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**DEPARTMENT OF LABOR, LICENSING AND REGULATION**

**BOARD OF PHARMACY**

CHAPTER 99

Statutory Authority: 1976 Code Sections 40‑1‑70 and 40‑43‑60(D)(5)

99‑47. Purpose of Regulations.

99‑48. Definitions.

99‑49. Training for Pharmacists and Technicians Engaging in Sterile and Nonsterile Compounding.

99‑50. Nonsterile and Sterile Compounding; Current Minimum Good Compounding Practices.

99‑51. Nonsterile Compounding; Beyond‑Use Date.

99‑52. Nonsterile Compounding; “Simple Compounding” Exempt.

99‑53. Nonsterile Compounding; Specifically Designated and Adequate Area for Compounding.

99‑54. Sterile Compounding; Current Minimum Good Compounding Practices.

**Synopsis:**

 The South Carolina Board of Pharmacy proposes to promulgate a regulation setting forth the minimum specifications and practice standards governing pharmacies and pharmacists engaged in sterile and nonsterile compounding.

 A Notice of Drafting was published in the *State Register* on October 28, 2016.

**Instructions:**

 Regulation 99-47 through 99-54 is added as shown below.

~~Indicates Matter Stricken~~

Indicates New Matter

**Text:**

99‑47. Purpose of Regulations.

 The following regulations are promulgated pursuant to S.C. Code 40‑43‑60(D)(5) to establish the minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding or dispensing, or both, of drugs or devices, and for the monitoring of drug therapy. The requirements set forth herein supplement, and are in addition to, any and all requirements of the South Carolina Pharmacy Practice Act, as set forth in S.C. Code 40‑43‑10, *et seq.* The purpose of these regulations is to set forth an objective standard of care for the practice of compounding in South Carolina and to provide guidance to licensees on the standards by which they will be inspected. These regulations do not apply to licensees who perform only simple compounding, as defined below.

99‑48. Definitions.

 A. All terms not specifically defined herein shall retain their definitions as set forth in the South Carolina Pharmacy Practice Act, S.C. Code Ann. 40‑43‑10 *et seq.*

 B. ‘Ante area’ means an ISO 8 or greater area where personnel perform hand hygiene, garbing, and stage components. An ante area precedes a buffer area, provided:

 (1) a buffer area must be separated by a wall from an ante area if high‑risk preparations are compounded; and

 (2) if only low‑risk and medium‑risk preparations are compounded, separating an ante room from a buffer area is recommended.

 C. ‘API’ means active pharmaceutical ingredient.

 D. ‘Aseptic preparation’ means the technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

 E. ‘Beyond use date’ or ‘BUD’ means the date or time after which a compounded preparation is recommended not to be dispensed or used. The date is determined from the date or time the preparation is compounded.

 F. ‘Buffer area’ means an area where the primary engineering control is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.

 G. ‘Colony‑forming unit’ or ‘CFU’ means an estimate of cell quantity.

 H. ‘Closed system transfer device’ or ‘CSTD’ means a closed system hazardous drug handling device comprising a number of interlocking parts for reconstituting, injecting, and administering doses of hazardous drugs.

 I. ‘Compounded sterile preparation’ or ‘CSP’ means a compounded biologic, diagnostic, drug, nutrient, or radiopharmaceutical that must be sterile when administered to a patient. Among other things, CSPs include:

 (1) aqueous bronchial and nasal inhalations;

 (2) baths and soaks for live organs and tissues;

 (3) injections, such as colloidal dispersions, emulsions, solutions, suspensions, among others;

 (4) irrigations for wounds and body cavities;

 (5) ophthalmic drops and ointments; and

 (6) tissue implants.

 J. ‘Compounding aseptic containment isolator’ or ‘CACI’ means a completely enclosed isolating cabinet that makes use of airtight glove ports designed to protect the user from exposure to airborne drugs and other agents during the compounding and material transfer processes. A CACI also provides an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur in a CACI unless the air is first passed through a HEPA medium, microbial retentive filter 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.

 K. ‘Compounding aseptic isolator’ or ‘CAI’ means a completely enclosed isolating cabinet that makes use of airtight glove ports designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a HEPA medium, microbial retentive filter. A CAI is used for nonhazardous drug preparations

 L. ‘Critical site’ means an opening that provides a direct pathway between a CSP and the environment or any surface coming in contact with the preparation or environment.

