Adopt Ph 404 and Ph 405, previously effective 3-26-05 (Doc. # 8316), and expired 3-26-13, to read as follows:

PART Ph 404 STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PHARMACEUTICALS

Ph 404.01 Purpose and Scope. The Board requires all compounders engaging in compounding in all situations to adhere to and comply with the current edition of the United States Pharmacopeia including but not limited to Chapters 795 (USP 795) and 797 (USP 797), following those guidelines that apply to their practice setting. These chapters should be reviewed in full and followed by compounders prior to non-sterile or sterile pharmaceutical compounding. The purpose of this Regulation is to provide all compounders with guidance on applying good compounding practices for the preparation of non-sterile and sterile compounded formulations for dispensing and/or administration to humans and animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. These regulations apply to non-sterile and sterile compounding of medications.

Ph 404.02 Definitions.

(a) "Active pharmaceutical ingredients" refers to chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(b) "Added substances" means the ingredients necessary to prepare the Drug product but are not intended or expected to cause human pharmacological response if administered alone in the amount or concentration contained in a single doses of the compounded preparation. The term "added substances" is used synonymously with the terms "inactive ingredients", "excipients", and "pharmaceutical ingredients."

(c) "Beyond-use date" (BUD) is the date after which a compounded preparation should not to be used; determined from the date the preparation is compounded. BUD shall not exceed the following dates:

(1) Low Risk

a. At controlled room temperature for 48 hours

b. At a cold temperature for 14 days or

c. In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days

(2) Moderate Risk

a. At controlled room temperature for 30 hours

b. At cold temperature for 9 days or

c. In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days

(3) High Risk

a. At controlled room temperature for 24 hours

b. At a cold temperature for 3 days or In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days

(d) “Component” mean any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

(e) “Compounder” means a licensed professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

(f) “Compounding” means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

(1) Preparation of drug dosage forms for both human and animal patients

(2) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns

(3) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients

(4) Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis

(5) Preparation of drugs and devices on the order of a practitioner, which may be sold to the practitioner for use in his or her office to administer to a specific patient, in limited quantities, but not for resale.

(g) “CSPs” means Compounded Sterile Preparations.

(h) “Hazardous drugs” means any drug in studies of animals or humans that have been classified as carcinogenic, toxic to development or reproduction, or toxic to organs.

(i) “Limited quantities” shall be defined as a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient. Each batch shall be assigned a unique lot number and shall be tested by an independent lab for sterility, potency, and endotoxins. Only a batch that has passed all three tests shall be made available to provide to a hospital or practitioner.

Compounders supplying limited quantities to Providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner. (A template of the MOU shall be provided on the Board of Pharmacy website).

(j) “Manufacturing” means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of

such drugs and devices for resale Manufacturing shall be governed by Good Manufacturing Practices as adopted and enforced by the federal Food and Drug Administration.

(k) "Memorandum of Understanding" for purposes of this chapter shall mean a document specific to the preparation(s) provided to a practitioner by a compounder outlining the distinct responsibilities of the compounder and practitioner, and shall be

(l) "Preparation" for purposes of this chapter, means a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

(m) "Product" for the purposes of this chapter, describes manufactured pharmaceutical dosage forms.

(n) "Stability" the extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.

(o) "Vehicle" means a component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

(p) "Ante-Area" —Means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.1

(q) "Aseptic Processing" — A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers–closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

(r) "Biological Safety Cabinet (BSC)" — A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

(s) "Buffer Area" — An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

(t) "Clean Room" — A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(u) "Compounding Aseptic Containment Isolator (CACI)" — A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug

throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

(v) "Compounding Aseptic Isolator (CAI)" — A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).

(w) "Critical Area" — An ISO Class 5 environment.

(x) "Critical Site" — A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(y) "Direct Compounding Area (DCA)" — A critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(z) "Disinfectant" — An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(aa) "First Air" — The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(ab) "Hazardous Drugs" — Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs. (See current NIOSH publication.)

(ac) "Labeling" — A term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(ad) "Media-Fill Test" — A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.3 The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

(ae) "Multiple-Dose Container" — A multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. The beyond-use

date (BUD) for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days unless otherwise specified by the manufacturer.

(af) "Negative Pressure Room" — A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is into the room.1

(ag) "Pharmacy Bulk Package" — A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

(ah) 'Primary Engineering Control (PEC)" — A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

(ai) "Preparation" — A preparation, or a CSP, that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

(aj) "Product" — A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

(ak) "Positive Pressure Room" — A room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

(al) "Single-Dose Container" — A single-dose container is a single-unit container for articles (see General Notices and Requirements) or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(am) "Segregated Compounding Area" — A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

(an) "Sterilizing Grade Membranes" — Membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.

