Requirements for the Medication Compounding Certification

General Responsibilities (MDCGR) Chapter

Standard MDCGR.01
The organization’s leaders are responsible for the safety and quality of care provided through its pharmaceutical compounding services.

Element(s) of Performance for MDCGR.01

1. Leaders develop pharmaceutical compounding policies in collaboration with the compounding supervisor.
2. Leaders approve pharmacy compounding policies and procedures.
3. Leaders provide for a sufficient number and mix of individuals to support the safety and quality of pharmaceutical compounding.
4. Leaders provide for the space, equipment, and utility systems to support the scope of pharmaceutical compounding performed in the organization.
5. Leaders are responsible for assuring that quality standards on pharmaceutical compounding, such as USP chapters <795>, <797>, and <800> (effective July 1, 2018) for nonsterile, sterile, and hazardous preparations respectively, are effectively implemented in the organization.
6. The organization implements and maintains quality assurance procedures for in-process inspections, consistent with USP and state board of pharmacy requirements. These inspections include, but are not limited to, the following:
   - Identity
   - Sterility
   - Accuracy
   - Precision
   - Particulate matter
   - Safe limits and ranges for strength of preparation
   - Beyond-use dating
   - Packaging and storage
   - Antimicrobial effectiveness testing for compounded multiple-dose containers
7. The organization collects and analyzes data on pharmaceutical compounding.
8. The organization takes action on improvement opportunities identified for pharmaceutical compounding.
Requirements for the Medication Compounding Certification

Standard MDCGR.02
The organization defines the responsibilities of staff who compound and dispense sterile and nonsterile medication preparations.

Element(s) of Performance for MDCGR.02

1. The compounding supervisor(s) is responsible for safe preparation, accurate strength, precise labeling, integrity, and sterility of all compounded preparations in accordance with current requirements in USP chapters <795>, <797>, and <800> (effective July 1, 2018) for nonsterile, sterile, and hazardous preparations, respectively.

2. The compounding supervisor(s) is responsible for implementing quality assurance procedures that focus on the following:
   - Aseptic techniques
   - Beyond-use dating
   - Facility requirements
   - Environmental monitoring requirements
   - Ingredients' identity, quality, and purity
   - Labeling
   - Packaging
   - Sterility and sterilization methods
   - Training and competency assessment of staff
   - All other requirements as detailed in the current USP compounding chapters for sterile, nonsterile, and hazardous compounding

3. The compounding staff have defined responsibilities related to the following:
   - Adherence to the prescription or medication order
   - The strength, quality, and purity of compounded preparations
   - Packaging, labeling, and dispensing consistent with applicable state agencies, boards of pharmacy, laws and regulations

Standard MDCGR.03
When dispensing a compounded preparation, the organization provides education to the patient or the patient's caregiver on the safe storage, handling, and administration of dispensed compounded medications.

Element(s) of Performance for MDCGR.03

1. Education of the patient or caregiver includes, but is not limited to, the following:
   - How to inspect, store, and handle the preparation and related supplies and equipment to support effective and safe use
   - Signs of therapeutic complications or infection
   - When to contact the organization, the patient's physician, or emergency services
   - When and how to report to the compounder any adverse events or changes in the characteristics of the compounded preparation
   - Safe disposal and cleaning practices

2. The compounder reviews, documents, and resolves all reported problems with a compounded preparation reported by the patient or caregiver.
Requirements for the Medication Compounding Certification

Education, Training, and Evaluation (MDCED) Chapter

Standard MDCED.01
The organization has policies and procedures that facilitate the knowledge, skill, and effective performance of all compounding staff.

Element(s) of Performance for MDCED.01

1. The organization has written policies and procedures requiring training and competency assessment for all compounding staff consistent with USP chapters <795>, <797>, and <800> (effective July 1, 2018), laws and regulations, and state board of pharmacy requirements.

2. Compounding staff have been oriented to and have ongoing access to the following information and resources, consistent with their job functions:
   - USP General Notices
   - USP chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
   - USP chapter <797> Pharmaceutical Compounding – Sterile Preparations
   - USP chapter <800> (effective July 1, 2018) Hazardous Drugs – Handling in Healthcare Settings
   - USP chapter <1151> Pharmaceutical Dosage Forms
   - USP chapter <1160> Pharmaceutical Calculations in Pharmacy Compounding
   - USP chapter <1163> Quality Assurance in Pharmaceutical Compounding
   - USP chapter <1176> Prescription Balances and Volumetric Apparatus Used in Compounding
   - USP chapter <1191> Stability Considerations in Dispensing Practice
   - USP chapter <1265> Written Prescription Drug Information – Guidelines
   - USP chapter <51> Antimicrobial Effectiveness Testing
   - USP chapter <71> Sterility Tests
   - USP chapter <17> Prescription Container Labeling
   - USP chapter <1225> Validation of Compendial Methods
   - USP chapter <659> Packaging and Storage Requirements
   - USP chapter <1066> Physical Environments that Promote Safe Medication Use
   - USP chapter <7> Labeling – All applicable compounding laws and regulations

3. Compounding staff are oriented on how to access, retrieve, and interpret information from the Safety Data Sheets (SDSs).

4. Compounding staff are provided education, training, and supervision consistent with their job functions. Sterile compounding education and training includes, but is not limited to, mastering aseptic techniques, safe labeling, storage, and dispensing.

5. The organization provides education, training, and supervision for non-compounding staff assigned to compounding functions.

6. The organization either provides or provides for continuing education to compounding staff consistent with their assigned job functions.
Requirements for the Medication Compounding Certification

Standard MDCED.02

The compounding supervisor(s) implements a program for initial and ongoing education and training of all staff involved in the compounding, evaluating, packaging, and/or dispensing of sterile and nonsterile compounded preparations.

Element(s) of Performance for MDCED.02

1. Compounding staff are trained in procedures, relevant to their job functions, related to facilities, equipment, compounding, evaluation, packaging, storage, and dispensing.

2. Before participating in the storage, handling, or disposal of hazardous medications, any staff performing such functions are trained in the safe and effective practices specific to hazardous medications.

3. Staff who prepare, store, or handle hazardous medications are trained in safe practices that minimize the risk of exposure to themselves and the environment.

4. Staff assigned to clean and remove waste from hazardous storage and preparation areas are trained in safe practices that protect themselves and others and prevent contamination. Disposal of all hazardous medication wastes complies with all applicable federal and state regulations. Note: The following are references for the safe handling of antineoplastic and hazardous medications in healthcare settings: OSHA Technical Manual—Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs and NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings [DHHS (NIOSH) Publication No. 2004-165].