 M. ‘Disinfectant’ means 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.

 N. ‘Expiration date’ means the maximum time period that a manufactured, compounded, or repackaged product may be used based on specified storage requirements.

 O. ‘First air’ means the air exiting the HEPA filter in a unidirectional airstream that is essentially particulate free.

 P. ‘Glove fingertip test’ means a test where the gloved fingertips and thumb are lightly pressed into appropriate agar plates. The plates are incubated for an appropriate time period and at an appropriate temperature.

 Q. ‘Hazardous drug’ means a drug that has at least one of the following properties: carcinogenicity; teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low doses in humans or animals; genotoxicity; or new drugs that mimic existing hazardous drugs in structure or toxicity.

 R. ‘High‑efficiency particulate arrestance’ or ‘HEPA’ means a type of air filter that must satisfy certain efficiency standards set by the United States Department of Energy. A filter that qualifies as a HEPA is subject to interior classifications.

 S. ‘ISO’ means the International Organization for Standardization.

 T. ‘ISO 5 environment’ means an atmospheric environment that contains fewer than 3,520 particles no greater than 0.5 millimeters in diameter per cubic meter of air.

 U. ‘ISO 7 environment’ means an atmospheric environment that contains fewer than 352,000 particles no greater than 0.5 millimeters in diameter per cubic meter of air.

 V. ‘ISO 8 environment’ means an atmospheric environment that contains fewer than 3,520,000 particles no greater than 0.5 millimeters in diameter per cubic meter of air.

 W. ‘Isolator’ means a self‑contained primary engineering control defined by having fixed walls, a floor, and a ceiling, and includes barriers such as gloves, sleeves, and air locks that separate transfers of materials into and out of the environment.

 X. ‘Laminar air flow workbench’ or ‘LAFW’ means a primary engineering control that uses an ISO 5 controlled environment created by a HEPA filter to retain airborne particles and microorganisms, and has horizontal air flow or vertical air flow.

 Y. ‘Material safety data sheet’ or ‘MSDS’ means a resource that provides information concerning a chemical, including:

 (1) the identity, physical and chemical characteristics, physical and health hazards, primary routes of entry, and exposure limits of the chemical;

 (2) whether the chemical is a carcinogen;

 (3) precautions for safe handling and use of the chemical;

 (4) control measures;

 (5) emergency and first aid procedures;

 (6) the latter of the date the MSDS was prepared or last modified; and

 (7) the name, address, and telephone number of the manufacturer, importer, or employer who distributes the MSDS.

 Z. ‘Media fill test’ means a test to evaluate the aseptic technique of:

 (1) compounding personnel;

 (2) a process to ensure that the process used can produce sterile preparation that has no microbial contamination.

 AA. ‘Negative pressure’ means a room or device that is at a lower pressure than adjacent space; the air flow moves into the room or device.

 BB. ‘Personal protective equipment’ or ‘PPE’ means a gown, glove, mask, hair cover, shoe cover, eye shield, and similar items intended to protect the compounder from hazards and minimize particle shedding.

 CC. ‘Positive pressure’ means a room or device with higher pressure than adjacent space so that air flow moves out of, rather than into, the room or device.

 DD. ‘Preparation’ means a drug, device, or nutrient compounded in a licensed pharmacy or licensed health care facility.

 EE. ‘Primary engineering control’ or ‘PEC’ means a device, such as a laminar airflow workbench or an isolator, or a room that provides an ISO 5 environment.

 FF. ‘Process verification and validation’ means the process:

 (1) used to evaluate whether a preparation, service, or system meets specifications and fulfills its intended purpose; and

 (2) of establishing evidence that provides a high degree of assurance that a preparation, service, or system accomplishes its intended requirements.

 GG. ‘Product’ means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. A product is accompanied by FDA approved manufacturer labeling or a product package insert.

 HH. ‘Pyrogen’ means a substance or agent that tends to cause a rise in body temperature or fever.

