This is an amendment to 16.19.36 NMAC, Section 7, 8, 9, 10, 11, 13 and 15 effective 8/13/2024

16.19.36.7 DEFINITIONS:

A. "Air changes per hour" (ACPH) means the number of times a volume of air equivalent to the room passes through the room each hour.

B. "[~~**Ante-area**~~] **Anteroom"** means an ISO Class 8 or [~~better~~] cleaner 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~~] contains a line of demarcation which is a visible line on the floor that separates the clean and dirty sides of the anteroom.

C. "Aseptic processing" A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration or by autoclave).

[~~**C**~~] **D. "Aseptic technique"** means proper manipulation of preparations to maintain sterility.

[~~**D**~~] **E. "Batch"** [~~means more than one unit of a compounded preparation that is intended to have uniform character and quality within specified limits, prepared in a single process, and completed during the same and limited time period.~~] More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.

[~~**E**~~] **F. "Beyond-use date"** (BUD) means the date, or as appropriate, date and time, after which a compounded preparation is not to be used and is determined from the date and time the preparation is compounded.

[~~**F**~~] **G. "Biological safety cabinet"** (BSC) [~~means a ventilated cabinet that provides ISO Class 5 environment for CSP's, provides personnel, preparation, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for preparation protection, and HEPA-filtered exhausted air for environmental protection.~~] A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).

H. "Biological safety cabinet (BSC), Class II" A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class five or better environment for preparation of the CSPs.

[~~**G**~~] **I. "Buffer** [~~**area**~~] **room"** [~~means an area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the staging of components and supplies used when compounding CSP's~~] An ISO Class seven or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class five environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.

J. "Category one CSP" A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category one CSPs in USP/NF <797>.

K. "Category two CSP" A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in USP/NF <797>.

L. "Category three CSP" A CSP that may be assigned a BUD exceeding the limits in for Category two CSPs and is compounded in accordance with all applicable requirements for Category three CSPs in USP/NF <797>.

[~~**H**~~] **M. "Certification"** means independent third party documentation declaring that the specific requirements of USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* have been met.

N. "Cleaning" The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.

O. "Cleaning agent" An agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.

[~~I~~] **P. "Cleanroom suite"** [~~means 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~~] A classified area that consists of both an anteroom and buffer room.

[~~J~~] **Q. "Closed system vial-transfer device"** means a vial-transfer system that allows no venting or exposure of substances to the environment.

R. "Component" Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

[~~K~~] **S. "Compounded sterile preparations"** (CSP's) include, but are not limited, to the following dosage forms which must be sterile when administered to patients:

(1) parenteral preparations;

(2) aqueous bronchial and nasal inhalations;

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

(4) injections (e.g. colloidal dispersions, emulsions, solutions, suspensions);

(5) irrigations for wounds and internal body cavities;

(6) ophthalmic drops and ointments; and

(7) [~~tissue~~] implants.

[~~L~~] **T. "Compounding aseptic containment isolator"** (CACI) [~~means an enclosed ISO Class 5 environment workspace for compounding of hazardous sterile preparations, provides personnel protection with negative pressure and appropriate ventilation and provides preparation protection by isolation from the environment and high-efficiency particulate air (HEPA)-filtered laminar airflow. 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~~] A type of RABS that uses HEPA filtration to provide an ISO Class five unidirectional air environment designed for the compounding of sterile HDs.

[~~M~~] **U. "Compounding aseptic isolator"** (CAI) [~~means an enclosed ISO Class 5 environments 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 microbial retentive filter (HEPA minimum)~~] A type of RABS that uses HEPA filtration to provide an ISO Class five unidirectional air environment designed for compounding of sterile non-HDs.

V. "Compounding record" (CR) Documents the compounding of each CSP.

W. "Container closure system" Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.

X. "Containment ventilated enclosure" (CVE) A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.

[~~N~~] **Y. "Critical area"** means an ISO Class [~~5~~] five environment.

[~~O~~] **Z. "Critical site"** means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, 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.~~]

AA. "Designated person" Individual assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs. For pharmacies the designated person must be the pharmacist-in-charge. For clinic facilities the designated person must be the consultant pharmacist.

