

ARTICLE 20:51

PHARMACISTS

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CHAPTER 20:51:26

STERILE PRODUCTS FOR HOME CARE PATIENTS

(Repealed)

CHAPTER 20:51:31

STERILE COMPOUNDING PRACTICES

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20:51:31:01. Definitions. Terms used in this chapter mean:

(1) "Anteroom" or "ante area," an ISO Class 8 or superior area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, preparation labeling, and other high-particulate generating activities;

(2) "Aseptic preparation," the technique involving procedures designed to preclude contamination by microorganisms during processing;

(3) "Batch preparation," compounding or repackaging of multiple units, in a single process, by the same operator;

(4) "Beyond-use date," the date or time following compounding after which the preparation shall not be stored or transported. The beyond-use date is determined from the date or time compounding of the preparation is completed;

(5) "Biological safety cabinet, Class II" or "BSC," a ventilated cabinet having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection;

(6) "Buffer area" or "cleanroom," a room or area where the primary engineering control device is physically located and in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class;

(7) "Compounding," the constitution, reconstitution, combination, dilution, or another process causing a change in the form, composition, or strength of any ingredient or any other attribute of a product;

(8) "Compounding aseptic isolator" or "CAI," a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. A CAI is 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 it has first passed through a microbially retentive filter, HEPA minimum;

(9) "Critical site," a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampoules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination;

(10) "Hazardous drug," a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic;

(11) "HEPA Filter," a high efficiency particulate air filter where air is forced through in a uniform flow and 99.97% of all particles three-tenths (0.3) microns or larger are removed;

(12) "High-risk preparation," a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; for that meets the conditions of § 20:51:26:20;

(13) "ISO (International Organization for Standardization) Classification of Particulate Matter in Room Air," limits in particles of 0.5 microns or larger in diameter per cubic foot of air:

(a) ISO Class 5, less than 100 particles per cubic foot,

(b) ISO Class 7, less than 10,000 per cubic foot; and

(c) ISO Class 8, less than 100,000 per cubic foot;

(14) "Laminar airflow workbench" or "LAFW," an apparatus designed to provide an ISO Class 5 environment for the preparation of sterile products that uses air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and the particles generated within the controlled environment;

(15) "Low-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of § 20:51:26:18;

(16) "Medium-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of § 20:51:26:19;

(17) "Media-fill test" or "MFT," a test used to validate aseptic technique of compounding personnel or of processes and to ensure that the processes used are able to produce sterile product without microbial contamination;

(18) "Multiple-dose container," a multiple-unit container for articles or preparations intended for parenteral administration only usually containing antimicrobial preservatives;

(19) "Negative pressure room," a room that is at a lower pressure compared to adjacent spaces, creating a new airflow into the room;

(20) "Positive pressure room," a room that is at a higher pressure compared to adjacent spaces, creating a net airflow out of the room;

(21) "Preparation" or "compounded sterile preparation," a sterile drug or nutrient that is

compounded in a licensed pharmacy or other health care-related facility pursuant to the order of a licensed prescriber, which preparation may or may not contain sterile products;

(22) “Primary engineering control device,” a device or room that provides an ISO Class 5 environment during the compounding process. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), and compounding aseptic isolators (CAIs);

(23) “Product,” a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA; and

(24) “Sterile compounding,” the aseptic processing in a clean air environment of any pharmaceutical including, but not limited to, the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Source:

General Authority: SDCL 36-11-11(1),(3), (4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:02. Standards and procedures. These rules establish standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a physician’s order or prescription; for sterile product quality and characteristics; and for pharmaceutical care. The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

(1) Is prepared according to the manufacturer’s labeled instructions and requires other manipulations that expose the original contents to potential contamination;

(2) Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or

(3) Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either (1) or (2) above and includes, but is not limited to, the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections, aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Source:

General Authority: SDCL 36-11-11(1) and (4).

Law Implemented: SDCL 36-11-11.

20:51:31:03. Policies and procedures. A written policy and procedure manual shall be prepared, implemented, maintained and adhered to for the compounding, dispensing, administration, storage, and use of sterile preparations. The manual shall be available for inspection by the board. Policies and procedures shall address the following:

- (1) Responsibilities of compounding personnel;
- (2) Personnel training and testing;
- (3) Competency practices and assessment of compounding personnel;
- (4) Quality Assessment and Quality Improvement activities;
- (5) Proper use and deployment of environmental controls;
- (6) Gowning and garbing practices;
- (7) Inspection of finished products, labeling, storage, and transfer to final use areas for storage or use;
- (8) Introduction of supplies and products into the compounding area; and
- (9) The formulation, process for compounding, beyond-use dating, and storage requirements for each routinely compounded sterile preparation.