5. Education and training activities of all staff involved in compounding are documented.

Standard MDCED.03

Education and training in nonsterile compounding procedures includes observation and demonstration of competency.

Element(s) of Performance for MDCED.03

1. The compounding supervisor(s) demonstrates compounding procedures and then observes and guides the staff member in carrying out the procedures.

2. In order for a staff member to demonstrate the required knowledge to perform compounding procedures accurately without supervision, a compounding supervisor is present to approve all ingredients, observe technique, and inspect the final preparations.

3. When the staff member achieves the required knowledge and competency, a compounding supervisor signs documentation confirming the completion of training.

Standard MDCED.04

Education and training in sterile compounding procedures includes knowledge and competency concerning designated compounding equipment and spaces.

Element(s) of Performance for MDCED.04

1. The training program for staff conducting sterile compounding includes:
   - Training on the use of all equipment, apparatuses, and devices staff members are required to operate or manipulate when preparing compounded sterile preparations (CSPs)
   - Development of the ability to identify malfunctioning equipment, apparatuses, and devices

2. Compounding staff are trained and have competency assessed on the avoidance of touching critical sites as described in USP chapter <797>.
3. Sampling of compounding staff glove fingertips is done for all CSP risk levels using sterile contact agar plates after staff garbing and after completing the media-fill preparation without applying sterile 70% IPA, as described in USP chapter <797>.

4. The visual observation of compounding staff garbing and gloving to assess competency is documented using a standardized form.
   Note: One example of a standardized form is the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Staff, described in the Appendix section of USP chapter <797>.

5. Ancillary supportive services staff performing cleaning and disinfecting in the clean room (such as environmental services and housekeeping) are trained in proper hand hygiene, garbing, cleaning, and disinfecting procedures as described in USP chapter <797>. This training is conducted by the compounding supervisor, other qualified compounding staff, or, if the organization chooses, a qualified compounding consultant.

6. Use and storage procedures for CSPs in the patient care setting include, but are not limited to, the training of patient-care-setting staff on delivering the CSP to the designated storage location.

**Standard MDCED.05**

Education and training in aseptic manipulation skills for sterile compounding includes testing of technique and demonstration of competency.

**Element(s) of Performance for MDCED.05**

1. Staff compounding sterile preparations are trained in aseptic manipulation skills consistent with USP requirements, current literature, and evidence-based didactic sources.

2. Compounding staff are assessed for the competency of their aseptic technique through written, media-fill, and fingertip sample testing based on the risk level of the preparations, as described in USP chapter <797>.

3. Media-fill and glove fingertip testing of aseptic technique of compounding staff is performed as described in USP chapter <797>, including the following:
   - Before beginning to prepare compounded sterile preparations (CSPs)
   - At least every six months thereafter for high risk–level compounding
   - At least annually thereafter for low and medium risk–level compounding

4. Compounding staff successfully pass an initial competency evaluation and gloved fingertip sampling procedure no less than three times before initially compounding CSPs for human use; success is defined by zero colony-forming-unit (CFU) findings. For details regarding fingertip sampling procedure and incubation period, refer to USP chapter <797>.

5. Compounding staff who fail assessment of their aseptic technique are retrained and reevaluated by expert compounding staff to address all aseptic technique deficiencies as described in USP chapter <797>.

6. Compounding staff must pass all aseptic technique evaluations as described in USP chapter <797> (such as didactic testing, gloved fingertip sampling, and media-fill testing) before they can compound.

7. Compounding staff demonstrate competence in proper hand hygiene, garbing, and consistent cleaning procedures in the compounding area as described in USP chapter <797>.

8. Staff training and competency assessments are conducted and documented consistent with USP chapter <797> and are readily available for review.
Requirements for the Medication Compounding Certification

**Standard MDCED.06**
The organization evaluates compounding staff performance.

**Element(s) of Performance for MDCED.06**

1. The organization maintains a list of all staff who compound medication.
2. Staff who compound nonsterile preparations are evaluated at least annually.
3. Staff who perform high-risk sterile compounding are evaluated at least every six months.
4. Staff who perform low- and medium-risk sterile compounding are evaluated at least every twelve months.
5. Compounding staff are evaluated in accordance with USP requirements, current literature, evidence-based didactic sources, and, for staff conducting sterile compounding preparations, practical skills of aseptic manipulation.
6. All evaluations of staff involved in compounding sterile preparations are documented in a standardized format (paper or electronic).
   Note: The organization can develop or adopt a standardized evaluation form. One example of a standardized form is the Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Staff, described in the Appendix section of USP chapter <797>.
7. Ancillary supportive services staff performing cleaning and disinfecting in the clean room (such as environmental services and housekeeping) have a competency assessment for proper hand hygiene, garbing, cleaning, and disinfecting procedures as described in USP chapter <797>. These assessments are conducted, at a minimum, when newly assigned and when procedures change.

**Standard MDCED.07**
The organization evaluates staff competency as it relates to quality improvement processes.

**Element(s) of Performance for MDCED.07**

1. Competency assessment of compounding staff includes the assessment and documentation of the following:
   - Procedural breaches
   - Administrative errors
   - Side effects
   - Allergic reactions
   - Complications associated with medication dosage or administration
2. Adverse events that are identified through competence assessments are reviewed using the organization’s adverse event reporting system or quality improvement process.
Compounding Sterile Preparations (MDCS) Chapter

**Standard MDCS.01**
The organization maintains work practices and an environment that is consistent with the low-, medium-, and high-risk levels of sterile compounding described in USP chapter <797>.

**Element(s) of Performance for MDCS.01**

1. The compounding supervisor(s) is responsible for implementing the following as defined in USP chapter <797>:
   - Aseptic processing
   - Cleaning and disinfecting procedures
   - Environmental sampling
   - Staff training and competency evaluation of garbing, gloving, and use of protective equipment

2. The compounding supervisor(s) is responsible for implementing quality assurance work practices per compounded sterile preparation (CSP) risk levels and as described in USP chapter <797>. These practices include, but are not limited to, the following:
   - Air quality monitoring
   - Routine disinfection
   - Maintaining International Organization of Standardization (ISO) 5 air quality in the compounding area
   - Visual inspection of particulate in CSPs
   - Review of medication orders
   - Review of ingredient packages

3. The compounding supervisor(s) is responsible for performing a media-fill test procedure that represents the most challenging or stressful conditions actually encountered by the compounding staff being evaluated per the CSP’s risk level, initially before beginning to prepare CSPs, and at least annually for low- and medium-risk, and every six months for high-risk levels, as described in USP chapter <797>.

