the biodistribution patterns which result from these altered kinetics, and the clinical significance of the resulting alterations
- 03 Requirements and techniques for the administration of radiopharmaceuticals and ancillary medications
- 04 Parameters that can and/or should be monitored when a patient is receiving a specific medication or drug regimen, or when a patient undergoes a specific surgical intervention or receives some other specific therapeutic measure

Task:

- 2. Provide information on the type and incidence of adverse reactions and assist in developing guidelines for the prevention, recognition, treatment, and reporting of adverse reactions

Knowledge of:

- 05 Nature and incidence of previously-reported adverse reactions to radiopharmaceuticals and ancillary medications
- 06 Mechanisms and symptomatology associated with adverse reactions to medications in general and radiopharmaceuticals specifically
- 07 Methods to treat or alleviate adverse drug reactions
- 08 Existing adverse reaction investigation and reporting systems
- 09 Type, incidence, mechanism/cause, and methods for the prediction, recognition, investigation, and reporting of factors that may cause unusual or unanticipated nuclear medicine imaging or therapy results
- 10 Factors that can alter radiopharmaceutical biodistribution
- 11 Other quality assurance failures associated with the clinical use of radiopharmaceuticals and ancillary medications

Task:

- 3. Analyze records and reports information regarding product defects or clinical problems associated with the use of radiopharmaceuticals and ancillary medications

Knowledge of:

- 03 Factors that cause product defects and /or clinical problems with radiopharmaceuticals and ancillary medications, and the mechanisms involved
- 04 Existing reporting systems which can be used to document product problems and/or clinical problems associated with radiopharmaceuticals and ancillary medications

Task:

- 4. Provide consultative services to practitioners to ensure proper utilization of molecular imaging and radiopharmaceuticals in patient care

Knowledge of:

- 04 Organ systems and pathophysiologic disorders evaluated and/or treated with radiopharmaceuticals
- 05 Role of molecular imaging in the diagnosis or management of specific disorders (relative to other diagnostic and therapeutic modalities)
- 06 Molecular imaging procedures used to monitor the safety and efficacy of therapeutic drug regimens or other therapeutic, surgical, or interventional procedures
- 07 Mechanisms by which selected medications can enhance the utility, safety, or efficacy of specific molecular imaging procedures
- 08 Economic ramifications of radiopharmaceutical care
- 09 Design and interpretation of drug use evaluation studies
- 10 Rational radiopharmaceutical and ancillary medication usage
- 11 Normal and atypical performance parameters (e.g., radiopharmaceutical biodistribution, image quality, dosimetry, therapeutic effect, likelihood of untoward effects) associated with the therapeutic use of radiopharmaceuticals
- 12 Patient factors that may interfere with the outcome of the molecular imaging procedure
- 13 Preparatory requirements and techniques to improve the safety or efficacy of the molecular imaging procedure (e.g., fasting, hydration, sedation, thyroid blockade)

- 14 Pregnancy and breast feeding guidelines for molecular imaging procedures
- 15 Patient education needs, requirements, methods, and aids
- 16 Availability and interpretation of nuclear medicine and radioimmunoassay procedures used to monitor drug efficacy and toxicity

Task:

- 5. Participate in the design, formulation, quality control testing, and evaluation of new radiopharmaceuticals or modified preparation of existing radiopharmaceuticals

Knowledge of:

- 3. Principles of pharmaceutical product formulation and drug dosage for design and evaluation
- 4. Pharmaceutical chemistry and radiochemistry
- 5. Pharmacology including localization, metabolism, and excretion
- 6. Physical and chemical properties of radiopharmaceuticals
- 7. Dosage form characteristics
- 8. Principles of quality control testing
- 9. Potential radiochemical, chemical, and pharmaceutical impurities

Task:

- 6. Participate in the clinical trials of new radiopharmaceuticals or the new formulations of existing radiopharmaceuticals, including the preparation and submission of radiopharmaceutical INDs to FDA and applications to local committees (e.g., IRB)

Knowledge of:

- 03 Stochastic and nonstochastic risks associated with exposure to low-level radiation
- 04 Radiation doses to specific organs which results from the administration of radiopharmaceuticals
- 05 Methods used to determine/estimate radiation absorbed doses, dose equivalents, an effective dose equivalents
- 06 Applicable record-keeping requirements

KEY TO ACRONYMS:

ALARA	As Low As Reasonably Achievable
ASHP	American Society of Health-System Pharmacists (formerly the American Society of Hospital Pharmacists)
CDC	Centers for Disease Control
DOT	Department of Transportation
EPA	Environmental Protection Agency
FDA	Food and Drug Administration

ICRP	International Commission on Radiological Protection
IND	Investigational New Drug
IRB	Institutional Review Board
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NABP	National Association of Boards of Pharmacy
NRC	Nuclear Regulatory Commission
NCRP	National Council on Radiation Protection and Measurements
OSHA	Occupational Safety and Health Administration
USP	United States Pharmacopoeia
USP/NF	United States Pharmacopoeia/national Formulary