(ao) "Sterilization by Filtration" — Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(ap) "Terminal Sterilization" — The application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10 6, or a probability of less than one in one million of a non-sterile unit.

(aq) "Unidirectional Flow" (see footnote 3) — An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

Ph 404.03 Non-sterile Pharmaceutical Compounding. Compliance with USP 795 for non-sterile pharmaceutical compounding includes but is not limited to:

(a) Categories of Compounding in the three general categories of non-sterile compounding described in this section, different levels of experience, training and physical facilities are associated with each category.

(1) Simple Compounding:

a. Reconstituting or manipulating a commercial product that may require the addition of one or more ingredients as directed by the manufacturer.

b. A preparation that has a USP compounding monograph or appears in a peer reviewed article that contains:

1. Specific quantities for all components;

2. Compounding procedures and equipment;

3. Stability data for that formulation with an appropriate BUD;

4. Examples include solutions, suspensions and gels.

(2) Moderate Compounding

a. Making a preparation that requires complex calculation or procedures to determine quantities of components per preparation or per individualized dosage units.

b. Making a preparation for which stability data for that specific formulation is not available.

c. Example: mixing two or more manufactured creams when the stability of the mixture is unknown.

(3) Complex Compounding

a. Making a preparation that requires specialized training, environment, facilities, equipment, and procedures. Examples include but not limited to transdermal dosage forms and modified-release preparations.

(b) Responsibility of the Compounder.

(1) The compounder is responsible for compounding preparations of accepted strength, quality, and purity and in accordance with the prescription or medication order.

(2) The compounder is also responsible for dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with 318:47a, federal law, and other regulatory agencies where appropriate.

(3) Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should expand their knowledge annually by participating in seminars and studying literature.

(4) To ensure the quality of compounded preparation, compounders shall adhere to the general principles listed in USP 795 and all applicable compounding laws, guidelines and standards including but not limited to:

a. Training of all the personnel must be current and documentation of such kept on site.

b. Compounding ingredients are purchased from reliable sources and are properly stored.

c. Bulk component containers are properly labeled and MSDS sheets available.

d. Equipment used is clean, properly used and maintained.

f. Environment is suitable to prevent cross contamination.

g. Compounding personnel shall wear appropriate and clean clothing. Protective apparel such as lab coats gowns, gloves, shoes, or masks shall be worn as necessary to protect personnel from chemical exposure and/or contamination.

h. Only authorized personnel are allowed in the compounding area.

i. Compounding Conditions and procedures are such to prevent errors

j. There is assurance that processes are always carried out as intended or specified and are reproducible.

k. All aspects of compounding are properly documented.

l. Procedures and records exist for investigating and correcting failures or problems in compounding and testing

m. A valid and reproducible recall policy and procedure

n. In addition to Chapter 795 the compounder should be familiar with all applicable USP chapters related to non-sterile compounding

(c) Compounding Process.

(1) The compounder is responsible for ensuring that each individual incidence of compounding meets the criteria in USP 795.

(d) Compounding Facilities.

(1) The compounding area must adhere to the general principles listed in USP 795 guidelines including but not limited to:

a. Must have an adequate space specifically designated for compounding and storage of equipment and materials;

b. Must be clean, orderly, and properly maintained;

c. Must have easily accessible hand washing, hot and cold water, soap or detergent, and an air-drier or single-use towels must be present;

d. Must be located in a separate area from sterile compounding area;

e. Purified water shall be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water;

f. Disposal of all hazardous drug wastes shall comply with applicable federal and state regulations;

g. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination including spill clean ups.

(f) Compounding Equipment

(1) All equipment and utensils used in compounding shall be of appropriate design and capacity, and shall be cleaned and stored in a manner to protect it from contamination.

(2) Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to the manufacturer's recommendations to ensure proper performance.

(3) Equipment should be stored to protect it from contamination. It shall be located in an area to facilitate its use, cleaning and maintenance.

(4) Extra care should be used when cleaning equipment used in compounding preparations containing substances requiring special handling (e.g. antibiotics, cytotoxic, or other hazardous materials).

(g) Component Selection, Handling and Storage

(1) A USP, NF, or FCC (Food Chemical Codex) substance is the recommended source of ingredients for compounding all preparations.

(2) If ingredients are from a non-FDA registered facility the professional judgment should be used in selecting an acceptable and reliable source and shall establish purity and safety including a Certificate of Analysis from the manufacturer or qualified third party

(3) Components for compounding shall be properly labeled with batch numbers and expiration dates. If a component is transferred from the original container to a new container, the new container shall be labeled with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that it is equal to or better than the original container.

(4) For Components that do not have expiration dates assigned by the manufacturer or supplier the Compounder shall label the container with the date of receipt and assign a conservative expiration date not to exceed three years after receipt.