4. The compounding supervisor(s) is responsible for implementing a compounding environment (that is, compounding aseptic isolators (CAI), compounding aseptic containment isolators (CACI), laminar airflow workbench (LAFW), ante-area, buffer areas, walls, floors, ceilings, fixtures, furniture, equipment, environmental temperature, room pressure, and so forth) that is consistent with the risk levels of CSPs and meets USP chapter <797>, applicable state board of pharmacy compounding requirements, and all applicable laws and regulations.

5. Leaders provide for a compounding environment consistent with the risk level of CSPs that meets USP chapter <797>, applicable board of pharmacy compounding requirements, and all applicable laws and regulations. This environment includes, but is not limited to, CAI, CACI, LAFW, ante-area, buffer areas, walls, floors, ceilings, fixtures, furniture, equipment, environmental temperature, and room pressure.

6. The compounding supervisor(s) meet all other responsibilities of his or her role as defined in the current USP chapter <797> and in evidence-based practices.

**Standard MDCS.02**
Compounded sterile preparations (CSPs) for immediate use are not to be batch-compounded or stored in anticipation of future needs.

**Element(s) of Performance for MDCS.02**

1. Only low risk–level CSPs can be prepared as immediate-use CSPs.
   Note: Immediate-use situations are limited to emergency or immediate patient administration.
2. Immediate-use CSPs meet specific criteria to be exempt from low risk–level CSP requirements as described in USP chapter <797>. These criteria relate to limiting the number of transfers of product from packages, vials, or bags to containers and devices; limiting the duration of the compounding procedure; the timing of administration; and the supervision, labeling, and disposal of product.

3. Hazardous medications such as antineoplastics are not to be prepared as immediate use CSPs.

**Standard MDCS.03**

The manipulation, work-flow, and storage of single-dose and multiple-dose containers follow safe practices as defined in USP chapter <797>.

**Element(s) of Performance for MDCS.03**

1. Single-dose containers opened in less than an International Organization of Standardization (ISO) Class 5 environment must be used within one hour; any remaining product must be disposed.

2. Single-dose containers opened in an ISO Class 5 environment or better can be stored and must be used within a six-hour period (or sooner if required by the manufacturer) from initial puncture.

3. Single-dose ampules are not stored for any time period once opened.

4. Opened multiple-dose containers are stored in an environment that protects their integrity and must be used within 28 days unless otherwise specified by the manufacturer.

**Standard MDCS.04**

The organization has written policies and procedures on compounding, handling, storing, dispensing, transporting, and administering radiopharmaceuticals.

**Element(s) of Performance for MDCS.04**

1. Written policies and procedures include environmental requirements as described in USP chapters <797> and <823>, state board of pharmacy requirements, and laws and regulations.

2. All reasonable methods limiting staff exposure to radiopharmaceuticals should be followed based on the “as low as reasonably achievable” (ALARA) concept and all applicable laws and regulations.

3. Radiopharmaceuticals prepared as low risk–level compounded sterile preparations with 12-hour or less beyond-use dates are prepared in a segregated compounding area as specified in USP chapter <797>.

4. The radiopharmaceutical policies and procedures meet all other related requirements in USP chapters <797> and <823>, board of pharmacy requirements, and applicable laws and regulations.

**Standard MDCS.05**

Single-dose and multiple-dose allergen extracts compounded by specially trained physicians or staff under their direct supervision for intradermal or subcutaneous injections are handled as compounded sterile preparations (CSPs).

**Element(s) of Performance for MDCS.05**

1. When allergen extracts as compounded sterile preparations meet all criteria specified in USP chapter <797>, they are not subject to the staff, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in the USP <797> chapter.

   Note: The criteria specified in USP chapter <797> relate to staff knowledge, training, competency, antiseptic hand cleaning, aseptic compounding manipulations, labeling, and adding preservatives, along with other aspects of compounding.
2. Single-dose allergen extracts as CSPs are not stored for later use.

3. The patient’s name, medication’s beyond-use date, and storage temperature range should be printed on each patient-specific dose extracted from a multiple-dose vial of allergen extracts as CSPs.

**Standard MDCS.06**

The accuracy and sterility of compounded sterile preparations (CSPs) is verified per USP chapter <797> requirements, state board of pharmacy, laws and regulations.

**Element(s) of Performance for MDCS.06**

1. Verification of the CSPs accuracy, purity, and sterility includes planned testing, monitoring, practices, documentation, environmental quality requirements, loss-on-drying test, pharmaceutical calculations in prescription compounding in adherence with USP chapters <731>, <797>, <800> (effective July 1, 2018), <1160>, <1035>, and <1211>; state board of pharmacy requirements; and laws and regulations.

   Note: Loss-on-drying is a test to determine the moisture content of a sample.

2. The compounding supervisor(s) is responsible for selecting the sterilization method for sterility assurance based on USP chapters <797> and <1211>, state board of pharmacy requirements, and laws and regulations.

**Standard MDCS.07**

High risk–level compounded sterile preparations (CSPs) are sterilized by filtration, steam, or dry heat or other USP-allowed methods as described in USP chapter <1211>.

**Element(s) of Performance for MDCS.07**

1. For sterilization by filtration: Filters used to sterilize CSPs by filtration meet the following minimal requirements and tests:
   - The filters must be sterile, pyrogen-free, and approved for human use
   - The filters must be chemically and physically stable at the pressure and temperature conditions to be used
   - The filters must have a nominal pore size of 0.2 or 0.22 micron
   - The filters must retain 10^7 microorganisms of a strain of pseudomonas diminuta on each square centimeter of upstream filter surface area

2. For sterilization by filtration: The filter’s capacity allows for rapid filtration of the required volume without requiring replacement.

3. For sterilization by filtration: Manufacturer-recommended integrity testing (for example, bubble-point testing) is performed on filters used to sterilize CSPs.

4. For sterilization by steam: Autoclaving is performed as described under sterilization and sterility assurance in USP chapter <1211>.

5. For sterilization by steam: Specifications for the containers require that stoppered and crimped empty containers have a small amount of moisture so they can generate steam internally once sealed.

6. For sterilization by steam: Solutions used to fill containers that are to be sterilized by steam are passed through a filter with a pore not larger than 1.2 microns.

7. For sterilization by steam: All material to be sterilized by steam is tightly wrapped in low-particle shedding fabric or paper or sealed in envelopes that prevent post-sterilization microbial penetration as described in USP chapter <797>. 
8. For sterilization by steam: All wrapped material to be sterilized by steam is exposed to steam 121 degrees Celsius under a pressure of about 1 atmosphere or 15 psi for the duration required to achieve sterility as described in USP chapter <797>.