 II. ‘Secondary engineering control’ means a buffer area and an ante area that meet the designated ISO classification.

 JJ. ‘Segregated compounding area for compounding sterile preparations’ means a designated space:

 (1) confined to a room or a demarcated area;

 (2) restricted to preparing low‑risk CSPs with a twelve hour or less beyond‑use time;

 (3) containing a device that provides unidirectional air flow of ISO 5 air quality;

 (4) free of materials extraneous to sterile compounding; and

 (5) not used for other activities or purposes.

 KK. ‘Simple Compounding’ is defined as:

 (1) reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer;

 (2) making twenty or less compounds of an oral liquid or topical dosage form utilizing five or less non‑hazardous APIs over any 30 day period (not exempt from S.C. Code Ann. Sec. 40‑43‑86(CC)(6), “Formulas and Logs Maintained”).

 LL. ‘Sterility test’ means a process designed to determine the presence of bacteria or fungi in or on a test device or solution.

 MM. ‘USP/NF’means the United States Pharmacopeia and the National Formulary.

 NN. ‘Velocity’ means the displacement air flow across the line of demarcation between a buffer area into the ante area in a single room.

 OO. ‘Zone of turbulence’ means the pattern of flow of air from the HEPA filter created behind an object placed within the LAFW pulling or allowing contaminated room air into the aseptic environment.

99‑49. Training for Pharmacists and Technicians Engaging in Sterile and Nonsterile Compounding.

 A. Pharmacists and technicians engaging in compounding shall achieve competence and maintain proficiency through current awareness, training and annual competency assessment in the art and science of compounding and the rules and regulations of compounding. Entities or facilities involved in compounding must have an education component for all personnel involved in the compounding process. Evidence of the employee training must be documented in the employee file at the pharmacy. Each employee must have six hours of initial training documented and must have four hours of CE or training on an annual basis. This education does not have to be Accreditation Counsel for Pharmacy Education or Continuing Medical Education—Category 1 sponsored, unless the individual intends to use the CE to satisfy the CE requirement for the renewal of his/her pharmacist license or technician registration.

 B. A pharmacist and/or technician engaged in both sterile and nonsterile compounding is only required to complete the requirements set forth in Section A and is not required to complete twelve hours of initial training and eight hours of CE training on an annual basis by virtue of engaging in both sterile and nonsterile compounding.

99‑50. Nonsterile and Sterile Compounding; Current Minimum Good Compounding Practices.

 The following are the minimum current good compounding practices for the preparation of medications by pharmacists licensed in the State for dispensing or administering, or both, to humans or animals:

 A. A compounder shall first attempt to use components manufactured in an FDA‑registered facility. When components cannot be obtained from an FDA‑registered facility, a compounder shall use his professional judgment in selecting an acceptable and reliable source and shall establish purity and safety by reasonable means, to include Certificate of Analysis, manufacturer reputation, and reliability of source.

 B. For components that do not have expiration dates assigned by the manufacturer or supplier, a compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt of the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions.

 C. Practitioners who administer compounded medications in an office or licensed ambulatory surgical facility setting shall be allowed to order and purchase those medications from the compounding pharmacy, store them in the office for future use but not for resale, and administer those medications according to their usual physician/patient/pharmacy practice relationship. A prescription for an individual patient for each administration of the drug shall not be required.

 D. Institutional pharmacies may order and store compounded preparations, both sterile and nonsterile, from compounding pharmacies in anticipation of patient orders based on the existence of a pharmacist/patient/practitioner relationship for regularly observed prescribing patterns. A chart order from a practitioner will be required for administration in an institutional facility.

 E. Pharmacy technicians may assist the pharmacist in compounding. The pharmacy technician’s duties must be consistent with the training received. The pharmacist must perform the final check of the compounded preparation to determine if the preparation is ready to dispense.

 F. All significant procedures performed in the compounding area must be covered in written policies and procedures. These procedures must be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounded preparations and ingredients to ensure accountability, accuracy, quality, safety, and uniformity in compounding as appropriate for the level of compounding performed at the facility.

 G. Material safety data sheets should be readily accessible from an internet website or otherwise to all personnel working with drug substances or bulk chemicals located on the compounding facility premises, and personnel should be instructed on how to retrieve needed information.”

 H. A pharmacist must maintain areas at temperatures and humidity levels to ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF or the labeling of the manufacturer or distributor, or both.

99‑51. Nonsterile Compounding; Beyond‑Use Date.