(5) Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

a. Capsule weight variation

b. Adequacy of mixing to insure uniformity and homogeneity

c. Clarity, completeness, or pH of solutions

d. Observation of instability

(6) When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.

(7) When compounding for food-producing animals, the compounder should consult the list of components prohibited for use in food-producing animals and consider withdrawal times. For example, treating animals in the food chain with certain antibiotics.

(8) All components used in compounding must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean, dry area under appropriate temperature conditions. All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

(h) Stability Criteria and Beyond-Use Dating

(1) The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage,

their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products.

(2) What follows is from USP 795

a. BUDs shall be assigned conservatively.

b. Compounders shall consult and apply drug-specific and general stability documentation and literature when available.

c. Compounders shall consider the following when determining BUDs:

1. Nature of the drug and degradation mechanism

2. Dosage form and its components

3. Potential for microbial proliferation in the preparation

4. Container when it is packaged e. Expected storage conditions

5. Intended duration of therapy.

d. When using manufactured solid dosage forms to prepare a solution or aqueous suspension, the compounder shall also consider factors such as hydrolysis, oxidation, and the freeze- thaw property of the final preparation.

e. When a manufactured product is used as the source of the active pharmaceutical ingredient for a non-sterile compounded preparation, the product expiration date is not used to assign a BUD for the compounded preparation. Instead the compounder shall refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility, and degradation of ingredients. All data must be carefully interpreted in relation to the actual compounded formulation

f. Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobials are contraindicated, storage of the preparation at controlled cold temperature is necessary to retard microbial growth. Appropriate patient or caregiver instruction regarding storage and handling is essential.

g. In the absence of reliable stability information or published date the following General Guidelines for maximum BUD are recommended for non-sterile compounded drug preparations. . The BUD cannot exceed the expiration date of the API or any other component.

Type of Formulation	Maximum BUD
Non-aqueous formulation	6 months
Water-containing oral formulation	14 days under refrigeration

Water-containing topical/dermal and mucosal liquid and semisolid formulation	30 days

(i) Packaging and Drug Preparation Containers

(1) The compounder shall ensure that the containers and closures used in packaging compounded preparations meet USP requirements.

a. The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded preparation.

b. Container-drug interaction should be considered for substances that have sorptive or leaching properties.

c. Containers and closures shall be handled and stored in such a way as to prevent contamination.

(j) Compounding Documentation

(1) Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the process of compounding and must be kept for 10 years.

(2) Documentation must comply with state and federal laws.

(3) Documentation is not required when preparing a compounded preparation according to the manufacturer's labeled instructions

(4) The record may be a copy of the prescription in written or machine-readable form and should include a master formula record and a compound record

(5) Master Formulation Record

a. Official or assigned name, strength, and dosage form of the preparation

b. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients

c. Description of all ingredients and their quantities

d. Compatibility and stability information, including references when available

e. Equipment needed

f. Mixing instructions

g. Order of mixing

h. Mixing temperature or other controls

i. Duration of mixing

j. Any other pertinent instruction

k. Labeling information in addition to legally required information RSA 318:47a:

1. Name and quantity or concentration of each active ingredient

2. Assigned BUD

3. Storage conditions

4. Prescription number

l. Container used in dispensing

m. Packaging and storage requirements

n. Description of final preparation

o. Quality control procedures and expected results

(6) Compounding Record

a. Official or assigned name, strength, and dosage of the preparation

b. Master Formulation Record reference for the preparation

c. Names and quantities of all components

d. Sources, lot numbers, and expiration dates of components

e. Total quantity compounded

f. Name of the person who prepared the compound, who performed the quality control procedures, and approved the preparation

g. Date of the preparation

h. Assigned controlled or prescription number

i. Assigned BUD

j. Description of final preparation

k. Results of quality control procedures (e.g. weight range of filled capsules, pH record, etc.)

l. Documentation of any QC issues and any ADRs reported by patient or caregiver

(k) Standard Operating Procedures

(1) All significant procedures performed in the compounding area should be covered by written standard operating procedures (SOPs). Procedures shall include but not limited to:

a. Facility maintenance, workflow, and cleaning

b. Equipment use and maintenance

c. Personnel

d. Training

e. Preparation

f. Packaging

g. Storage of Compounded Preparations

h. Quality Assurance

i. Safety

j. Uniformity

k. Continuous Quality Improvement

l. Maintain updated MSDS Library

(l) Quality Control

(1) The safety, quality, and performance of compounded preparations depend on correct ingredients, proper calculations, and accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness

(2) The compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

(m) Compounding Controls

(1) The compounder shall ensure that there are written procedures for the compounding of drug preparations to ensure that the finished preparations have the identity, strength, quality, and purity that they purport to have. These procedures shall be available in either written form or electronically stored.