9. The description of steam sterilization conditions and duration for specific CSPs must be included in written documentation in the compounding facility.

10. The effectiveness of steam sterilization is verified using appropriate biological indicators of Bacillus stearothermophilus (described in USP chapter <1035>) and other confirmation methods for sterilization such as temperature-sensing devices (described in USP chapters <1211> and <71>).

11. For sterilization by dry heat: Sterilization by dry heat is used only for materials that cannot be sterilized by steam.
   Note: Examples of such materials are zinc peroxide, polypropylene copolymer, and electronics.

12. For sterilization by dry heat: Sterilization by dry heat is conducted using an oven designed for sterilization and a blower device that evenly distributes heated filtered air.

13. For sterilization by dry heat: Space is left between materials to be sterilized by dry heat to allow good circulation of hot air.

14. For sterilization by dry heat: Sterility of CSPs are to be verified and documented based on the following:
   - Sterilization and sterility assurance as described in USP chapter <1211>
   - Using biological indicators (Bls) of Bacillus stearothermophilus as applicable for the method of sterilization used (described in USP chapter <1035>)
   - Other confirmation methods for sterility tests as described in USP chapter <71>

15. For depyrogenation by dry heat: Compounding supervisors are responsible for utilizing, verifying, and documenting depyrogenation by dry heat or other applicable methods of depyrogenation as described in USP chapters <797>, <1211>, and <85>.

16. For depyrogenation by dry heat: The compounding supervisor(s) is responsible for verifying effectiveness of depyrogenation by dry heat or other methods of depyrogenation using endotoxin challenge vials. The dry heat cycle should achieve at least a 3-log reduction in endotoxins as described in USP chapters <85>, <797>, and <1211>.

17. For endotoxin testing: Endotoxin testing is required for all high risk–level CSPs that meet one of the following:
   - Prepared in groups of more than 25 identical individual single-dose packages, or
   - Prepared in multiple-dose vials for administration to multiple patients, or
   - Exposed longer than 12 hours at 2 to 8 degrees Celsius and no longer than 6 hours at warmer than 8 degrees Celsius before they are sterilized.

18. For endotoxin testing: Compounding supervisors are responsible for documenting all results from endotoxin testing.

19. For endotoxin testing: The sterilization of high-risk CSPs meets all other related USP chapter <797> requirements, state board of pharmacy requirements, and laws and regulations.
Standard MDCS.08
The organization has written policies and procedures for environmental quality control for compounded sterile preparations (CSPs) for each risk level per USP chapter <797>, state board of pharmacy requirements, and laws and regulations.

Element(s) of Performance for MDCS.08

1. Written policies and procedures (as described in USP chapters <797> and <1116>) include, but are not limited to, the following:
   - Maintaining the sterility and cleanliness of critical sites.
   - Maintaining certification of primary engineering control (PEC) and secondary engineering control (SEC) at a minimum of every six months and when modified, including documentation of the results and measures taken.
   - Continuously monitoring pressure differentials between the ante-area and buffer area and between the ante-area and the general surrounding area. Results are documented.
   - Monitoring air quality via viable air sampling and nonviable air sampling as described in USP chapter <797> at a minimum of every six months and when modified.
   - Monitoring surface requirements via surface sampling as described in USP chapter <797> including, but not limited to, sampling locations, methods of collections, sampling frequency, time of day as related to compounding activities, and action levels.
   - Measures to be taken when action levels based on colony forming unit (CFU) counts for microbial contamination are exceeded.
   - Measures to be taken when pathogenic organisms are identified during airborne particle and surface sampling.
   
   Note: USP chapter <1116> addresses microbiological control and monitoring of aseptic processes and environments.

2. Sampling locations include locations within each International Organization for Standardization (ISO) Class 5, Class 7, Class 8 areas, and in segregated compounding areas at greater risk of contamination (for example, work areas near ISO Class 5 environment, counters near doors, pass-through boxes).

3. Primary engineering control (PEC) certification and testing are dependent on the device in use, as described below:
   - Biological safety cabinets (BSCs) are tested per NSF/ANSI Standard 49.
   - Unidirectional airflow isolators are tested per Controlled Environment Testing Association (CETA) guidelines.
   - Laminar air flow workbenches are tested as described in Institute of Environmental Sciences and Technology document IEST-RP-CC002.

4. All primary engineering controls (PECs) are tested for total particle counts (ISO Class 5 certification) and have air/surface microbial sampling.

5. Secondary engineering control (SEC) certification includes the following:
   - Total particle counts (ISO Class 7 or Class 8)
   - Supply HEPA filter airflow
   - HEPA filter leak tests
   - Room air changes
   - Room pressurization
   - Surface microbial sampling
   - Air microbial sampling

6. Compounding staff protect critical sites by preventing physical contact and airborne contamination.
   
   Note: Critical sites are equipment and locations that include any component or fluid pathway surfaces (for example, injection ports, beakers) or openings (for example, opened ampoules) that are exposed and at risk of direct contact with air (ambient room), moisture (for example, oral secretions), or touch contamination. See Glossary for detailed definition of critical sites.
7. The compounding supervisor(s) reviews the report from the certification company and forwards the report to leadership with recommendations for improvement on any deficiencies noted.

**Standard MDCS.09**
The compounding area has International Organization for Standardization (ISO) Class 5 (or better conditions) provided by primary engineering control (PEC) [that is, compounding aseptic isolators (CAI), compounding aseptic containment isolators (CACI), laminar airflow workbenches (LAFW), biological safety cabinets (BSCs)], and secondary engineering control (SEC) provided by buffer areas, ante-areas, and segregated compounding areas.

**Element(s) of Performance for MDCS.09**

1. PECs (LAFWs, BSCs, CAIs, and CACIs) are located within a restricted-access ISO Class 7 buffer area or segregated compounding area as described in USP chapter <797>.
2. The compounding supervisor(s) is responsible for implementing a comprehensive quality management program that includes environmental sampling.
3. Environmental sampling is conducted prior to the first use, during initial certification, during recertification, and after servicing facilities and equipment.
4. Environmental sampling is conducted when any of the following situations occurs as described in USP chapter <797>:
   - Issues related to staff technique or work practices
   - Concerns about CSPs or other end products
   - In response to patient-related infections potentially related to CSPs

**Standard MDCS.10**
The compounding supervisor(s) implements policies and procedures that address the integrity of the compounding area, the handling of compounded sterile preparations (CSPs), and staff use of protective equipment and practices.

