Examination Specifications
Nuclear Pharmacy
Board of Pharmacy Specialties

Name of Credential	BPS Board-Certified Nuclear Pharmacist
Certification-Issuing Body	Board of Pharmacy Specialties
Designation Awarded	BCNP
Level of Proficiency	Specialty Certification
Target Population	Pharmacists who specialize in the procurement, preparation, compounding, dispensing, and distribution of radiopharmaceuticals, as well as the regulatory aspects governing these processes
Program Purpose	To validate that the pharmacist has the advanced knowledge and experience to improve patient outcomes and public health through the safe and effective use of radioactive drugs for diagnosis and therapy
Eligibility Requirements	• Graduation from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the United States that qualifies the individual to practice in the jurisdiction • Current, active license or registration to practice pharmacy in the United States or another jurisdiction • 4,000 hours of training or experience in nuclear pharmacy, earned in one or more of the following pathways: o Completion of training/experience required for an authorized nuclear pharmacist as identified by the United States Nuclear Regulatory Commission Regulations (10 CFR) § 35.55 *Training for an authorized nuclear pharmacist* o PGY1 or PGY2 Residency in nuclear pharmacy with hour-for-hour credit to a maximum of 2,000 hours completed within the last 7 years o Internship to satisfy requirements of state boards of pharmacy with hour-for-hour credit in a licensed nuclear pharmacy or facility authorized to handle radioactive materials, to a maximum of 2,000 hours o Nuclear pharmacy practice in a licensed nuclear pharmacy or health care facility approved by state or federal agencies to handle radioactive materials, with hour-for-hour credit to a maximum of 4,000 hours within the last 7 years *Residency programs must be accredited by or deemed candidate status by the American Society of Health-System Pharmacists (ASHP) for PGY1, PGY2, and International Pharmacy Practice Residency Programs, or accredited by the Canadian Pharmacy Residency Board (CPRB) for year-1 programs.*
ECO Creation Date	August 2018

This document serves as examination specifications and certification scheme according to the respective requirements of the NCCA 2021 and ISO-IEC 17024:2012 standards.

For more information about the BCNP examination program, please refer to the BPS website and candidate's guide: www.bpsweb.org/specialty-exams/candidates-guide/.

Examination Content Outline

1	**Procurement, Storage, and Handling**
1.1	Define material specifications such as quantity, quality, concentration, availability, calibration, expiration, and manufacturer
1.1.1	Product specifications (e.g., quantity, concentration, availability, calibration, expiration, manufacturer, ingredients, and relative cost)
1.1.2	Inventory management of radiopharmaceuticals (e.g., anticipating adequate on-hand supply, possession limits)
1.1.3	Expirations and reasons for them
1.2	Confirm appropriate shipping and storage conditions of materials
1.2.1	Appropriate condition of materials upon receipt (e.g., temperature, light sensitivity, humidity)
1.2.2	Receipt requirements for radioactive and non-radioactive products, supplies, and other materials
1.2.3	Consequences of improper shipping (e.g., material stability, sterility, suitability for use, temperature excursions during shipping)
1.2.4	Storage requirements for radiopharmaceuticals, adjunct agents, components, and supplies, including the consequences of improper storage
1.2.5	Appropriate shielding requirements for radiopharmaceuticals and other radioactive materials
1.3	Assess acceptability of materials for use
1.3.1	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)
1.3.2	Required documentation and record retention to ensure traceability of all drugs and related components (e.g., certificates of analysis / compliance)
2	**Preparation, Compounding, Repackaging, End-product Testing, and Dispensing**
2.1	Review orders for radiopharmaceuticals, devices, and adjunct agents for appropriateness.
2.1.1	Indications, dosage recommendations, route of administration (pursuant to manufacturer's prescribing information) and use environment for radiopharmaceuticals and adjunct agents
2.1.2	Physical, chemical and kinetic properties, mechanisms of localization, and pharmacologic and therapeutic effects of radiopharmaceuticals and adjunct agents
2.1.3	Half-lives, modes of decay, and emission energies associated with radiopharmaceuticals
2.2	Select products, components, supplies, and equipment needed to prepare and compound prescription orders
2.2.1	Ingredients, components, and preparation techniques (such as heating or incubation times) of radiopharmaceuticals, including the purpose of each
2.2.2	Formulation factors that may adversely affect preparation and use
2.2.3	Containers, closures, and other packaging materials used in the compounding of radiopharmaceuticals
2.2.4	Physical and chemical incompatibilities that impact radiopharmaceutical preparation and use
2.3	Elute radionuclide generators, and end-product test the generator eluate
2.3.1	Physical and chemical characteristics of available radionuclide generators (e.g., Mo-99 including HSA and LSA; Ge-68; Sr-82)
2.3.2	Radionuclide generator operation, kinetics, and elution techniques
2.3.3	Minimal acceptable release criteria for eluate
2.3.4	Factors that affect the stability and shelf-life of reagent kits and radiopharmaceuticals, including radionuclidic, radiochemical, and chemical contamination