(2) The written procedures shall be followed in execution of the compounding process

(3) The compounder shall check and document each weight and measurement. The identity of the person(s) actually performing the compounding and of the compounder shall be recorded. Records must be maintained with the compounding record for 4 years.

(4) The compounder shall have established written procedures that will describe quality assurance tests or examinations to be conducted on the compounded preparation to ensure uniformity and integrity.
(5) Appropriate control procedures shall be established to monitor the output and to validate the performance of those compounding processes and equipment that may be responsible for causing variability in the final compounded preparation.

(n) Patient Counseling as per 5.2

(1) At the time of dispensing, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to observe and report to the compounder any changes in the physical characteristics of the compounded preparation. Counseling may be in written, oral, electronic, or other formats. The compounding pharmacist shall investigate any reported problem with a compounded preparation and take corrective action.

(o) Training

(1) It is the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training procedure include the following:

a. All employees involved in pharmaceutical compounding shall read and become familiar with USP Chapter 795. They should also be familiar with other relevant publications including how to read and interpret MSDSs.

b. All employees shall read and become familiar with each of the procedures related to compounding including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage and dispensing

c. All personnel who compound hazardous drugs shall be fully trained in the storage, handling and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs.

d. All training activities shall be documented. The Compounder shall meet with employees to review their work and answer any questions the employee may have concerning compounding procedures.

e. The Compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee will then repeat the procedure without any assistance from, but under the supervision of the compounder

f. When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without direct supervision. However the compounder should be physically present and shall approve all ingredients and their quantities and the final preparation.

g. When the Compounder is satisfied with the employee's knowledge and proficiency, the compounder will sign the documentation records to show that the employee was appropriately trained

h. The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed

i. The compounder is solely responsible for the finished preparation

(p) Compounding for Animal Patients

(1) All portions of this section apply to compounded preparations formulated for both human and animal patients. Intended use on any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient. Because humans can consume animals as food, care must be taken to prevent drug residue from entering the human food chain.

(2) Compounding for animals shall possess a functional knowledge of drug regulation and disposition in animal patients.

(3) The compounding pharmacist shall be knowledgeable about the individual species limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, pharmacists compounding for animals should use when possible, formulations developed specifically for animal patients. If such formulations are not available, the compounding pharmacist shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Compounded preparations are not to be dispensed or sold to veterinary offices for resale.

Ph 404.04 Regulatory Requirements Sterile Compounding.

(a) A Compounder shall have and maintain a permit issued by the NH Board of Pharmacy that allows for the compounding of sterile products as defined by the Board.

(b) When a Compounder prepares a significant number of non-patient specific preparations (e.g. >5% of the compounder's volume) for sale or another organization, the compounder shall be registered as a drug manufacturer with the FDA, when required.

(c) All pharmacists who compound sterile products shall be licensed in the state in which they are practicing.

(d) All pharmacy technicians who compound sterile products shall be licensed or registered in the state in which they practice.

(e) A Compounder shall meet or exceed state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located.

(f) A Compounder shall not compound a sterile product of an FDA-approved product when the product is commercially available (i.e., not on the FDA backorder list).

(g) When no commercial source of a sterile product exists (i.e., listed on the FDA backorder list), the compounder only uses USP grade bulk ingredients obtained from a cGMP compliant supplier. The Compounder shall obtain and keep on file for at least 3 years a certificate of analysis and potency testing of all bulk ingredients used to compound each and every sterile compounded product made with a bulk, non-sterile ingredient.

(h) A Compounder who uses hazardous products shall meet State and Federal requirements for handling of hazardous agents.

Ph 404.05 Quality Requirements.

(a) Compounder shall maintain documentation that confirms staff training and competency (garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures) are evaluated prior to compounding of any actual sterile product preparation.

(b) Compounder shall maintain documentation that confirms that the compounder tests aseptic techniques of all staff that compounds sterile products by preparing media fill units per USP standards.

(c) Compounder shall maintain documentation that confirms all staff that compounds sterile products is pre-qualified using media fills before compounding of actual drug preparations.

(d) When a positive media fill occurs, compounder performs a comprehensive investigation to identify root cause, and documents the finding.

(e) When a positive media fill occurs, compounder institutes corrective and preventive action, and documents the corrective action.

(f) Compounder shall verify that all personnel who compound sterile products are complying with gowning, gloving, and glove-tip processes consistent with USP standards.

(1) Low and Medium Risk: Glove fingertip test three times initially then annually.

(2) High Risk: Glove fingertip test three times initially then semi-annually.

(g) Compounder shall perform routine surface microbiological and fungal environmental monitoring to minimize contamination at least monthly, or in accordance with facilities policies.

(h) Compounder shall perform comprehensive investigations of out-of-limit findings, as recommended by USP standards to determine root cause, followed by corrective and preventative actions at least weekly. Compounder shall maintain all documentation of its findings.