**Element(s) of Performance for MDCS.10**

1. The compounding supervisor(s) implements standard operating procedures (SOPs) that prohibit food, drinks, and materials exposed in patient care areas from entering ante-areas, buffer areas, and segregated compounding areas where components of CSPs are located.
2. The compounding supervisor(s) implements policies and procedures that mitigate cross-contamination when manipulating patient blood–derived material or other biological material, per USP chapter <797>.
3. The compounding supervisor(s) implements policies and procedures regarding handling packaged compounding supplies and components (needles, syringes, tubing sets) per USP chapter <797>.
4. The compounding supervisor(s) implements policies and procedures for cart work flows across demarcation lines consistent with USP chapter <797> as follows:
   - Movement of supply carts between the storeroom and ante-room
   - Cleaning and disinfecting carts used in the buffer area
5. The compounding supervisor(s) implements policies and procedures addressing supplies that are frequently required in the compounding area including the following:
   - Supplies that must be readily available are decontaminated and stored in the ante-area.
   - Paper-related items (for example, paper syringe overwraps, work records contained in a protective sleeve) are not brought into the buffer area until they are wiped with an appropriate disinfecting agent as described in USP chapter <797>.
6. The compounding supervisor(s) implements policies and procedures addressing the presence, use, and prohibition of nonessential supplies in the compounding area, as described in USP chapter <797>.

7. Nonessential objects that shed particles (for example, pencils, cardboard cartons, paper towels, cotton items, gauze pads) are not permitted in the buffer area.

8. The compounding supervisor(s) implements policies and procedures regarding movement within and through the compounding area as follows:
   - All supply items are arranged to provide maximum work-flow efficiency and reduce clutter.
   - Traffic in the compounding area is minimized and controlled.

9. For compounding pharmacies performing high risk–level compounding using nonsterile ingredients and devices, compounding supervisors implement policies and procedures addressing compounding using nonsterile components and devices in accordance with USP chapter <797>, state board of pharmacy requirements, laws and regulations.

10. Compounding supervisors implement the following procedures with defined time frames as described in USP chapter <797>:
    - Required equipment calibration
    - Routine and annual maintenance of the equipment
    - Monitoring proper function of the equipment
    - Controlled procedures for use of the equipment

11. Results from equipment calibration, routine maintenance, and annual maintenance reports are documented and kept on file either as a hardcopy or electronically for the lifetime of the equipment as described in USP chapter <797>.

12. Packages are removed from their cartons and wiped down with a disinfectant that does not leave a residue in an ante-area prior to supplies going to the buffer areas, per USP chapter <797>.

13. Unit-dose swabs are used to disinfect the sterile entry point of containers and devices, per USP chapter <797>.
    Note: Particle-generating material (such as gauze) should not be used in lieu of unit dose swabs.

14. The compounding supervisor(s) implements policies and procedures addressing hand hygiene and garbing performed in the ante-area, per USP chapter <797>.

15. The compounding supervisor(s) enforces clean-room policies and procedures regarding the prohibition of specific staff activities as described in USP chapter <797>; these include, but are not limited to, the following:
    - Using personal cell phones
    - Wearing or removing outerwear (such as hats and sweaters) in restricted areas
    - Tucking scrub pants into shoe covers to prevent them from dragging on floor
    - Wearing makeup and nail polish
    - Wearing jewelry that can interfere with the effectiveness of personal protective equipment (PPE)
    - Chewing gum
    - Coming to work with infectious conditions (such as conjunctivitis, upper respiratory infection, rashes)

**Standard MDCS.11**

The compounding supervisor(s) implements policies and procedures for the use of personal protective equipment in sterile compounding.

**Element(s) of Performance for MDCS.11**

1. The work flow for garbing activities proceeds from the dirtiest activities to the cleanest.
   Note: Garbing activities considered the dirtiest include putting on dedicated shoes, shoe covers, head and facial covers (for example, beard covers in addition to face masks), face masks.
2. Eye shields are required when working with irritants or when preparing hazardous medications.

**Standard MDCS.12**

The compounding supervisor(s) implements policies and procedures for hand and forearm cleansing prior to sterile compounding.

**Element(s) of Performance for MDCS.12**

1. Compounding staff start cleansing procedures by removing debris from underneath fingernails using a nail cleaner under warm running water followed by rigorous hand washing as described in USP chapter <797>.

2. Compounding staff wash hands and forearms to the elbows for at least 30 seconds with soap and water in the ante-area, as described in USP chapter <797>.

3. Compounding staff use lint-free disposable towels or hand dryers to dry hands and forearms, as described in USP chapter <797>.

4. Compounding staff are required to wear a nonshedding gown with sleeves with a snug fit around the wrist and neck that is disposable or laundered, as described in USP chapter <797>.

5. Compounding staff in the buffer area or segregated compounding area use antiseptic hand cleansing with a waterless, alcohol-based surgical hand scrub, following hand-hygiene guidelines defined by the Centers for Disease Control and Prevention (CDC) and in USP chapter <797>.

6. Compounding staff allow hands to dry thoroughly before putting on sterile gloves. Note: Putting sterile gloves on should be the last step in the sterile compounding garbing process as described in USP chapter <797>.

7. Contaminated gloves are disinfected by rubbing 70% isopropyl alcohol (IPA) to all contact surface areas of the gloves and letting the gloves dry thoroughly. Routine disinfection of the gloves occurs throughout the compounding procedure and whenever nonsterile surfaces are touched, as described in USP chapter <797>.

8. Compounding staff routinely inspect their donned gloves for holes, punctures, tears and then replace them immediately if such are discovered, as described in USP chapter <797>.

9. If the exterior gown is not visibly soiled, compounding staff may remove it and leave it in the compounding area to be redonned when exiting the compounding space. Exterior gowns must be discarded at the end of the compounder’s work day.

10. When reentering the compounding area, proper hand hygiene is conducted and new shoe covers, hair and facial hair covers, face masks, eye shields, and gloves are used, as described in USP chapter <797>.

11. When performing high-risk compounding activities that precede terminal sterilization, including weighing and mixing nonsterile ingredients, compounding staff are garbed and gloved the same as when performing compounding in an International Organization for Standardization (ISO) Class 5 environment, as described in USP chapter <797>.

12. Whenever properly garbed compounding staff are exposed or suspected of exposure to a less than ISO Class 7 environment, they put on new personal protective equipment, wash and perform antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and put on sterile gloves upon reentering the ISO Class 7 buffer area, as described in USP chapter <797>.