[~~P~~] **BB. "Direct compounding area"** (DCA) means a critical area within the ISO Class [~~5~~] five primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

[~~Q~~] **CC. "Disinfectant"** [~~means an agent that frees from infection and destroys disease-causing pathogens or other harmful microorganisms, but may not kill bacterial and fungal spores. It refers to substances applied to~~

~~inanimate agents, usually a chemical agent, but sometimes a physical one~~] A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.

DD. "Dynamic airflow smoke pattern test" A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for Dynamic operating conditions). This test is not appropriate for ISO Class seven or ISO Class eight cleanrooms that do not have unidirectional airflow (see the entry for Visual smoke study).

EE. "Dynamic operating conditions" Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

FF. "Garb" Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).

[~~R~~] **GG. "Hazardous [~~drugs~~] drug"** [~~means drugs classified as hazardous if studies in animals or humans indicate exposures to them have a potential for causing cancer, development or reproductive toxicity or harm to organs~~] (HD) Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity. (Reference current NIOSH publications).

HH. "High-efficiency particulate air (HEPA) filtration" Being, using, or containing a filter designed to remove ninety-nine and ninety-seven one-hundredths percent of airborne particles measuring zero and three-micron or greater in diameter passing through it.

[~~S~~] **II. "Home care"** means health care provided in the patient's home (not a hospital or skilled nursing facility) by either licensed health professionals or trained caregivers. May include hospice care.

JJ. "Integrated vertical laminar flow zone" (IVLFZ) A designated ISO Class five area serving as the PEC within an ISO Class seven or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.

[~~T. **"Immediate use"** means administration begins not later than one hour following the start of the compounding procedure. For those events in which delay in preparation would subject patient to additional risk and meeting USP/NF <797> (*Immediate-Use CSP Provision*) criteria.~~

~~U. **"ISO 5"** means air containing no more than 100 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3520 particles per cubic meter).~~

~~V. **"ISO 7"** means air containing no more than 10,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (352,000 particles per cubic meter).~~

~~W. **"ISO 8"** means air containing no more than 100,000 particles per cubic foot of air of a size at least 0.5 micron or larger in diameter (3,520,000 particles per cubic meter).~~]

KK. "ISO class" An air-quality classification from the International Organization for Standardization.

[~~X~~] **LL. "Laminar airflow"** means a non-turbulent, non-mixing streamline flow of air in parallel layers.

MM. "Laminar airflow system" (LAFS) A device or zone within a buffer room that provides an ISO Class five or better air quality environment for sterile compounding. The system provides a unidirectional HEPA filtered airflow.

[~~Y~~] **NN. "Laminar airflow workbench"** (LAFW) [~~means a ventilated cabinet for compounding of sterile preparations. Provides preparation protection with high-efficiency particulate air (HEPA) filtered laminar airflow, ISO Class 5. Airflow may be horizontal (back to front) or vertical (top to bottom) in direction~~] A device that is a type of LAFS that provides an ISO Class five or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.

OO. "Line of demarcation" A visible line on the floor that separates the clean and dirty sides of the anteroom.

PP. "Master formulation record" (MFR) A detailed record of procedures that describes how the CSP is to be prepared.

[~~Z~~] **QQ. "Media-fill test"** [~~means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation 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. 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~~] A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

[~~AA~~] **RR. "Multiple-dose container"** means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. Once opened or entered, a multiple dose container with antimicrobial preservative has a BUD of 28 days unless otherwise specified by the manufacturer.

[~~BB~~] **SS. "Negative pressure room"** means a room that is at a lower pressure than the adjacent spaces and therefore, the net flow of air is *into* the room.

TT. "One-step disinfectant cleaner" A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

[~~CC~~] **UU. "Parenteral product"** means any preparation administered by injection through one or more layers of skin tissue.

VV. "Pass-through chamber" An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

[~~DD~~] **WW. "Personal protective equipment"** (PPE) means items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

[~~EE~~] **XX. "Pharmacy bulk packages"** means a container of a sterile preparation for parenteral use that contains many single doses. Contents are intended for use in a pharmacy admixture program and are restricted to use in a suitable ISO Class 5 environment.

[~~FF~~] **YY. "Plan of care"** means an individualized care plan for each patient receiving parenteral products in a home setting to include the following:

(1) description of actual or potential drug therapy problems and their proposed solutions;

(2) a description of desired outcomes of drug therapy provided;

(3) a proposal for patient education and counseling; and

(4) a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and noncompliance) and the frequency with which monitoring is to occur.