Source:

General Authority: SDCL 36-11-11(1) and (4).

Law Implemented: SDCL 36-11-11.

20:51:31:04. Physical environment requirements for sterile products. The pharmacy shall have a designated area for compounding sterile preparations with entry restricted to designated personnel. The area shall be used only for sterile compounding. The area shall be structurally isolated from other areas and shall be designed to avoid unnecessary traffic and airflow disturbances. The area shall be of sufficient size to accommodate at least one primary engineering control device and to provide for the storage of drugs and supplies under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

Source:

General Authority: SDCL 36-11-11(1), (3), and (4).

Law Implemented: SDCL 36-11-11.

20:51:31:05. Requirement for primary engineering control device. The primary engineering control device shall be capable of maintaining at least ISO Class 5 air quality in the area where critical objects are exposed and critical activities are performed. The device shall be capable of maintaining ISO Class 5 air quality during normal activity. A primary engineering

control device includes, but is not limited to, a horizontal or vertical laminar airflow workbench or CAI.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:06. Placement of primary engineering control device. The primary engineering control device shall be placed in a buffer area where HEPA filters are employed and the air quality is maintained at ISO Class 7. This area shall have cleanable, nonshedding, smooth surfaces; all junctures shall be coved; and all cracks and crevices shall be caulked. The ceiling shall be impervious and hydrophobic. The buffer area shall not contain any drains or sinks. Only the furniture, equipment, supplies and other material required for compounding activities to be performed shall be brought into the room. Such items brought into the room shall be cleaned and disinfected. Placement in buffer areas of objects and devices not essential to the compounding process is dictated by the measured effect of those objects and devices on the required environmental quality of air atmospheres and surfaces.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:07. Exception for placement of CAI. The CAI shall be placed in an ISO Class 7 cleanroom unless the CAI meets each of the following conditions:

(1) The CAI provides isolation from the room and maintains ISO Class 5 conditions when ingredients, components, and devices are transferred into and out of the CAI during the preparation process; and

(2) The manufacturer provides documentation verifying that the CAI meets the standard in paragraph (1) when the CAI is located in an environment inferior to ISO Class 7.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:08. Anteroom requirements. An anteroom or ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. If the ante area is adjacent to a negative pressure buffer area, then the ante area must maintain ISO class 7 air quality.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-1, 36-11-41.

20:51:31:09. Delayed implementation. A pharmacy whose sterile compounding area is in substantial compliance with the physical and structural requirements of this rule shall be authorized to engage in the compounding of sterile preparations pursuant to the practice standards established by this chapter and subject to the following:

(1) Any pharmacy that commences, on or after December 31, 2010, or any new construction or remodeling of a pharmacy sterile compounding area shall comply with the physical and structural requirements of this rule; or

(2) Any pharmacy engaged in the compounding of sterile preparations shall, no later than December 31, 2011, complete any necessary changes or improvements to the sterile compounding area to ensure compliance with the physical and structural requirements of this rule.

Source:

General Authority: SDCL 36-11-11(1), (4), and (5).

Law Implemented: SDCL 36-11-1, 36-11-41.

20:51:31:10. Cleaning, maintenance and supplies. The pharmacy shall have the following appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations:

(1) Required supplies and equipment shall include, but may not be limited to, the following:

(a) Appropriate attire including nonshedding coveralls or gowns, head and facial covers, face masks, appropriate gloves, and shoe covers; and

(b) A sink with hot and cold running water, with soap available for the purpose of hand and forearm scrubs, which shall be located convenient to the area used for compounding sterile preparations but outside the buffer area;

(2) Documented procedures shall include, but not be limited to, the following:

(a) Specific cleaning procedures and frequencies for each compounding area involved;

(b) A list of approved cleaning agents for each procedure;

(c) A written plan and schedule for the evaluation of airborne microorganisms in each controlled air environment (e.g., LAFW, barrier isolators, buffer area, and anteroom);

(d) Equipment calibration and monitoring of proper function of equipment, apparatus,

and devices used to compound sterile preparations, in accordance with § 20:51:31.25; and

(e) An appropriate cleansing and garbing procedure. Coveralls and gowns may be hung outside the entry of the buffer area and reused for one shift, provided the coveralls and gowns are not visibly soiled and have not been worn during the compounding of hazardous drugs.