13. Compounding staff are required to follow either the garbing and cleansing requirements described in USP chapter <797> when compounding in ISO Class 5 environments created by compounding aseptic isolators (CAIs) or compounding aseptic containment isolators (CACIs), or the garbing and cleansing requirements provided in writing by the manufacturer and validated through recognized environmental testing.
Standard MDCS.13
Compounding staff follow evidence-based cleaning and disinfecting practices in the sterile compounding areas.

Element(s) of Performance for MDCS.13

1. For International Organization for Standardization (ISO) Class 5 primary engineering controls (PECs), cleaning and disinfecting activities occur in the following time frames consistent with USP chapter <797>:
   - At the beginning of every shift
   - Before each batch
   - Not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring
   - After spills
   - When surface contamination is known or suspected

2. Staff clean and disinfect each month in the ISO Class 7 buffer areas and ISO Class 8 ante-areas as described in USP chapter <797> for counters, floors, work surfaces, walls, ceilings, and storage shelving. This cleaning and disinfecting are documented.

3. Cleaning and disinfecting agents used together do not produce toxic residues and are not otherwise incompatible in terms of safety or effectiveness.

4. Sponges, mops, and other cleaning materials are nonshedding, made of microfiber, and are otherwise consistent with composition requirements defined in USP chapter <797>.

5. Sponges, mops, and other cleaning materials are used exclusively in the buffer areas, clean areas, ante-areas and segregated compounding areas, and are removed only for disposal.

6. Supplies and equipment removed from shipping cartons are wiped with an appropriate disinfecting agent (that is, sterile 70% isopropyl alcohol (IPA)) per USP chapter <797>. The disinfectant is allowed to dry completely before items are used for compounding purposes.

7. Disinfecting entry points on bags and vials is done using 70% IPA unit dose swabs; entry points are vigorously swabbed and disinfecting agents are allowed to dry before piercing stoppers with sterile needles and opening ampules, per USP chapter <797>.

8. The unit dose swabs used to disinfect entry points of sterile containers do not contact any other object before contacting the surface of the entry point, per USP chapter <797>.

9. Sealed pouches containing sterile supplies may be opened as they enter the ISO Class 5 primary engineering control (PEC) without disinfecting the sterile entry point of packages and devices, per USP chapter <797>.

10. Shipment boxes and external cartons are not taken into the buffer area or segregated compounding area, per USP chapter <797>.

11. The organization meets all other USP chapter <797> requirements related to cleaning and disinfecting the compounding area.
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Standard MDCS.14
Automated compounding devices (ACDs), including those for parenteral nutrition compounding, IV robotics and IV room work-flow systems, undergo comprehensive technological, clinical, and architectural assessments.

Element(s) of Performance for MDCS.14

1. The organization develops and implements standard operating procedures (SOPs) addressing the accuracy assessments required for all ingredients in the final compounded sterile products.
2. The organization uses the assessment methods defined in its SOP (for example, spectroscopy, refractometry, specific gravity) to determine the quantitative accuracy of all ingredients in the final compounded sterile product.
3. The organization develops and implements standard operating procedures (SOPs) addressing precision assessments of all automatic compounding devices (ACDs).
4. The organization uses the assessment methods defined in its SOP to determine variations and deviations in the performance of ACDs to prevent errors.
5. The compounding supervisor(s) implements policies and procedures related to ACDs detailing the following:
   - Work flows
   - Cleansing
   - Maintenance
   - Competency
   - Routine checks of precision and accuracy of ACDs
   - Physical inspection and accuracy of compounded sterile products
6. The compounding supervisor(s) implements policies and procedures related to finished preparation release checks and tests in accordance with USP chapter <797>, state board of pharmacy requirements, laws and regulations. These include, but are not limited to, physical inspection, double-checking accuracy of CSPs, and accuracy of labeling.
7. Compounding staff maintain a daily record of variations in accuracy and precision.
8. Trends in variations related to accuracy or precision are assessed and documented at least on a weekly basis as described in USP chapter <797>, and necessary actions are taken to correct these identified trends.
9. Compounded sterile products using ACDs meet sterility and stability requirements per each risk-level preparation as described in USP chapter <797>, state board of pharmacy requirements, and laws and regulations.

Standard MDCS.15
The organization develops and implements policies and procedures for maintaining the sterility, purity, and stability of compounded sterile preparations (CSPs) prepared by or dispensed by the organization.

Element(s) of Performance for MDCS.15

1. The organization has written policies that define how the organization will address the sterility, purity, stability, storage, and security of the CSPs that the organization dispenses and prepares.
2. CSPs are properly stored and secured by compounding staff until their beyond-use date, unless they are dispensed to patients.
3. The organization implements procedures for proper packaging, handling, transport, and storage when preparing or dispensing CSPs.
4. The compounding supervisor(s) develops procedures to be used by noncompounding staff who are assigned compounding tasks.

Standard MDCS.16
Organizational policies and procedures define the circumstances and methods for packaging, handling, and transporting compounded sterile preparations (CSPs).

Element(s) of Performance for MDCS.16

1. Procedures for packaging, handling, and transporting CSPs are developed by compounding staff in collaboration with other departments’ staff involved in CSP-related functions.
2. The organization monitors compounding staff on an ongoing basis to manage consistent implementation of procedures.
3. The organization evaluates the effectiveness and reliability of the packaging, handling, and transport procedures.

Standard MDCS.17
The organization protects the quality of compounded sterile preparations (CSPs) until they are administered.

Element(s) of Performance for MDCS.17

1. The organization implements procedures for use and storage of CSPs within the patient care setting that includes immediate labeling of the CSP container with the beyond-use date.
2. Organizations that accept returned (expired or unused) CSPs in the compounding facility have defined procedures for handling their receipt and disposition.
3. The organization implements procedures to maintain quality and sterility of CSPs for subsequent administration that are consistent with the type of CSP and devices or techniques in use. At a minimum, the procedures include the following:
   - Hand hygiene
   - Aseptic technique
   - Critical site of CSPs
   - Change of administration sets

Standard MDCS.18
Organizational policies and procedures define the circumstances and method for unopened, returned compounded sterile preparations (CSPs) to be dispensed.

Element(s) of Performance for MDCS.18

1. Procedures guiding the safe redispensing of CSPs include documentation of the following:
   - Initial preparation and thaw times
   - Measures taken to prevent and detect tampering
   - Preservation through continuous refrigeration and protection from light
2. CSPs that were readied for use (prepared, packaged, labeled, checked, and dispensed or delivered) outside the compounding facility should not be redispensed.
3. For returned CSPs, the organization assigns new storage times and beyond-use dates that exceed the original dates only when there is supporting evidence from sterility testing and quantitative assay of ingredients.
4. CSPs are redispensed only when they meet all requirements defined in organization policies and procedures, USP chapter <797>, state board of pharmacy requirements, and laws and regulations.