 The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned control number and the beyond‑use date based on appropriate testing, or published data. In the absence of stability information applicable to the specific compound, the maximum BUD must be determined by:

 (1) the type of formulation, such as nonaqueous, water containing, or topical; and

 (2) professional judgment.

99‑52. Nonsterile Compounding; “Simple Compounding” Exempt.

 Pharmacies who perform only “simple compounding” are exempt from the applicability of Regulations 99‑47 through 99‑54.

99‑53. Nonsterile Compounding; Specifically Designated and Adequate Area for Compounding.

 A. The nonsterile area is a controlled environment. The area must be:

 (1) A room that is separated from the pharmacy area by a wall or curtain and allows for pharmacist observation; or

 (2) A low traffic area, within the pharmacy area, that has a powder containment hood.

 B. There must be sufficient space available for the type and amount of compounding performed and the space must be orderly to prevent mix‑ups between ingredients, containers, labels, in‑process materials, and finished preparations.

99‑54. Sterile Compounding; Current Minimum Good Compounding Practices.

 A. The purpose of this section is to provide standards for the preparation, labeling, storing, dispensing, and distribution of sterile preparations by pharmacies and other facilities permitted by the board.

 B. Compounded sterile preparation (CSP) microbial contamination risk level is assigned according to the corresponding probability of contamination.

 (1) A low‑risk level CSP is compounded under the following conditions:

 (a) The CSP must be compounded with aseptic manipulations entirely within ISO 5 environment or better air quality using only sterile ingredients, products, components, and devices with the exception of radiopharmaceuticals as stated in S.C. Code Ann. Section 40‑43‑87.

 (b) The compounding only may involve transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into one sterile container or package of sterile product or administration container or device to prepare the CSP.

 (c) For a low‑risk level preparation, in the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

 (i) not more than forty‑eight hours at controlled room temperature;

 (ii) not more than fourteen days at a cold temperature; and

 (iii) not more than forty‑five days in solid frozen state.

 (2) A low‑risk level CSP prepared in a PEC and that cannot be located within an ISO 7 environment or better buffer area requires a twelve hour or less BUD. A low‑risk level CSP with a BUD of twelve hours or less must meet the following criteria:

 (a) PECs must be certified and maintain ISO 5 environment for exposure to critical sites and must be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.

 (b) The segregated compounding area must not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.

 (c) Personnel shall follow all procedures outlined in subsection (F), below, prior to compounding. A sink may not be located adjacent to the ISO 5 environment PEC and must be separated from the immediate area of the ISO 5 environment PEC.

 (d) The specifications for cleaning and disinfecting the sterile compounding area, personnel training and responsibilities, aseptic procedures, and air sampling must be followed as described in subsection (F), below.

 (3) A medium‑risk level CSP occurs under low‑risk conditions when one or more of the following conditions exist:

 (a) Multiple individual or small doses of sterile products are combined or pooled to prepare CSPs that will be administered either to multiple patients or to one patient on multiple occasions.

 (b) The compounding process includes complex aseptic manipulations other than the single volume transfer.

 (c) The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

 (d) In the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

 (i) not more than thirty hours at controlled room temperature;

 (ii) not more than nine days at a cold temperature; and

 (iii) not more than forty‑five days in solid frozen state.

 (4) A CSP is considered high‑risk if it is compounded under the following conditions due to contamination or high‑risk of becoming contaminated:

 (a) Nonsterile ingredients and products are incorporated or a nonsterile device is employed before terminal sterilization.

 (b) Any of the following are exposed to air quality worse than ISO 5 environment for more than one hour:

 (i) sterile contents of commercially manufactured products;

 (ii) CSPs that lack effective antimicrobial preservatives; and

 (iii) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

 (c) Presterilization procedures for high‑risk level CSP, such as weighing and mixing, are completed in an ISO 8 or better environment.

 (d) Preparations are appropriately sterilized before dispensing.

(e) For a high‑risk level preparation, in the absence of passing a sterility test or process validation, the storage periods should not exceed the following time periods before administration and with proper storage:

(i) not more than twenty‑four hours at controlled room temperature;

(ii) not more than three days at a cold temperature; and

(iii) not more than forty‑five days in solid frozen state.