(i) Compounder shall perform, at least monthly, viable particle testing in primary engineering controls (e.g. laminar flow workbench, biological safety cabinet) and room air according to USP standards.

(j) Compounder shall ensure that all compounded sterile products that require refrigeration are stored in appropriate refrigeration at all times.

(k) When Compounder assigns a BUD for a sterile product that exceeds BUD limits established in USP Standards, a Compounder shall have substantial evidence that supports extended expiration dating for compounded sterile preparations to any patient or organization that request such documentation.

(l) Compounder shall perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists.

(m) Compounder shall have a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability.

(n) Compounder shall have a quality assurance program to promptly address equipment problems.

(o) Compounder shall have a quality assurance program for compounding that includes at least the following separate, but integrated components: (1) training; (2) standard operating procedures; (3) documentation; (4) verification; (5) testing; (6) cleaning and disinfecting; (7) containers, packaging, repackaging, and storage

(p) All personnel involved in the compounding, evaluation, packaging and dispensing of compounded preparations are properly trained and evaluated to include:

(1) Low and Medium Risk: Glove fingertip test three times initially then annually.

(2) High Risk: Glove fingertip test three times initially then semi-annually.

(3) Low and Medium Risk: Media fill test three times initially then annually.

(4) High Risk: Media fill test three times initially then semi-annually.

(q) Personnel shall undergo re-qualification using media fills annually for low and medium risk sterile compounding and semi-annually for high risk sterile compounding.

(r) Compounder shall have an action plan and alert limits for environmental monitoring.

(s) Compounder shall develop and implement methods for improving quality based on analyzed data found in its environmental monitoring.

(t) Compounder shall evaluate and continuously monitor the methods used for the packaging, handling, and transport of CSPs.

(u) Compounder shall evaluate and continuously monitor the storage of CSPs to ensure compliance with appropriate storage conditions.

(v) Compounder shall ensure drug storage refrigerators, freezers and medication storage areas have daily monitoring and documentation of temperatures.

(w) Compounder personnel shall inspect all drug storage areas routinely to ensure drugs are stored separately from food.

(x) Compounder shall ensure all solutions, medications, equipment, and supplies (in all areas) are stored according to the manufacturer or USP requirements and are inspected routinely (per P&P) for proper conditions of light, temperature, moisture, and ventilation.

(y) Compounder shall ensure all outdated and unused CSPs are segregated in a separate area for return and disposal per P&P.

(z) Compounder shall ensure only pharmacists training in sterile compounding determine whether a CSP not administered as originally intended can be used for an alternate patient or under alternate conditions.

(aa) Compounder shall have an environmental sampling plan based on the compounding activities performed, locations to be monitored, the device used to monitor, the frequency of collection, and procedures if readings exceed established thresholds.

(1) Two types of monitoring - Viable and Non-Viable Environmental Monitoring.

a. Non-Viable monitoring includes: particle counts, monitoring pressure or velocity difference between the buffer area, ante area and non-classified shall be done at least every 6 months.

b. Viable monitoring detects microbial or fungal contaminants in the compounding area shall be done using a volumetric collection method. Monitoring, sampling, and testing for surface contamination from hazardous drugs is conducted at least every month or earlier in cases of contamination from fluid or solid dosage form spills.

(ab) Compounder shall ensure certification of its Primary Engineering Control (PEC) complies with the requirements of USP Standards. Certification shall be done by an independent entity certified to perform the test. Certifying entity shall leave a signed copy of the test with the Compounder who shall retain the document for at least 3 years.

(ac) Compounder shall ensure the PEC is certified every 6 months or sooner if recommended by manufacturer.

(ad) Compounder shall ensure viable and non-viable airborne sampling occurs minimally every 6 months. Monitoring shall include all areas at risk of contamination must be monitored (including inside of PEC, counters, anteroom, areas near doorways, and any pass-through), counters, storage areas, shelves, shipping and receiving areas, and employee work areas (if necessary).

(ae) Compounder shall ensure sampling data is base-lined, evaluated and documented on a routine basis as defined by USP Standards.

(af) Compounder shall have a written plan and schedule for environmental monitoring.

(ag) Compounder shall have a written environmental plan that adequately evaluates the various controlled air environment areas (PEC, buffer area, anteroom area).

(ah) Compounder facility personnel, or external personnel, who complete the environmental monitoring are appropriately trained and certified by a NH Board approved entity.

Ph 404.06 Compounding Environment.

(a) Compounder shall ensure there is sufficient space for the type and amount of compounding done.

(b) Compounder shall ensure there is appropriate space for orderly placement of equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process materials, finished preparations.

(c) Compounder shall ensure it has procedures to prevent cross-contamination.