**Standard MDCS.19**

The quality and safety of compounded sterile preparations (CSPs) is maintained when they are packed and transported for use outside the location where they were compounded.

**Element(s) of Performance for MDCS.19**

1. The organization uses packing procedures and materials that protect the integrity, sterility, and stability of the CSPs.
2. Packing procedures and materials protect staff from exposure when transporting CSPs.
3. Compounding staff obtain confirmation from the transporter that the temperature ranges required by the CSPs are maintained by the transporter for the duration of transit. Note: Disposable thermometers can be used to validate that appropriate temperatures are maintained.
4. Compounding staff communicate handling and exposure instructions to each transporter and attach the instructions to the exterior of packages containing CSPs.
5. The organization assesses that the mode of transportation protects the integrity, sterility, and stability of the CSPs.

**Standard MDCS.20**

The organization communicates refrigeration and storage requirements to patients and other recipients receiving shipments of compounded sterile preparations (CSPs).

**Element(s) of Performance for MDCS.20**

1. Before shipping CSPs to patients or other recipients outside its own premises, the organization informs the patient or recipient of the need for a properly functioning refrigerator or freezer as required for CSP storage. The organization documents the patient’s or recipient’s confirmation that proper refrigerator or freezer capacity is available.
2. Before shipping CSPs to patients or other recipients outside their own premises, the organization labels the CSPs with beyond-use dates, storage instructions, and disposal instructions for out-of-date preparations.

**Standard MDCS.21**

The organization develops and implements an education and training program for patients and caregivers to facilitate safe storage, handling, and administration of compounded sterile preparations (CSPs) in the home.

**Element(s) of Performance for MDCS.21**

1. The scope of the formal education and training program includes the CSP storage, handling, and administration responsibilities that the patient and caregiver will need to carry out in the home.
2. The organization defines in writing the specific skills and competencies the patient or caregiver will need to develop before self-administering CSP(s) without the supervision of health care staff.
3. **Education** of the patient and caregiver includes, but is not limited to, the following:
   - The diagnosis and goals of therapy
   - The CSP(s) and its side effects
   - How to inspect, store, and handle the CSP and related supplies and equipment to support effective and safe use
   - Signs of therapeutic complications or infection
   - When to contact the organization, the patient’s physician, or emergency services
   - Safe disposal and cleaning practices

4. **Education and training** of the patient and caregiver includes the following:
   - A hands-on demonstration and return demonstration with items the patient or caregiver will use, including CSP containers, devices, and equipment
   - Patient or caregiver return demonstration of aseptic and injection technique under the direct observation of compounding staff

5. Following education and training, the patient or caregiver is assessed for understanding, competence, ability, and willingness to comply with the CSP procedures in the home.

6. The organization provides CSPs for home use only when competencies are met. Note: The organization provides additional training, information, or support, or consults with the patient’s licensed independent practitioner for alternatives when competencies are not met.

7. The organization periodically reassesses the patient’s and caregiver’s competencies for using CSPs in the home in a time frame consistent with the patient’s assessed needs.

8. The education on and validation of required patient and caregiver competencies are documented in the patient record.

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**Compounding Sterile and Nonsterile Preparations (MDCSN) Chapter**

**Standard MDCSN.01**

Compounding supervisors implement policies and procedures pertaining to storage of compounded sterile preparations (CSPs) and assigning beyond-use dates (BUD) to maintain the sterility, strength, quality, and purity of the CSPs.

**Element(s) of Performance for MDCSN.01**

1. Compounding staff assign beyond-use dates for sterile preparations using one of the following approaches:
   - Manufacturer’s recommendation for the specific product, based on chemical and physical stability parameters as described in USP chapter <797>
   - In the absence of manufacturer’s recommendations on BUD, USP chapter <797> requirements based on risk level of a specific CSP

2. If sterility testing is lacking, low-risk CSPs are stored for a maximum of 48 hours at a controlled room temperature between 20 and 25 degrees Celsius, 14 days at a cold temperature between 2 and 8 degrees Celsius, and for a maximum of 45 days at a freezing temperature between -10 and -25 degrees Celsius.

3. If sterility testing is lacking, medium-risk CSPs are stored for a maximum of 30 hours at a controlled room temperature between 20 and 25 degrees Celsius, 9 days at a cold temperature between 2 and 8 degrees Celsius, and for a maximum of 45 days at a freezing temperature between -10 and -25 degrees Celsius.
4. If sterility testing is lacking, high-risk CSPs are stored for a maximum of 24 hours at a controlled room temperature between 20 and 25 degrees Celsius, 3 days at a cold temperature between 2 and 8 degrees Celsius, and for a maximum of 45 days at a freezing temperature between -10 and -25 degrees Celsius.

5. Whenever compounding staff assign BUDs exceeding USP chapter <797> requirements, they base the rationale for extended BUDs on one or more of the following references:
   - USP monographs
   - National Formulary (NF) monographs
   - Manufacturer recommendations
   - Evidence-based literature
   - Stability and sterility information through adequate testing
   - Storage environment
   - Peer-reviewed published studies

6. The BUD and the rationale for assigning extended BUDs are documented in a master formula record (MFR).

7. BUD for proprietary bag and vials systems are assigned based on manufacturers’ recommendations. Note: Examples of proprietary bag and vial systems are ADD-Vantage and Mini Bag Plus.

8. The storage and BUD policies and procedures meet all other related expectations in USP chapter <797>, evidence-based literature, state board of pharmacy requirements, and laws and regulations.

**Standard MDCSN.02**
The organization implements policies and procedures addressing stability criteria and beyond-use dates (BUD) for nonsterile preparations.

**Element(s) of Performance for MDCSN.02**

1. Compounders base BUD on evidence-based and best-practice literature on general stability and, where available, on the specific medication being compounded.

2. Compounders base beyond-use dates on the following, consistent with USP chapter <795>:
   - The nature of the drug and its degradation mechanism
   - The dosage form and its components
   - The potential for microbial proliferation in the preparation
   - The container in which it is packaged
   - The expected storage conditions
   - The intended duration of therapy

3. When evidence-based or best-practice literature is not available regarding stability for a specific medication and preparation, beyond-use dating follows the packaging, storage condition, and duration specified in the BUD by Type Formulation requirements in USP chapter <795>.

**Standard MDCSN.03**
The compounding supervisor(s) implements policies and procedures addressing hazardous sterile and nonsterile compounding operations based on the risk level for sterile compounding and the category of complexity for nonsterile compounding, consistent with USP chapters <795>, <797>, and <800> (effective July 1, 2018); state board of pharmacy requirements; and all applicable laws and regulations.