[~~GG~~] **ZZ. "Positive pressure room"** means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out* of the room.

[~~**HH. "Preparation"** means 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.~~]

[~~H~~] **AAA. "Primary engineering control"** (PEC)[~~means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSP's. Such devices include, but may not be limited to, laminar airflow workbenches (LAFW's), biological safety cabinets (BSC's), compounding aseptic isolators (CAI's), and compounding aseptic containment isolators (CACI's)~~] A device or zone that provides an ISO Class five air quality environment for sterile compounding.

[~~JJ~~] **BBB. "Process validation"** means documented evidence providing a high degree of assurance that a specific process will consistently produce a preparation meeting its predetermined specifications and quality attributes.

[~~KK~~] **CCC. "Product"** means a commercially manufactured 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.

[~~LL~~] **DDD. "Quality assurance"** means a program for the systematic monitoring and evaluation of the various aspects of a service or facility to ensure that standards of quality are being met.

[~~MM~~] **EEE. "Quality control"** means a system for verifying and maintaining a desired level of quality in a preparations or process, as by planning, continued inspection, and corrective action as required.

FFF. "Reconstitution" The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.

GGG. "Repackaging" The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.

HHH. "Restricted-access barrier system" (RABS) An enclosure that provides HEPA-filtered ISO Class five unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

[~~NN~~] **III. "Secondary engineering control"** [~~means the ante area and buffer area or cleanroom in which primary engineering controls are placed~~] The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

[~~OO~~] **JJJ. "Segregated compounding area"** [~~means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSP's 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 CSP's and shall be void of activities and materials that are extraneous to sterile compounding~~] A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category one CSPs only.

[~~PP~~] **KKK. "Single-dose container"** means a single-dose, or a single-unit, container for articles or preparations intended for parenteral administration only. It is intended for a single use. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

LLL. "Sporicidal disinfectant" A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

MMM. "Stability" The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.

[~~QQ~~] **NNN. "Standard operating procedure"** (SOP) means a written protocol detailing the required standards for performance of tasks and operations within a facility.

OOO. "Sterile Compounding" The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.

[~~**RR. "Sterile"** means free from bacteria or other living microorganisms.~~]

PPP. "**Sterility**" The absence of viable microorganisms.

[~~SS~~] **QQQ. "Sterilization by filtration"** means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

[~~TT~~] **RRR. "Sterilizing grade** [~~**membranes**~~] **filter"** means filter membranes that are documented to retain [~~100%~~] one hundred percent of a culture of 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally at [~~0.22~~] zero and twenty-two μm or [~~0.2~~] zero and two μm [~~porosity, depending on the manufacturer's practice~~] pore size.

[~~UU~~] **SSS. "Terminal sterilization"** means the application of a lethal process (e.g., steam, [~~under pressure or autoclaving~~] dry heat, irradiation) 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.

[~~VV~~] **UUU. "Unidirectional airflow"** [~~means 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~~] Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.

[~~WW~~] **VVV. "USP"** means United States pharmacopeia.

WWW. "Visual smoke study" A test, used in ISO Class seven and ISO Class eight rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for Dynamic airflow smoke pattern test).

XXX. "Workflow management system" Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

[16.19.36.7 NMAC – N, 06-28-14; A, 03-22-15; A, 8/13/2024]

16.19.36.8 PHARMACIST IN CHARGE:

A. All facilities compounding sterile preparations must designate a pharmacist in charge of operations who is licensed as a pharmacist in the state of residence of the facility.

B. The pharmacist-in-charge (or consultant pharmacist, for in-state clinics) is responsible for:

(1) the development, implementation and continuing review and maintenance of written policies, procedures and SOP's which comply with USP/NF standards;

(2) providing a pharmacist who is available for 24 hour seven-day-a-week services;

(3) establishing a system to ensure that the CSP's prepared by compounding personnel are administered by licensed personnel or properly trained and instructed patients;

(4) establishing a system to ensure that CSP's prepared by compounding personnel are prepared in compliance with USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*standards;

(5) ensuring facility personnel comply with written policies, procedures, and SOP's; and

(6) developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral preparations in a home setting.