(d) Compounder shall ensure areas used for sterile preparation are separate and distinct from areas used for non-sterile preparation.

(e) Compounder shall have a well-lighted sterile compounding environment suitable for the amount of compounding done.

(f) Compounder shall ensure all heating, ventilation and air conditioning systems are controlled to maintain a constant temperature 24 hours per day, 7 days per week.

(g) Compounder shall maintain a bulk storage area that is adequately arranged, proper temperature and humidity maintained and suitably controlled.

(h) Compounder shall supply hot and cold potable water for hand and equipment washing in the compounding area, and soap or detergent and single-use towels or driers are readily available.

(i) Compounder shall ensure all compounding areas are maintained in a clean and sanitary condition.

(j) When Compounder uses hard-wall construction, the finished surface shall provide a non-porous, durable and washable surface.

(k) When Compounder uses modular construction methods, a surface material such as fiberglass-reinforced plastic (FRP) should be used.

(1) All ceilings shall be smooth, impervious, free from cracks and non-shedding (plastic covered clean room grade ceiling tiles), and all tiles are sealed.

(2) All floors shall be smooth, impervious, free from cracks and non-shedding, and the floor must be of seamless vinyl.

(3) All fixtures shall be smooth, impervious, free from cracks and non-shedding. All fixtures mounted to wall in a way that "seals" any space between wall and fixture.

(4) All shelving shall be smooth, impervious, free from cracks and non-shedding.

(5) Counters are smooth, impervious, free from cracks and non-shedding. (all exposed surfaces including underside).

(6) All cabinets are smooth, impervious, free from cracks and non-shedding.

(7) Ceiling to wall junctures are coved or caulked to avoid cracks.

(8) Inlaid ceiling panels are impervious and hydrophobic.

(9) Ceiling panels are caulked around the perimeter to seal them to frame.

(10) Floors are overlaid with wide sheet vinyl flooring with heat welded seams and coving to the sidewall.

(11) There are no dust-collecting overhangs.

(12) There are no windowsills.

(13) Exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed.

(14) There are no sinks in primary and secondary compounding areas.

(15) There are no floor drains in primary and secondary compounding areas.

(16) Carts are made of stainless steel wire or sheet metal. A minimum of two stainless steel carts with cleanable castors are essential.

(17) Carts have cleanable casters and are mobile.

(18) All surfaces are designed to provide effective cleaning.

(19) All surfaces are resistant to damage by cleaning agents.

(20) There are no cardboard containers in buffer area at any time.

(21) There are no electronics (computers, printers, radios and refrigerators) in the buffer area at any time.

(22) The bulk storage area is maintained in a clean and sanitary condition.

(23) Trash is disposed of in a safe, sanitary and timely manner.

(24) All components, containers and equipment are stored off the floor in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

(l) Compounder shall ensure equipment is of appropriate design and size for the compounding that is performed.

(m) Compounder shall ensure that all equipment is of appropriate design such that the surfaces that contact pharmaceutical components, in-process materials or finished preparations is not reactive, additive or adsorptive.

(n) Compounder shall ensure that all equipment is thoroughly cleaned immediately after use to avoid cross-contamination.

(o) Compounder shall ensure all equipment is stored to prevent it from contamination and is located to facilitate its use, maintenance, and cleaning.

(p) Compounder shall ensure all equipment used for allergenic ingredients is appropriately handled, cleaned and stored immediately after use.

(q) Compounder shall ensure all work surfaces are cleaned of loose materials and residue from spills before compounding.

(r) Compounder shall ensure all floors in the buffer area and ante area must be mopped daily with a cleaning and disinfecting agent at a time when no aseptic compounding is in progress.

(s) Compounder shall ensure it has reviewed and approved all cleansing and sanitizing agents (considering compatibilities, effectiveness, and presence of inappropriate or toxic residues), and shall ensure the following:

(1) Mops, wipes, sponges, and other cleaning materials must be non-shedding and dedicated for use only in the sterile compounding area (buffer room).

(2) Cleaning tools are replaced as soon as they are identified as unsuitable for use

(3) All cleaning materials are disposable and discarded after one use.

(4) All trash is collected in suitable plastic bags and removed on a daily basis with minimal agitation

(5) Daily cleaning and sanitizing of workspaces including all buffer room carts, equipment, workbenches, work surfaces, and floors, and document the activity.

(6) Storage shelving in buffer and ante areas are emptied of all supplies, cleaned, and sanitized at planned intervals (at least monthly).

(7) Walls and ceilings in buffer and ante areas are cleaned at least monthly.

(8) All equipment is clean, properly maintained, validated and documented at appropriate intervals as defined by USP Standards.

Ph 404.07 Engineering Controls.

