TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 36 COMPOUNDED STERILE PREPARATIONS

16.19.36.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.36.1 NMAC - N, 06-28-14]

16.19.36.2 SCOPE: All facilities as defined in Paragraph (1), (2), (5) through (11) and (15) of Subsection B of 61-11-14 NMSA 1978, and all persons or entities that own or operate, or are employed by a facility for the purpose of providing pharmaceutical compounded sterile preparations or services.
[16.19.36.2 NMAC - N, 06-28-14; A, 03-22-15]

16.19.36.3 STATUTORY AUTHORITY: Paragraph (6) of Subsection A of Section 61-11-6 NMSA 1978 authorizes the board of pharmacy to provide for the licensing of all places where dangerous drugs are stored, dispensed, distributed or administered and for the inspection of their facilities and activities. Paragraph (7) of Subsection A of 61-11-6 NMSA 1978 authorizes the board to enforce the provisions of all laws of the state pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs and their standards of strength and purity.
[16.19.36.3 NMAC - N, 06-28-14]

16.19.36.4 DURATION: Permanent.
[16.19.36.4 NMAC - N, 06-28-14]

16.19.36.5 EFFECTIVE DATE: June 28, 2014, unless a different date is cited at the end of a section.
[16.19.36.5 NMAC - N, 06-28-14]

16.19.36.6 OBJECTIVE: The objective of Part 36 of Chapter 19 is to establish standards to ensure that the citizens of New Mexico receive properly compounded contaminant-free sterile preparations properly compounded in accordance with all applicable USP/NF General Chapters numbered below 1000.
[16.19.36.6 NMAC - N, 6-28-14; A, 03-22-15]

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" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities are performed. It is also a transition area that:

(1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

(2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

C. "Aseptic technique" means proper manipulation of preparations to maintain sterility.

D. "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.

E. "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. "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.

G. "Buffer area" 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.

H. "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.

I. **"Cleanroom"** 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.

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

K. **"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 body cavities;

(6) ophthalmic drops and ointments; and

(7) tissue implants.

L. **"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.

M. **"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).

N. **"Critical area"** means an ISO Class 5 environment.

O. **"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.

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

Q. **"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.

R. **"Hazardous drugs"** 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. (Reference current NIOSH publications).

S. **"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.

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).

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

Y. "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.

Z. "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.

AA. "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. "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.

CC. "Parenteral product" means any preparation administered by injection through one or more layers of skin tissue.

DD. "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. "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. "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. "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.

II. "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).

JJ. "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. "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. "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. "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.

NN. "Secondary engineering control" means the ante area and buffer area or cleanroom in which primary engineering controls are placed.

OO. "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.

PP. "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.

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

RR. "Sterile" means free from bacteria or other living microorganisms.

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

TT. "Sterilizing grade membranes" means membranes that are documented to retain 100% 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 μm or 0.2 μm porosity, depending on the manufacturer's practice.

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

VV. "Unidirectional flow" 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.

WW. "USP" means United States pharmacopeia.

[16.19.36.7 NMAC - N, 06-28-14; A, 03-22-15]

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 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]

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 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.

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]

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 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) *USP/NF* or *USP on Compounding: A Guide for the Compounding Practitioner*;

(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]

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.

B. Written policies and procedures must be submitted to the state board of pharmacy prior to the issuance of any license. These records 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]

16.19.36.12 RECORD KEEPING AND PATIENT PROFILE: The compounded sterile preparations facility is required to maintain patient's records which include but are not limited to the following.

A. Prescription records or provider orders including the original prescription or original provider order, refill authorization, alterations in the original prescription or original provider order, and interruptions in therapy due to hospitalization.

B. Patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patient.

C. Patients receiving parenteral preparations in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition.

D. Documentation that the patient receiving parenteral preparations in a home setting or the agent has received a written copy of the plan of care and training in the safe administration of the medication.

[16.19.36.12 NMAC - N, 06-28-14]

16.19.36.13 REQUIREMENTS FOR TRAINING: All personnel, including pharmacists, pharmacists who supervise compounding personnel, 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;

(3) environmental monitoring;

(4) facilities;

(5) equipment and supplies;

(6) sterile pharmaceutical calculations and terminology;

(7) sterile pharmaceutical compounding documentation;

(8) quality assurance procedures;

(9) proper gowning and gloving technique;

(10) the handling of cytotoxic and hazardous drugs; and

(11) general conduct in the controlled area.

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.

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 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;

(4) six-month testing of glove fingertip and media fill testing for high risk compounding.

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 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]

16.19.36.14 PATIENT OR CAREGIVER TRAINING FOR USE OF COMPOUNDED STERILE PREPARATIONS IN A HOME SETTING:

A. The pharmacist shall maintain documentation that the patient has received training consistent with Subsection F of 16.19.4.16 NMAC.

B. The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy.

C. There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

(1) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(2) patient monitoring plans that include written outcome measures and systems for routine patient assessment;

(3) documentation of patient training.

[16.19.36.14 NMAC - N, 6-28-14]

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;

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

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

(e) route of administration when applicable;

(f) date of preparation;

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

(i) device instructions when needed.

(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) route of administration;

(e) directions for use, including infusion rates, specific times scheduled, when appropriate and applicable;

(f) 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) when appropriate, ancillary instructions such as storage instructions or cautionary systems, including hazardous material warning labels and containment bags; and

(h) device instructions when needed;

(i) 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 record must be maintained for each batch.

(1) A formulation record shall provide a consistent source document (recipe) for CSP preparation and shall include the following:

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

(b) all ingredients and their quantities;

(c) equipment needed to prepare the CSP, when appropriate, and mixing instructions;

(d) other environmental controls, such as the duration of mixing and other factors pertinent to consistent preparation of the CSP;

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

(f) information need for proper labeling (e.g. sample label).

(2) The compounding record for each CSP batch shall verify accurate compounding in accordance with the formulation record and shall include:

(a) reference to the formulation record for the CSP;

(b) name, strength, volume, manufacturer, and manufacturer's lot number for each component;

(c) name, strength, 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., pharmacist intern or pharmacy technician), the identifier of the pharmacist that completed the final check;

(f) date of preparation;

(g) batch lot or control number assigned;

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

(i) results of applicable quality control procedures.

[16.19.36.15 NMAC - N, 09-07-14; A, 03-22-15]

HISTORY OF 16.19.36 NMAC: [RESERVED]