(5) The immediate use CSP provision stated here only may be used for situations where a need for emergency or immediate patient administration of a CSP exists. An immediate use preparation may not include a medium‑risk level or a high‑risk level CSP. An immediate use CSP is exempt from the requirements described in subsection (B)(1) if:

(a) The compounding process involves simple transfer of commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers’ original containers into any one container or package of sterile infusion solution or administration container or device.

(b) During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mixups with other CSPs, and direct contact of outside surfaces.

(c) Administration begins not later than one hour following the start of the preparation of the CSP.

(d) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP must bear a label listing the patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact one hour BUD and time.

(e) If administration has not begun within one hour following the start of preparing the CSP, the CSP must be discarded.

C. The compounding area of the facility must meet the facility requirements relative to the risk level of preparations they prepare.

(1) Facility design and environmental control must be designed to minimize airborne contamination from contacting critical sites.

(a) A PEC must maintain ISO 5 environment or better conditions while compounding.

(b) The PEC HEPA‑filtered air must be supplied in critical areas at a velocity sufficient to sweep particles away from the compounding area.

(2) The buffer area must maintain at least ISO 7 environment under dynamic operating conditions.

(a) The room must be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the HEPA‑filtered airflow environment.

(b) For buffer areas not physically separated from the ante areas, the principle of displacement airflow must be employed. The displacement concept shall not be used for high–risk compounding.

(c) The PEC must be placed out of the traffic flow in a manner to avoid conditions that could adversely affect their operation.

(d) Cleaning materials must be nonshedding and dedicated for use only in the sterile compounding area.

(e) Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed may be brought into the buffer area, and they must be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. They must be cleaned, then disinfected before brought into the area.

(f) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area must be smooth, impervious, and nonshedding in order to promote cleanliness.

(g) The buffer area shall not contain sources of water or floor drains with the exception of emergency safety devices.

(3) An ISO 7 environment buffer area and ante area supplied with HEPA‑filtered air must have air changes per hour (ACPH) of not less than thirty.

(4) HEPA‑filtered supply air should be introduced at the ceiling and returns must be mounted low on the wall, creating a general top down dilution of area air.

(5) The floors in the clean and ante areas are cleaned by mopping on each day of operation when no aseptic operations are in progress.

(6) The environment for compounding must contain an ante area that is ISO 8 environment quality air or better. Areas participating in high‑risk compounding must have a separate ante area. Supplies and equipment must be removed from shipping cartons outside of the ante area, and must be wiped with a sanitizing agent before being transported to the clean room.

(7) The buffer area designated for placement of the ISO 5 environment PEC must be constructed to allow visual observation.

(8) The buffer area may not be used for storage of bulk supplies and materials contained in corrugated cardboard containers.

(9) Maintain areas at temperatures and humidity levels to ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF or the labeling of the manufacturer or distributor, or both.

D. Environmental quality and control practices include:

(1) Giving the highest priority in a sterile compounding practice to the protection of critical sites by precluding physical contact and airborne contamination.

(2) Performing viable and nonviable environmental air sampling testing every six months as part of a comprehensive quality management program and:

(a) as part of the commissioning and certification of new facilities and equipment;

(b) as part of the recertification of facilities and equipment; or

(c) in response to identified problems with the sterility of end preparations.

(3) Secondary Engineering control performance verification procedures must be performed by a qualified individual no less than every six months and when the room is altered. Certification documents must be retained for two years.

(4) All certification records must be maintained and reviewed by pharmacy personnel to ensure that the controlled environments are in compliance.

(5) A pressure gauge or velocity meter must be installed to monitor the pressure differential or airflow between the buffer area and the ante area and between the ante area and the general environment outside the compounding area.

(a) The pressure between the positive ISO 7 environment or better buffer area, the ante area, and the general pharmacy area may not be less than a 0.02 inch water column.

(b) The pressure between the negative ISO 7 environment or better buffer area, the ante area, and the general pharmacy area may not be less than a –0.01 inch water column. For negative pressure buffer areas, the ante area must be ISO 7 environment or better.

(c) The results must be reviewed and documented on a log maintained either electronically or manually at least every work shift or by a continuous recording device.

(6) An appropriate facility specific environmental sampling procedure must be followed for airborne viable particles based on a risk assessment of compounding activities performed.