Source:

General Authority: SDCL 36-11-11(1), (3), (4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41, 36-11-42.

20:51:31:11. Additional records required. In addition to records required in § 20:51:24:02, the pharmacy shall maintain records of lot numbers of the components used in compounding sterile products when:

- (1) The preparation will be dispensed to a home care patient; and
- (2) Non-sterile ingredients are used in preparing high risk sterile products.

Source:

General Authority: SDCL 36-11-11(1) and (4).

Law Implemented: SDCL 36-11-11.

20:51:31:12. Quality assurance. The pharmacy shall establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

(1) The portion of the quality assurance program that monitors facilities, equipment, and personnel performance shall include the following:

(a) Methods for verification of automated compounding devices for parenteral nutrition compounding;

(b) Methods for sampling finished preparations to ensure that the pharmacy is capable of consistently preparing sterile preparations that meet appropriate risk level specifications and to ensure product integrity;

(c) Procedures for inspection of all prescription orders, written compounding procedures, preparation records, and materials used to compound at all contamination risk levels, to ensure accuracy of ingredients, aseptic mixing, sterilizing, packaging, labeling, and expected physical appearance of the finished preparation;

(d) Procedures for visual inspection of preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling;

(e) Procedures for review of all orders and packages of ingredients to ensure that the correct ingredients and quantity of ingredients were compounded;

(f) Methods for routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality;

(g) Methods for ensuring personnel qualifications, training, and performance, including periodic performance of applicable MFT procedures;

(h) Procedures for visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; and

(i) Methods for establishing beyond-use dates of preparations.

(2) The portion of the quality assurance program that monitors patient care shall include the following:

(a) Utilizing specific procedures for recording, filing, and evaluating reports of adverse events and the quality of preparation identified in the adverse event;

(b) Utilizing written policies and procedures that include specific procedures or instructions for receiving, acknowledging, and dating the receipt of products;

(c) Reviewing documented patient or caregiver education and training required pursuant to ARSD 20:51:26:10;

(d) Ensuring that a qualified pharmacist is available and accessible at all times to respond to the questions and needs of other health professionals, the patient, or the patient's caregiver; and

(e) Identifying activities and processes that are deemed high-risk, high-volume, or problem-prone and providing effective corrective actions to remedy these activities and processes.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:13. Pharmacist responsibilities. Each pharmacy shall have a pharmacist responsible for ensuring that:

(1) Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed;

(2) Cleanliness is maintained, including preservation of the sterile environment during the compounding process;

(3) Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen

beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used;

(4) Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits;

(5) Procedures are followed for measuring, mixing, diluting, purifying, sterilizing, packaging, and labeling of the specific preparation;

(6) Packaging selection is appropriate to preserve the sterility and strength of the preparation; and

(7) All functions performed by non-pharmacists are verified by the pharmacist before the preparation is dispensed to the patient. Pharmacist verification of a preparation shall include visual inspection of labeling, physical integrity, and expected appearance, including final fill amount.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:14. Training documentation. Documentation of training shall verify that compounding personnel are able to adequately complete the following activities:

(1) Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;

(2) Select and appropriately don protective garb;

(3) Maintain or achieve sterility of preparations in ISO Class 5 primary engineering control devices;

(4) Identify, weigh, and measure ingredients;

(5) Manipulate sterile products aseptically, sterilize high-risk preparations, and label preparations; and

(6) Protect personnel and compounding environments from contamination by hazardous drugs.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:15. Reference requirements. The pharmacy shall have current reference materials related to sterile products and preparations. References may be printed or computer-accessed. In addition to meeting the requirements set forth in § 20:51:07:04, all pharmacies

involved in sterile compounding shall maintain a minimum of one current reference, including access to current periodic updates, from each of the following categories:

- (1) An injectable drug compatibility reference; and
- (2) If the pharmacy is compounding hazardous drugs, a reference related to hazardous

drugs.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:16. Labeling Requirements. Requirements for labeling containers include:

(1) At the time of delivery, a patient-specific dispensing container used for a preparation shall bear a label with at least the following information:

- (a) Name and quantity of all contents;
- (b) Patient's name;
- (c) For home care patient prescriptions, unique serial number or prescription number;
- (d) Preparer's and reviewing pharmacist's initials or unique identifiers;
- (e) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual (unless the contents will be used within 24 hours of preparation);
- (f) The prescribed flow rate in ml/hr, if applicable; and
- (g) Auxiliary labels as needed.