(a) Compounder shall ensure the Primary Engineering Controls (PEC): e.g., airflow workbench (LAFW) and Biological safety cabinets (BSCs) provide ISO Class 5 air quality.

(b) Compounder shall ensure the PECs are located in ISO Class 7 buffer room (cleanroom)

(c) Compounder shall ensure the buffer room (secondary engineering control) is designed to reduce the risk of contaminants being blown into primary compounding area (PCA). To be considered a clean room, buffer area must meet specific air quality, HEPA filtration, air changes per hour, and room pressure differentiation criteria (provide at least ISO Class 7 air quality). The buffer room provides ISO Class 7 air quality.

(d) Compounder shall ensure that within the buffer area, the PEC should be kept away from excess traffic, doors, air vents, or anything that could introduce contaminates into the workbench.

(e) Compounder shall ensure that the anteroom is separate from buffer area.

(f) Compounder shall ensure that the anteroom provides ISO Class 8 air quality, or ISO Class 7 air quality, depending on the connecting buffer area.

(g) Compounder shall ensure the anteroom area should store an adequate amount of gowning supplies but should not be part of high traffic area or corridor.

(h) Compounder shall ensure the anteroom is used to un-carton and sanitize all supplies to be taken into buffer area, and the (1) hand sanitizing and gowning activities occur in anteroom. (2) Faucet handles are designed to be hands-free, and that the (3) buffer area can be accessed without the use of hands.

(i) Compounders that only compound low and/or medium risk preparations, the ante room may be in the same area as buffer room, separated by line of demarcation. However, a separate ante room is still recommended.

(j) Compounders that compound high risk preparations, the buffer room and the ante room need to be two separate rooms.

(k) Compounder shall ensure all supplies brought into buffer area are non-permeable, non-shedding, and resistant to disinfectants.

(l) Compounder shall ensure all materials exposed to patient care areas are kept out of buffer area.

(m) Compounder shall ensure the PECs are cleaned and disinfected at the beginning of each shift, before each batch, at least every 30 minutes during compounding, when surfaces are visibly soiled, and when surface contamination is known or even suspected.

(n) Compounder shall ensure all interior working surfaces are cleaned and disinfected of LAFW from top to bottom, back to front, away from the HEPA filter. Cleaning is performed with purified water, and disinfecting with sterile 70% isopropyl alcohol or similar antimicrobial, residue-free sanitizing agent.

(o) Compounder shall ensure nothing should be permitted to come in contact with the HEPA filter. This includes cleaning solutions, aspirate from syringes, or glass from ampules, which should not be broken towards the filter.

Ph 404.08 Compounding Procedures.

(a) Compounder shall ensure that all personnel adhere to the following when they are in the LAFW or buffer areas:

(1) No smoking, food, drink, or chewing gum allowed in the buffer area at any time;

(2) Wear no jewelry on the hands or wrist or any visible piercings;

(3) No make-up is worn in the buffer area as it can shed particles;

(4) Before putting on gloves, the nails should be cleaned, and the hands, wrists, and forearms should be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser;

(5) Personnel shall appropriately utilize gowns, masks, gloves, hair covers, and shoe covers;

(6) No paper, pens, labels, or trays are placed in the workbench;

(7) No objects that shed particles are brought into the buffer area (cardboard cartons, paper towels, and cotton items).

(b) Compounder shall ensure when cleaning and disinfecting the interior work surfaces of the LAFW it is done from top to bottom, back to front, away for the HEPA filter.

(c) Compounding shall ensure personnel check the quality, purity, amount, and identity of all ingredients.

(d) Compounder shall ensure all personnel use the correct compounding procedures when compounding sterile products, and periodically disinfect gloves with sterile 70% isopropyl alcohol and allow them to dry thoroughly before continuing.

(e) Compounder shall ensure that open and partially used containers are properly labeled and stored.

(f) Compounder shall ensure the following:

(1) Has an appropriate beyond-use date that is identified on all product labels;

(2) When the BUD exceeds USP standards, it is based on scientific criteria;

(3) Packaging is appropriate for sterility and stability;

(4) Product labels are appropriate and complete for safe use;

(5) Products are visually inspected for physical integrity during and after compounding, and a final check of the CSP is performed.

(g) Compounder shall ensure any deficiencies in compounding procedures can be rapidly identified and corrected.

(h) Compounder shall ensure that finished compounded products are maintained in a separate area away from the active compounding area, and that no more than two entries into any one sterile container or sterile administration device

(i) Compounder shall ensure all compounding activities only involves closed or sealed packaging systems.

(j) Compounder shall use BUD based on USP standards, scientifically based BUD

(1) Low Risk Compounding: In the absence of sterility testing, storage does not exceed 48 hours at room temperature or 14 days at cold temperature or 45 days in a frozen state if the stability of the product allows.