2.4	Prepare sterile and non-sterile medications and devices using appropriate aseptic and radiation control techniques
2.4.1	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)
2.4.2	Approved blood labeling procedures and precautions for blood-borne pathogens
2.4.3	Appropriate documentation supplied by the vendor (e.g., prescribing information and operator guides)
2.4.4	General chemistry and radiolabeling preparation methods (e.g., redox reactions, chelation, substitution, radioiodination) as well as methods for optimizing yield of radiolabeled compounds
2.5	Compound sterile and non-sterile preparations according to professional standards and regulations
2.5.1	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)
2.5.2	Custom compounding blood labeling procedures and precautions for blood-borne pathogens
2.5.3	Documentation supplied by the vendor(s) supporting compounding (e.g., clinical research, peer-reviewed published literature)
2.5.4	General chemistry and radiolabeling compounding methods (e.g., redox reactions, chelation, substitution, radioiodination) as well as methods for optimizing yield of radiolabeled compounds
2.6	Perform appropriate end-product testing for radiopharmaceutical preparations
2.6.1	Methods and principles for performing appropriate and validated end-product testing
2.6.2	Release criteria for radiopharmaceuticals
2.6.3	Factors that affect the stability and shelf-life of reagent kits and radiopharmaceuticals, including radionuclidic, radiochemical, and chemical contamination
2.6.4	USP standards for drugs, pharmaceutical ingredients, reagents, tests and assays, and other materials
2.7	Verify the identity, integrity, concentration, container labeling, and proper storage of preparations
2.7.1	Regulatory requirements for container labeling of radiopharmaceuticals and adjunct agents
2.7.2	Proper storage conditions of prepared radiopharmaceuticals pursuant to manufacturer's package insert
2.7.3	Applicable regulatory requirements pertaining to record keeping and traceability of radiopharmaceuticals and adjunct agents
2.7.4	Preparation verification methods and applications
3	**Personnel, Equipment and Environmental Requirements**
3.1	Perform appropriate quality assurance procedures for nuclear pharmacy personnel, instrumentation, equipment, and environment.
3.1.1	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)
3.1.2	Appropriate dose calibrator testing procedures
3.1.3	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)

3.1.4	Regulatory requirements and standards regarding personnel aseptic performance (e.g., media fill testing, gloved fingertip sampling, hand hygiene, garbing assessment)
3.2	Ensure appropriate processes are in place for maintenance of sterility of aseptic preparations
3.2.1	Appropriate cleaning and maintenance of primary and secondary engineering controls
3.3	Maintain applicable quality assurance records to identify trends and document compliance.
3.3.1	Evaluation of equipment documentation (e.g., anomalous testing results, testing result trending, documentation of appropriate response)
3.3.2	Evaluation of environmental documentation (e.g., microbial identification and susceptibility paired with disinfecting agent selection and identifying potential routes of incursion)
3.3.3	Evaluation of equipment documentation (e.g., anomalous testing results, testing result trending, documentation of appropriate response)
3.4	Ensure facility compliance with applicable USP standards
3.4.1	Regulatory requirements and standards regarding primary and secondary engineering controls (e.g., testing, certification, and equipment specifications)
3.4.2	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	**Licensing and Occupational Safety**
4.1	Ensure compliance with radioactive materials regulations and license requirements for radiation and radiopharmaceuticals.
4.1.1	Radiation protection principles, techniques, and standards (e.g., NRC)
4.1.2	Regulatory requirements related to the receipt, storage, handling, and medical use of radioactive materials
4.1.3	Regulatory requirements governing the storage, possession, testing, and use of sealed sources
4.1.4	Radioactive material license designation and scope of practice in both clinical and investigational radiopharmaceutical settings
4.1.5	Regulatory requirements for effluent release and derived air concentration (e.g., NRC, EPA)
4.2	Ensure compliance with regulatory requirements concerning handling, packaging, labeling, and transporting radioactive, biohazardous, and chemical substances and waste.
4.2.1	Regulatory requirements (e.g., IATA/ICAO and DOT) concerning packaging, labeling, and transportation of dangerous goods, (e.g., radioactive material, biohazardous material, compressed gas)
4.2.2	Regulatory requirements governing the storage and disposal of waste materials
4.3	Assure adequate development and application of policies and procedures for a safe working environment.
4.3.1	Regulatory requirements for providing a safe working environment (e.g., NRC, CDC, OSHA, NFPA)
4.3.2	Allowable personal exposure limits in normal and special populations (including units of measurement, TEDE, general public, etc.)
4.3.3	Evaluation of shielding effectiveness using attenuation coefficients and HVLs
4.4	Assure adequate development and application of policies and procedures in regulatory situations and medical events.
4.4.1	Regulatory requirements governing the handling and reporting of radiation incidents (e.g., medical events, spills, dispensing errors, overexposures)
4.4.2	Procedures used in response to radiation incidents
4.4.3	Scientific basis for the operation of equipment or devices used to measure radioactivity and radiation exposure rates