(2) Each container of a batch preparation that is compounded in anticipation of later dispensing shall bear a label with at least the following information:

- (a) Name and quantity of all contents;
- (b) Internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers;
- (c) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual; and
- (d) Auxiliary labels as needed.

Source:

General Authority: SDCL 36-11-11(1) and (12).

Law Implemented: SDCL 36-11-11.

20:51:31:17. Microbial contamination risk levels. Preparations shall be assigned the appropriate risk level—low, medium or high—according to the corresponding probability of

contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter. The characteristics described in §§ 20:51:31:18 to 20:51:31:20, inclusive, are intended as guides to the diligence required in compounding at each risk level.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:18. Low-risk preparations. Preparations compounded under all of the following conditions are at a low risk of contamination:

(1) The preparations are compounded with aseptic manipulations entirely within ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices;

(2) The compounding involves only transferring, measuring, and mixing no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the preparation;

(3) Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, containers of other sterile products, and containers for storage and dispensing;

(4) In the absence of the preparation's passing a sterility test and provided that the preparation is properly stored before administration, storage periods shall not exceed the following:

(a) At controlled room temperature for 48 hours;

(b) At a cold temperature for 14 days; or

(c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days;

(5) Examples of low-risk compounding include:

(a) The single-volume transfer of sterile dosage forms from ampoules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. When ampoules are employed, solution content shall be passed through a sterile filter to remove any particles; and

(b) The manual measuring and mixing of no more than three manufactured products including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:19. Medium-risk preparations. Preparations compounded aseptically under low-risk conditions with one or more of the following additional conditions are at a medium risk of contamination:

(1) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile preparation for administration either to multiple patients or to one patient on multiple occasions;

(2) The compounding process includes complex aseptic manipulations other than the single- volume transfer;

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

(4) In the absence of the preparation's passing a sterility test and provided that the preparation is properly stored before administration, storage periods shall not exceed the following:

(a) At controlled room temperature for 30 hours;

(b) At a cold temperature for 9 days; or

(c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days;

(5) Examples of medium-risk compounding include:

(a) Compounding total parenteral nutrition fluids, using manual or automated devices and involving multiple injections, detachments, or attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container;

(b) Filling reservoirs of injection or infusion devices with more than three sterile drug products and evacuating air from those reservoirs before dispensing the filled device; and

(c) Transferring volumes from multiple ampoules or vials into one or more final sterile containers.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:20. High-risk preparations. Preparations that are either contaminated or likely to become contaminated with infectious microorganisms when compounded under any of the following conditions are at a high risk of contamination:

(1) Nonsterile ingredients, including manufactured products not intended for sterile use, are incorporated or a nonsterile device is used in the compounding process before terminal sterilization;

(2) Sterile contents of commercially manufactured products, preparations that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers intended for the preparation, transfer, sterilization, and packaging of preparations are exposed to air quality inferior to ISO Class 5 for more than one hour;

(3) Nonsterile procedures such as weighing and mixing in air quality inferior to ISO Class 7 are performed before sterilization, compounding personnel are not properly garbed and gloved, or water-containing preparations are stored for more than six hours;

(4) The chemical purity and content strength of bulk ingredients, whether the ingredients are in opened or unopened packages, are not verified by examination of labeling and documentation of suppliers or by direct determination;

(5) For a sterilized high-risk preparation, in the absence of the preparation's passing a sterility test, the storage periods shall not exceed the following:

(a) At controlled room temperature for 24 hours;

(b) At a cold temperature for 3 days; or

(c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days;

(6) Examples of high-risk compounding include:

(a) Dissolving nonsterile bulk drugs or nutrient powders to make solutions that will be terminally sterilized;

(b) Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed;

(c) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95 percent by weight of their active chemical moiety and have not been contaminated or adulterated between uses; and

(d) Exposing the sterile ingredients and components used to prepare and package the preparation to air quality inferior to ISO Class 5 for more than one hour.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:21. Immediate-use preparations. For the purpose of emergency or immediate patient care, pharmacies are exempted from requirements described in this chapter for low- and medium-risk preparations when all of the following criteria are met:

(1) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile commercial drug products including an infusion or diluent solution;

(2) Unless required for the preparation, the compounding procedure occurs

continuously without delays or interruptions and does not exceed one hour;

(3) At no point during preparation are critical surfaces and ingredients of the preparation directly exposed to contact contamination, such as human touch, cosmetic flakes or particulates, blood, human body substances (e.g., nasal and oral excretions and secretions), and nonsterile inanimate sources;

(4) Unless immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact beyond-use date and time;

(5) Administration begins not later than two hours after compounding of the preparation has begun; and

(6) If administration has not begun within two hours after compounding of the preparation has begun, the preparation is promptly and safely discarded. Immediate-use preparations shall not be stored for later use.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:22. Utilization of single-dose and multiple-dose containers. Pharmacies utilizing single-dose and multiple-dose containers in sterile compounding shall comply with the following:

(1) Single-dose containers that are opened or needle-punctured shall be used within one hour if opened in air quality conditions inferior to ISO Class 5;

(2) Single-dose vials that are continuously exposed to ISO Class 5 air shall be used within six hours after initial needle puncture;

(3) Opened single-dose ampoules shall not be stored for any period of time under any air quality conditions;

(4) Multiple-dose containers that are entered or opened shall be used within 28 days of initial entry or opening unless otherwise specified by the manufacturer; and

(5) Multiple-dose and single-dose sterile products shall not be combined for use as multiple-dose applications.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:23. Utilization of proprietary bag and vial systems. Sterility, storage, and beyond-use times for attached and activated container pairs of drug products for intravascular administration shall follow manufacturers' instructions for handling and storage.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:24. Sterilization methods. The selected sterilization methods employed shall be compliant with standards identified in United States Pharmacopeia, Chapter 797.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

Reference: Page 337, **The United States Pharmacopeia, Thirtieth Revision – The National Formulary, Twenty-Fifth Edition**, May 1, 2007, published by the United States Pharmacopeial Convention Inc., 12601 Twinbrook Parkway, Rockville Maryland 20852.

20:51:31:25. Media-fill testing by personnel. The pharmacy shall develop, maintain, and implement written procedures that include media-fill testing by personnel authorized to compound preparations. Tests shall be performed without interruption in an ISO Class 5 environment under conditions that closely simulate the stressful conditions encountered during compounding of the specific risk level preparations for which the test is intended. The pharmacy shall maintain records of media-fill testing performed, and results of testing procedures shall be available to the board or agents of the board. Compounding personnel whose media-fill test vials result in gross microbial colonization shall be immediately instructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

Each person authorized to compound low-risk and medium-risk preparations shall annually perform a successful MFT procedure.

Each person authorized to compound high-risk preparations shall semiannually perform a successful MFT procedure.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:26. Environmental monitoring requirements. Certification and procedures required include the following:

(1) All cleanrooms, laminar airflow workbenches, and barrier isolators shall be certified according to ISO Standards 14644-1:1999(E) and ISO Standards 14664-3:2005(E), or National Sanitation Foundation Standard 49, for operational efficiency at least every six months and whenever the device or room is relocated or altered or whenever major service to the facility is performed. Inspection and certification records shall be maintained for two years from the date of certification; and

(2) The pharmacy shall establish written procedures appropriate for the risk level preparations compounded by the pharmacy. The procedures shall include environmental testing, end testing, and evaluation of validation results of the following:

(a) Microbial sampling of air within the primary engineering control devices, buffer areas, and anterooms is required every six months; and

(b) Unidirectional air flow shall be maintained and validated. It is recommended that this be done using a pressure gauge or a velocity meter installed between the buffer zone and ante-area. In absence of a pressure gauge or velocity meter, unidirectional flow and velocity should be tested and documented semi-annually at the time of hood and room certification.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:27. Storage and delivery of sterile preparations. The pharmacy is responsible for proper packaging, labeling, handling, transport, and storage of preparations compounded and dispensed by the pharmacy and for education, training, and supervision of pharmacy and non-pharmacy personnel responsible for such functions. The pharmacy shall establish, maintain, and implement written policies and procedures to ensure product quality and packaging integrity until the preparation is administered. Policies and procedures shall address:

(1) Storage areas – Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature;

(2) Packaging, handling and transport including:

(a) Instruction in proper hand washing, aseptic techniques, site care, and change of administration sets to ensure the quality and sterility of the preparation;

(b) Special needs related to those products and techniques for the pharmacy that compounds or prepares products or devices or uses techniques where in-line filtration, automated infusion control devices, or replenishment of drug products into reservoirs of portable infusion pumps is required;

(c) Provisions for the return to the pharmacy of unused preparations for appropriate disposition. Unused preparations may be redispensed only if the continuing quality and sterility of the preparation can be fully ensured. To avoid contamination of the ISO 5 containment area (hood), any returned preparation should not be placed in the containment area unless properly decontaminated. The pharmacy shall be the sole authority for determining whether a preparation that was not administered as originally intended can be used for an alternate patient or under alternate conditions; and

(d) Handling of hazardous preparations shall identify safeguards intended to maintain the integrity of the preparations and to minimize the exposure potential of these products to the environment and to personnel who have contact with the products.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:28. Additional requirements for preparation of hazardous drugs.

Hazardous drugs shall only be prepared for administration under conditions that protect pharmacy personnel in the preparation area. The following additional requirements shall be met by pharmacies that prepare hazardous drugs:

(1) Policies and procedures shall identify requirements for storage and handling of hazardous drugs to prevent contamination and personnel exposure;

(2) Preparations containing hazardous drugs shall be labeled on the primary container and placed in an overwrap bag that is also properly labeled. Prepared doses of dispensed hazardous drugs shall be labeled and distributed in a manner to minimize the risk of accidental rupture of the primary container. Proper labeling shall include any necessary precautions;

(3) All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities:

(a) It is preferable for the ISO Class 5 BSC or CAI to be placed in a contained environment where air pressure is negative and where the ISO Class 5 BSC or CAI is appropriately vented to the outside of the building; and

(b) If the pharmacy compounds fewer than five preparations per week in a BSC or

CAI and uses a closed system vial transfer device to compound the preparations, the BSC or CAI may be located in a positive pressure room;

(4) Personnel compounding hazardous drugs shall wear proper protective apparel in accordance with documented procedures. Protective apparel may include disposable, non-shedding coveralls or gowns with tight cuffs, face masks, eye protection, hair covers, double gloves, and shoe covers;

(5) Proper safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for processing sterile preparations;

(6) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before personnel prepare or handle hazardous preparations and shall be verified and documented for each person at least annually;

(7) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements; and

(8) Written procedures for handling both major and minor spills of hazardous drugs shall be developed, maintained, implemented, and adhered to. The procedures shall be maintained with the policies and procedures required in § 20:51:31:03.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11.

20:51:31:29. Responsibilities for patient care. If sterile products are provided to the patient in the home, the pharmacy and pharmacist have the following responsibilities:

(1) The pharmacist shall be knowledgeable of the roles of the physician, patient, pharmacy, and home health care provider related to delivery of care and the monitoring of the patients;

(2) The pharmacy shall have a pharmacist accessible at all times to respond to a patient's and other health professional's questions and needs;

(3) The pharmacist shall use the clinical and laboratory data of each patient to monitor initial and ongoing drug therapy. If the pharmacist does not have access to the data, the name of the health care provider assuming responsibility for monitoring drug therapy shall be documented in the patient's profile; and

(4) The pharmacist shall report to the prescribing physician any knowledge of unexpected or untoward response to drug therapy.

Source:

General Authority: SDCL 36-11-11(1) and (12).

Law Implemented: SDCL 36-11-11.

20:51:31:30. Patient or caregiver education and training. If sterile products are provided to the patient in the home environment, the pharmacist, in conjunction with nursing or medical personnel, shall verify and document the patient's or caregiver's training and competence in managing therapy.

(1) A pharmacist shall be actively involved in patient training processes relating to drug compounding, labeling, administration, storage, stability, compatibility, or disposal. The pharmacist shall continually reassess the patient's or caregiver's competency in these areas.

(2) Training programs shall include hands-on demonstrations and practice with actual items that the patient or caregiver is expected to use in managing the specific type of therapy.

(3) Printed materials and verbal counseling shall be used periodically to reinforce initial training programs and to ensure the patient's or caregiver's continuing correct and complete fulfillment of responsibilities.

Source:

General Authority: SDCL 36-11-11(1) and (12).

Law Implemented: SDCL 36-11-11.