(2) Medium Risk Compounding: In the absence of sterility testing, storage does not exceed 30 hours at controlled room temperature or 9 days at cold temperature or 45 days in a frozen state

(3) High Risk Compounding: In the absence of sterility testing, storage does not exceed 24 hours at room temperature or 3 days at cold temperature or 45 days in a frozen state

Ph 404.09 Records Management.

(a). Compounder shall maintain the following records related to compounding of sterile products for at least 4 (four) years:

(1) PEC certification records

(2) GAP analyses

(3) Detailed formulation record of each sterile compounded preparation that

a. Includes: name of preparation, strength and dosage form;

b. All ingredients and their quantities; equipment used for the preparation;

c. Admixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors; assigned beyond-use date;

d. Container used; storage requirements; quality control procedures.

(b) Compounder shall have procedures developed for the facility, equipment, personnel, preparation, packaging and storage of compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding.

(c) Compounder shall have a procedure for recalls. The recall file should be maintained with information concerning any applicable recalled products affecting the pharmacy.

(d) Compounder shall perform and maintain a quality control history and quality assurance trend reports on a regular basis and upon request.

(e) Compounder shall maintain documentation that confirms that sterile media used is certified by the manufacturer to be sterile and guaranteed to promote growth.

(f) Compounder shall maintain detailed reports on the incidence of positive media test results and the follow-up retests after corrective action is completed.

(g) Compounder shall provide a guaranteed shelf life upon delivery. This date shall be based on USP Standards, or based on established scientific criteria.

(h) Compounder shall document its processes and procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle.

(i) Compounder shall ensure that all personnel annually receive didactic training and visual process validation including written documentation of both processes.

(j) Compounder shall maintain documentation that its cleaning methods and agents are effective in preventing contamination of the sterile preparations area.

PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose and Scope. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. These rules shall supplement the rules/regulations of other state and federal agencies.

Ph 405.02 Definitions.

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.

(c) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the department of health and human services, bureau of radiological health.

(e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) A permit to operate a pharmacy, which provides radiopharmaceutical services shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and shall be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or satisfy each of the following requirements:

(1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the department of health and human services, bureau of radiological health;

(2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy, or other training program recognized by the department of health and human services, bureau of radiological health;

(3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

a. Radiation physics and instrumentation, 85 hours;

b. Radiation protection, 45 hours;

c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;

d. Radiation biology, 20 hours; and

e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

a. Procuring radioactive materials;

b. Compounding radiopharmaceuticals;

c. Performing routine quality control procedures;

d. Dispensing radiopharmaceuticals;

e. Distributing radiopharmaceuticals;

f. Implementing basic radiation protection procedures; and

g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the department of health and human services, bureau of radiological health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

(1) Radiopharmaceutical preparation/dispensing area;

(2) Radioactive material shipping/receiving area;

(3) Radioactive material storage area; and

(4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the department of health and human services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the department of health and human services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

(1) The name of the institution and prescriber, or prescribers' agent;

(2) The date of dispensing and the calibration time of the radiopharmaceutical;

(3) The name of the procedure;

(4) The name of the radiopharmaceutical;

(5) The dose or quantity of the radiopharmaceutical;

(6) The serial number assigned to the order for the radiopharmaceutical;

(7) Any specific instructions;

(8) The initials of the person who received the order; and

(9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name and address of the pharmacy;

(2) The name of the prescriber;

(3) The date of dispensing;

(4) The serial number assigned to the order for the radiopharmaceutical;

(5) The standard radiation symbol;

(6) The words "Caution Radioactive Material";

(7) The name of the procedure;

(8) The radionuclide and chemical form;

(9) The amount of radioactivity and the calibration date and time;

(10) If a liquid, the volume;

(11) If a solid, the number of items or weight;

(12) If a gas, the number of ampules or vials;

(13) Molybdenum 99 content to USP limits; and

(14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name of the pharmacy;

(2) The standard radiation symbol;

(3) The words "Caution Radioactive Material";

(4) The identity of the radionuclide;

(5) The chemical form;

(6) The name of the procedure; and

(7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

(a) A radionuclide dose calibrator;

(b) A refrigerator;

(c) A single or multiple channel scintillation counter with well-type NaI (Tl) or Ge (Li) detector;

(d) A radiochemical fume hood and filter system with air sampling equipment;

(e) An area survey meter;

(f) At least 2 GM survey meters including one high-range meter;

(g) A microscope and hemacytometer;

(h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;

(i) Syringe and vial radiation shields;

(j) A lead-shielded drawing station;

(k) Decontamination supplies;

(l) Supplies to perform quality assurance testing;

(m) Lead transport shields for syringes and vials; and

(n) New Hampshire department of transportation approved USA Type A - 7A approved transport containers and other labels and supplies for shipping radioactive materials.