4.5	Assure adequate development and application of policies and procedures for security of the facility, radioactive materials, medications, and supplies.
4.5.1	Regulatory requirements and standards governing the security of the facility, radioactive materials, medications, and supplies (e.g., NRC)
5	**Drug Information and Professional Consultation**
5.1	Evaluate factors affecting patient outcomes in nuclear medicine procedures.
5.1.1	Radiopharmaceutical kinetics, biodistribution, and image acquisition or therapy application
5.1.2	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)
5.1.3	Requirements and techniques for the administration of radiopharmaceuticals and adjunct agents
5.2	Consult with practitioners to ensure optimal utilization of radiopharmaceuticals and adjunct agents in patient care.
5.2.1	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)
5.2.2	Nuclear medicine procedures used to monitor the safety, efficacy, and toxicity of therapeutic drug regimens or other therapeutic, surgical, or interventional procedures
5.2.3	Mechanisms by which selected medications can enhance the utility, safety, or efficacy of specific radiopharmaceuticals
5.2.4	Patient preparation to improve the safety or efficacy of the nuclear medicine procedure (e.g., fasting, hydration, sedation, thyroid blockade)
5.2.5	Education of patients and other health-care professionals
5.3	Provide information on the prevention, recognition, treatment, reporting, and analysis of adverse drug events.
5.3.1	Mechanisms, symptoms, incidence, and management of reported adverse drug events to radiopharmaceuticals and adjunct agents
5.4	Report information regarding drug defects or clinical issues associated with the use of radiopharmaceuticals and adjunct agents.
5.4.1	Drug defects, and resulting clinical issues, (e.g., identification, investigation, reporting systems)
5.5	Provide information about health physics and radiation safety compliance.
5.5.1	Patient release criteria post-radiopharmaceutical administration (e.g., caregivers, members of public)
5.5.2	Concepts of radiation safety (e.g., dose, exposure, time, pharmacokinetics, routes of excretion)
5.5.3	Radiation biology, nuclear physics, instrumentation, and radiation safety to provide education to the public (e.g., patients, employees, administrative staff, families, and community organizations)
5.6	Determine proper dose of radiopharmaceuticals and adjunct pharmaceuticals based on patient-specific parameters.
5.6.1	Procedure selection factors such as patient-specific parameters and study sequencing
5.6.2	Pregnancy and nursing mother guidelines for nuclear medicine procedures
5.6.3	Organ systems and pathophysiologic disorders in patients administered radiopharmaceuticals and adjunct agents

The examination content outline is a product of a job analysis (aka role delineation study) that includes facilitation of discussions with a representative panel of 15-20 subject matter experts who identify competencies required for safe and effective pharmacy practice in this specialty area as well as a validation survey soliciting endorsement of the identified competencies from certified pharmacists in this specialty area. The job analysis process is conducted every 5 years to help ensure that the competencies in the examination content outline reflect current pharmacy practice in the specialty area.

Examination Administration and Scoring

Number of Examination Items		Certification Exam	Recertification Exam
1	Procurement, Storage, and Handling	28	16
2	Preparation, Compounding, Repackaging, End-product Testing, and Dispensing	70	40
3	Personnel, Equipment and Environmental Requirements	28	16
4	Licensing and Occupational Safety	28	16
5	Drug Information and Professional Consultation	21	12
	TOTAL	**175**	**100**

	Certification Exam	Recertification Exam
Exam Administration Time	4 hours 23 minutes	2 hours 30 minutes
Minimum Score	200	200
Minimum Passing Score	500	500
Maximum Score	800	800

The certification examination is split into two parts with an optional break (up to 30 minutes) in between. Part 1 consists of 100 items (2 hours 30 minutes) and Part 2 consists of 75 items (1 hour 53 minutes).

Maintenance of Certification

Recertification Requirements	Pharmacists who earn the BCNP designation will be required to maintain their certification over a 7-year period by completing one of the following recertification pathways: • Achieving a passing score on the BCNP recertification examination in their seventh year following initial certification • Earning 100 hours of BPS-approved continuing pharmacy education (CPE) credit provided by the professional development programs offered by Purdue University. *The Nuclear Pharmacy Preparatory Review and Recertification Course offered by either of the approved providers may only be completed for recertification credit up to two times, in nonconsecutive years, during the 7-year recertification cycle.*
Ethics and Professionalism	The Board of Pharmacy Specialties ascribes to the belief that certification carries an obligation for ethical behavior and professionalism necessary in all conduct. Candidates or certificants who are found to have exhibited unethical behavior or lack of professionalism may be prevented from pursuing certification or may be subject to suspension or withdrawal of certification, at the discretion of the Board of Pharmacy Specialties. Please refer to the BPS Ethics and Professionalism Policy: https://www.bpsweb.org/wp-content/uploads/2015/11/ethics.pdf