[16.19.36.8 NMAC – N, 06-28-14; A, 8/13/2024]

16.19.36.9 FACILITIES:

A. The room or area in which compounded sterile preparations (CSP's) are prepared:

(1) must be physically designed and environmentally controlled to meet standards of compliance as required by USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*;

(2) must be periodically monitored, evaluated, tested, and certified by environmental sampling testing (includes both viable and nonviable particle sampling) as required by USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* with documentation retained for three years;

(3) must have a minimum of 100 square feet dedicated to compounding sterile preparations;

(a) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet with 100 square feet exclusive to compounding sterile preparations;

(b) the stand alone CSP facility must have a minimum of 240 square feet with 100 square feet exclusive to compounding sterile preparations; and

(4) must be clean, lighted, and at an average of 80-150 foot candles; and

(5) must minimize particle generating activities[~~.~~] ; and

(6) must have a sink of sufficient size for compounding personnel to adequately wash hands and forearms up to the elbows with soap and water.

B. Addition of a compounding sterile preparations area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure.

C. A new CSP facility must comply with 16.19.6.8 NMAC through 16.19.6.11 NMAC of the regulations.

[16.19.36.9 NMAC - N, 06-28-14; A, 8/13/2024]

16.19.36.10 EQUIPMENT: Each facility compounding sterile preparations shall have sufficient equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparation of compounded sterile preparations drugs and parenteral preparations appropriate to the scope of pharmaceutical services provided and as specified in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*.

A. All equipment shall be cleaned, maintained, monitored, calibrated, tested, and certified as appropriate to insure proper function and operation with documentation retained for three years.

B. Primary and secondary engineering controls used to provide an aseptic environment shall be tested in the course of normal operation by an independent qualified contractor and certified as meeting the requirements presented in USP/NF <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* at least every six months and when relocated, certification records will be maintained for three years.

C. A library of current references (hard copy or electronic) shall be available including:

(1) All *USP/NF* [~~or *USP on Compounding: A Guide for the Compounding Practitioner*~~] chapters applicable to the facility's sterile compounding practice;

(2) New Mexico pharmacy laws, rules and regulations;

(3) specialty references (stability and incompatibility references, sterilization and preservation references, pediatric dosing, and drug monograph references) as appropriate for the scope of services provided.

D. Automated compounding devices shall:

(1) have accuracy verified on a routine basis at least every 30 days per manufacturer's specifications;

(2) be observed every 30 days by the operator during the mixing process to ensure the device is working properly;

(3) have data entry verified by a pharmacist prior to compounding or have accurate final documentation of compounded preparations to allow for verification of ingredients by a pharmacist prior to dispensing; and

(4) have accuracy of delivery of the end product verified according to written policies and procedures.

[16.19.36.10 NMAC – N, 06-28-14; A, 8/13/2024]

16.19.36.11 DOCUMENTATION REQUIRED:

A. Written policies, procedures and SOPs consistent with USP/NF <797> *(General Chapter <797> Pharmaceutical Compounding-Sterile Preparations) s*tandards as well as those required below, must be established, implemented, followed by facility personnel, and available for inspection and review by authorized agents of the board of pharmacy. All personnel who perform or oversee sterile compounding must be trained in these policies, procedures and SOPs.

B. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These [~~records~~] policies and procedures must include but are not limited to:

(1) cleaning, disinfection, evaluation, validation, testing, certification, and maintenance of the sterile compounding area;

(2) personnel qualifications, training, assessment and performance validation;

(3) operation, maintenance, validation, testing, and certification of facility and equipment;

(4) SOP's for compounding, storing, handling, and dispensing of all components used and all compounded sterile preparations;

(5) SOP's for proper disposal of physical, chemical, and infectious waste;

(6) quality control guidelines and standards;

(7) quality assurance guidelines and standards;

(8) SOP's for determination of stability, incompatibilities, and drug interactions;

(9) error prevention and incident reporting policies and procedure as per 16.19.25 NMAC.

C. All records required by this part shall be kept by the facility for at least three years and shall be readily available for inspection by the board or boards' agent.

[16.19.36.11 NMAC – N, 06-28-14; A, 03-22-15; A, 8/13/2024]

16.19.36.13 REQUIREMENTS FOR TRAINING: All personnel, including pharmacists, pharmacists who supervise compounding personnel (including designated persons), pharmacists interns and pharmacy technicians , shall have completed didactic and experiential training with competency evaluation through demonstration and testing (written or practical) as required by USP/NF <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)*and as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual, prior to compounding sterile preparations.