(a) The documentation must include sample location, method of collection, volume of air sampled, time of day and action levels.

 (b) Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments, including LAFWs, CAIs, clean room or buffer areas, and ante areas, must be performed by properly trained individuals for all compounding risk levels. Impaction is the preferred method of volumetric air sampling.

 (c) For all compounding risk levels, air sampling must be performed during dynamic compounding activities.

 (d) Corrective actions must be taken when CFU counts for each ISO classification are exceeded, per current USP <797> definition or when microorganisms are identified that are potentially harmful to patients receiving CSPs.

 E. Hazardous CSPs:

 (1) All hazardous CSPs must be compounded and prepared in an ISO 5 environment in a BSC or CACI with the exception of radiopharmaceuticals as stated in S.C. Code Ann. Section 40‑43‑87. Hazardous drugs may not be prepared in a laminar airflow workbench or a compounding aseptic isolator.

 (2) Appropriate personal protective equipment must be worn by personnel compounding hazardous agents.

 (3) Written procedures for disposal and handling spills of hazardous agents must be developed.

 (4) There must be immediate access to emergency spill supplies wherever hazardous drugs are prepared.

 (5) A hazardous CSP must be identified with warning labels in accordance with state and federal requirements.

 (6) A hazardous CSP must be packaged for handling and delivery in a manner that minimizes the risk of rupture of the primary container and ensures the stability, sterility, and potency of the solution.

 (7) A hazardous drug must be handled with caution at all times during receiving, distribution, stocking, inventorying, preparation for administration, and disposal.

 (8) Documentation that personnel have been trained in the compounding, handling, and disposal of hazardous agents must be available. This documentation must be updated annually. The training must include the following if applicable:

 (a) safe aseptic manipulation practices;

 (b) negative pressure techniques when utilizing a BSC or CACI;

 (c) correct use of CSTD devices;

 (d) containment, cleanup and disposal procedures for breakages and spills; and

 (e) treatment of personnel contact and inhalation exposure.

 F. Policies and procedures must be developed and implemented for the pharmacy. These policies and procedures must include the following as applicable:

 (1) annual training and evaluation of sterile compounding personnel to include skills observation of antiseptic hand cleansing, other personnel cleansing, media fill challenge, glove fingertip testing, cleaning of compounding environment, donning protective garb, maintaining or achieving sterility of CSPs;

 (2) semiannual media fill test representative of high‑risk compounding must be performed by all personnel authorized to prepare high‑risk CSPs;

 (3) cleaning and disinfecting of the sterile compounding areas and devices with supporting documentation;

 (4) ensuring identity, quality, and purity of ingredients;

 (5) sterilization methods for high‑risk CSPs;

 (6) establishment of appropriate storage requirements and BUDs;

 (7) measuring, mixing, dilution, purification, packaging, and labeling;

 (8) unpackaging and introducing supplies into the sterile compounding environment;

 (9) compounding activities that require the manipulation and disposal of a hazardous material;

 (10) expiration dating of single dose and multiple dose containers;

 (11) quality control and quality assurance of CSP processes;

 (12) written procedures outlining required equipment calibration, maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities must be established and followed. Results from the equipment calibration, semiannual certification reports, and routine maintenance must be kept on file for two years;

 (13) patient training and competency in managing therapy in the home environment;

 (14) safety measures to ensure accuracy of CSPs; and

 (15) compounding logs for nonpatient‑specific CSPs.

 G. Compounding personnel:

 (1) may not introduce food or drinks into the ante areas, buffer areas, or segregated compounding areas; and

 (2) shall ensure that all CSPs are checked by a pharmacist before dispensing.

**Fiscal Impact Statement:**

 There will be no cost incurred by the State or any of its political subdivisions for these regulations.

**Statement of Rationale:**

 The updated regulations will establish the minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding or dispensing, or both, of drugs or devices, and for the monitoring of drug therapy. The requirements set forth herein supplement, and are in addition to, any and all requirements of the South Carolina Pharmacy Practice Act, as set forth in S.C. Code 40‑43‑10, *et seq.* The purpose of these regulations is to set forth an objective standard of care for the practice of compounding in South Carolina and to provide guidance to licensees on the standards by which they will be inspected. These regulations do not apply to licensees who perform only simple compounding, as defined.