A. Instructional topics shall include:

(1) aseptic technique;

(2) [~~critical area contamination factors~~] achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components);

(3) principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class five area

[~~**(3)**~~] **(4)** environmental monitoring;

[~~**(4)**~~] **(5)** [~~facilities~~] proper use of PECs;

[~~**(5)**~~] **(6)** equipment and supplies;

[~~**(6)**~~] **(7)** sterile pharmaceutical calculations, measuring, mixing, and terminology;

[~~**(7)**~~] **(8)** [~~sterile pharmaceutical compounding documentation~~] documentation of the compounding process (MFR and CR);

[~~**(8)**~~] **(9)** quality assurance procedures;

(10) hand hygiene

[~~**(9)**~~] **(11)** proper gowning and gloving technique;

[~~**(10)**~~] **(12)** the handling of cytotoxic and hazardous drugs (if applicable); [~~and~~]

[~~**(11)**~~] **(13)** [~~general conduct in the controlled area.~~] principles of movement of materials and personnel within the compounding area; and

(14) cleaning and disinfection.

B. Training shall be obtained through completion of a site-specific, structured on-the-job didactic and experiential training program (not transferable to another practice site).

C. Pharmacy technicians shall complete 100 hours of documented experiential training in compounded sterile preparations in accordance with Section 61-11-11.1 of the Pharmacy Act NMSA 1978 prior to compounding sterile preparations. Documentation of experiential training as defined in Subsection A of this section is transferrable to another practice site.

D. Experiential training shall include those areas of training as outlined in USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* with appropriate observational assessment and testing of performance as outlined in USP <797> *(USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* including [~~glove fingertip and media fill tests~~] garbing competency and aseptic manipulation competency evaluations.

E. All personnel, including pharmacists compounding sterile hazardous drugs, pharmacists supervising compounding personnel, pharmacy interns compounding sterile hazardous drugs, and pharmacy technicians compounding sterile hazardous drugs, shall have completed didactic and experiential training with competency evaluation through demonstration and written or practical testing as required by USP/NF <800> *(USP General Chapters: <800> Hazardous Drugs – Handling in Healthcare Settings)* in addition to training in sterile non-hazardous preparations as listed above. Training will be conducted as outlined by the pharmacist-in-charge and described in the site policy and procedures or training manual and shall be completed prior to compounding sterile hazardous preparations.

F. Frequency of training and assessment shall be conducted as required by USP <797> (*USP General Chapters: <797> Pharmaceutical Compounding-Sterile Preparations)* to assure continuing competency and include:

(1) initial training before compounding sterile preparations;

(2) annual refresher training and assessment in didactic topics;

(3) [~~annual testing of glove fingertip and media fill for low and medium risk compounding~~] garbing competency and aseptic manipulation competency evaluations every six months for personnel compounding Category one and Category two CSPs;

(4) [~~six-month testing of glove fingertip and media fill testing for high risk compounding~~] garbing competency and aseptic manipulation competency evaluations every three months for personnel compounding Category three CSPs.

(5) Personnel who have direct oversight of compounding personnel (including designated persons) must complete garbing competency and aseptic manipulation competency evaluations annually (unless a more frequent requirement applies).

G. Documentation of training: Written documentation of initial and in-service training, the results of written or practical testing, and process validation of compounding, personnel shall be retained for three years and contain the following information:

(1) name of person receiving the training or completing the testing or process validation;

(2) date(s) of the training, testing, or process validation;

(3) general description of the topics covered in the training or testing or of the process validated;

(4) name of person supervising the training, testing, or process validation;

(5) signature of the person receiving the training or completing the testing or process validation and the [~~pharmacist-in-charge~~] designated person or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

[16.19.36.13 NMAC - N, 06-28-14; A, 03-22-15; A, 8/13/2024]

16.19.36.15 QUALITY ASSURANCE OF COMPOUNDED STERILE PREPARATIONS:

A. There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:

(1) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;

(2) if non-sterile to sterile bulk compounding of more than 25 units of compounded sterile preparations is performed using non-sterile chemicals, containers, or devices, and the results of appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;

(3) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(4) the batch label of each sterile compounded product shall contain:

(a) drug product name(s), diluent names(s), and amount(s) of each;

(b) [~~batch lot or control number~~] assigned internal identification number (e.g., barcode, prescription, order, or lot number);

(c) final concentration(s), and volume when appropriate, solution ingredient names and amounts;

(d) beyond use date, and time when applicable;

(e) dosage form

[~~**(e)**~~] **(f)** route of administration when applicable;

[~~**(f)**~~] **(g)** date of preparation;

[~~**(g)**~~] **(h)** [~~facility identifier;~~] name or initials of person preparing the product and, if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check;

[~~**(h)**~~] **(i)** when appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; [~~and~~]

[~~**(i)**~~] **(j)** device instructions when needed[~~.~~];

(k) if it is a single-dose container, a statement stating such;

(l) if it is a multiple-dose container, a statement stating such; and

(m) compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.

(5) the patient specific label of a CSP shall contain:

(a) patient name;

(b) solution, ingredient names, amounts;

(c) beyond use date, and time when applicable;

(d) dosage form;

[~~**(d)**~~] **(e)** route of administration;

[~~**(e)**~~] **(f)** directions for use, including infusion rates, specific times scheduled, when appropriate and applicable;

[~~**(f)**~~] **(g)** identifier of person preparing the product and, if prepared by supportive personnel (i.e., pharmacist intern or pharmacy technician), the identifier of the pharmacist that completed the final check;

[~~**(g)**~~] **(h)** when appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; [~~and~~]

[~~**(h)**~~] **(i)** device instructions when needed;

(j) assigned internal identification number (e.g., barcode, prescription, order, or lot number);

(k) if it is a single-dose container, a statement stating such;

(l) if it is a multiple-dose container, a statement stating such; and

[~~**(i)**~~] **(m)** if dispensed for other than inpatient use, the label shall include all other required information.

B. There shall be a mechanism for tracking and retrieving products which have been recalled. [~~If batch preparation of compounded sterile preparations is being performed, a~~] The following [~~record~~] records must be maintained for [~~each~~] CSPs [~~batch~~].

(1) A [~~formulation record~~] master formulation record (MFR) shall [~~provide a consistent source document (recipe) for CSP preparation~~] be created for all CSPs prepared from nonsterile ingredients(s) and CSP batch preparations and shall include the following:

(a) name, strength, dosage form, and final volume of the compounded preparation;

(b) all ingredients and their quantities; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)

(c) [~~equipment needed to prepare the CSP, when appropriate, and mixing instructions~~] complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions;

(d) [~~other environmental controls, such as the duration of mixing and other factors pertinent to consistent preparation of the CSP~~] other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter);

(e) beyond use dating [~~, the container for dispensing,~~] and storage requirements [~~, and quality control procedures~~] ; [~~and~~]

(f) information needed for proper labeling (e.g. sample label) [~~.~~];

(g) type and size of container closure system(s);

(h) physical description of the final CSP;

(i) quality control (QC) procedures (e.g., pH testing, filter integrity testing); and

(j) reference source to support the stability of the CSP.

(2) [~~The compounding record for each CSP batch shall verify accurate compounding in accordance with the formulation record and shall include:~~] A compounding record (CR) must be created for all Category one, Category two, and Category three CSPs. A CR must also be created for immediate-use CSPs prepared for more than one patient. The CR must include at least the following information:

(a) reference to the [~~formulation record~~] MFR for the CSP (if applicable);

(b) name, strength, weight or volume, manufacturer, [~~and~~] manufacturer's lot number, and expiration date for each component;

(c) name, strength, dosage form, and volume of the finished CSP;

(d) reconciliation of actual yield with anticipated yield, and total number of CSP units produced;

(e) identifier of person preparing the product and, if prepared by [~~support personnel (i.e.,~~] a pharmacist intern or pharmacy technician[~~)~~], the identifier of the pharmacist that completed the final check;

(f) date and time of preparation;

(g) [~~batch lot or control number~~] assigned internal identification number (e.g. prescription, order, or lot number);

(h) assigned beyond use date, and time when appropriate and storage requirements;

(i) results of applicable quality control procedures[~~.~~] ; and

(j) calculations made to determine and verify quantities and/or concentrations of components, if applicable.

[16.19.36.15 NMAC - N, 09-07-14; A, 03-22-15; A, 8/13/2024]