**Element(s) of Performance for MDCSN.03**

1. Leaders support and maintain a compounding environment that meets, at a minimum, the environmental requirements of USP chapters <797>, <800> (effective July 1, 2018); state board of pharmacy requirements; and all applicable laws and regulations while compounding sterile and nonsterile preparations.
2. The compounding supervisor(s) implements audits and perform quality control checks for compounded hazardous sterile and nonsterile preparations.

3. The compounding supervisor(s) implements policies and procedures addressing garbing and personal protective equipment (PPE) such as eye protection, face masks, hair covers, gowns, double gloving with sterile chemotherapy-type gloves when compounding hazardous preparations.

4. Hazardous medications and ingredients are stored separately from the rest of the medication inventory to prevent contamination and staff exposure while compounding sterile and nonsterile preparations.

5. Compounding staff follow USP chapters <797> and <800> (effective July 1, 2018) for double-gloving using chemotherapy gloves when receiving, distributing, stocking, inventorying, preparing, dispensing, and disposing of hazardous medications.

Note: Refer to the most up to date NIOSH list of hazardous medications.

6. Sterile hazardous medications are prepared in an International Organization of Standardization (ISO) Class 5 environment with primary engineering controls and aseptic technique per the risk level and complexity as defined in USP chapters <797>, <795>, and <800> (effective July 1, 2018).

7. Access to the hazardous compounding area is controlled by and restricted to the staff involved in compounding preparations.

8. Tasks conducted prior to the sterile steps are, at a minimum, performed on a Class I biological safety cabinet (BSC).

9. Sterile hazardous medications are prepared in a Class II or III BSC or a compounding aseptic containment isolator (CACI) that meets or exceeds the standards for CACI as defined in USP chapters <797> and <800> (effective July 1, 2018).

10. The ISO Class 5 BSC or CACI used to prepare sterile hazardous medications are placed in an ISO Class 7 area, as defined in USP chapters <797> and <800> (effective July 1, 2018). The ISO Class 7 area has the following characteristics:
   - The Class 7 area is physically separated from the other medication preparation areas.
   - The Class 7 area has not less than 0.01-inch water column negative pressure to adjacent positive pressure.
   - A pressure indicator is installed to monitor the hazardous sterile compounding area.

Note: See USP Compounding Compendium, June 2015, Physical Tests; USP chapter <797>, Pharmaceutical Compounding – Sterile

11. The BSC and CACI used for sterile hazardous compounding are 100% vented to the outside air through HEPA filtration as described in USP chapter <797>.

12. A CACI meeting USP chapter <797> requirements is used outside of a buffer area; the compounding area maintains a minimum negative pressure of 0.01-inch water column and has a minimum of 12 ACPHs as described in USP chapter <797>.

13. Closed-system vial-transfer devices (CSTD) are used within the ISO Class 5 environment of a BSC or CACI as described in USP chapter <797>.

14. Facilities preparing a low volume of hazardous medications may use a two-tier containment such as a CSTD within a BSC or CACI that is located in a non-negative pressure room as described in USP Chapter <797>.

15. Personal protective equipment such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and double gloving with sterile chemotherapy-type gloves are used when compounding in a BSC or CACI and when using CSTDs based on USP chapter <797> requirements and manufacturers’ recommendations.

16. If the organization prepares hazardous medications, it also performs environmental surface sampling to detect uncontained hazardous drugs.
17. Environmental sampling occurs initially as a benchmark, and at least every six months as described in USP chapter <797>.

18. Compounding staff dispose of all hazardous medication wastes in compliance with applicable laws and regulations and state board of pharmacy requirements.

Standard MDCSN.04

The compounding supervisor(s) implements policies and procedures that address hazardous sterile and nonsterile compounding training and competency assessments, per the risk level for sterile compounding, the category of complexity for nonsterile compounding, state board of pharmacy requirements, and all applicable laws and regulations.

Element(s) of Performance for MDCSN.04

1. Before preparing or handling any hazardous preparations, staff who compound hazardous medications are provided education and training in the storage, handling, preparing, dispensing, and disposing of these medications.

2. Education and training include a didactic overview of hazardous medications including mutagenic, teratogenic, and carcinogenic properties.

3. Education and training are provided for each new hazardous medication entering the market that is handled by the organization.

4. Training for compounding staff on hazardous compounded sterile preparations includes the following items, consistent with USP chapter <797>, state board of pharmacy requirements, and all applicable laws and regulations:
   - Safe aseptic technique
   - Negative pressure technique when utilizing a biological safety cabinet (BSC) or compounding aseptic containment isolators (CACIs)
   - Correct use of closed-system vial-transfer devices (CSTDs)
   - Containment, clean-up, and disposal procedures for breakages and spills
   - Treatment of staff contact and inhalation exposure

5. The compounding supervisor(s) verifies competency of compounding staff by testing specific hazardous medication preparation techniques.

6. The organization advises all compounding staff of the risks to their reproductive systems when handling hazardous medications and confirms in writing that staff understand these risks.

7. Compounding staff who will dispose of hazardous medication waste receive initial education and training in procedures to protect themselves and prevent contamination.

8. The compounding supervisor(s) assesses competency at least annually. The competency assessment is documented.

Compounding Nonsterile Preparations (MDCN) Chapter

Standard MDCN.01

The compounding supervisor(s) implements policies and procedures addressing nonsterile compounding principles as described in USP chapter <795>, state board of pharmacy requirements, laws and regulations.

Element(s) of Performance for MDCN.01

1. The compounding supervisor(s) defines the procedures required for the three specific categories of nonsterile compounding (simple, moderate, and complex) as described in USP chapter <795>.
2. The compounding supervisor(s) defines the staff training, competencies, assessment, and documentation required for the categories of simple, moderate, and complex nonsterile compounding.

3. Compounding staff follow a prescription or medication order for accurate and precise preparations.

4. Compounding staff dispense nonsterile compounded preparations with appropriate packaging and labeling in accordance with the USP chapter <795>, state board of pharmacy requirements, and laws and regulations.

5. Nonsterile compounding ingredients are stored according to manufacturers' recommendations and/or USP-NF monograph requirements.

6. Bulk component containers have appropriate labeling per OSHA (Occupational Safety and Health Administration) hazard communication labels, state board of pharmacy requirements, and laws and regulations.

7. Safety data sheets are readily available to compounding staff for all ingredients, bulk chemicals, and medications used for nonsterile compounding.

8. The organization implements procedures to prevent cross-contamination, especially when compounding medications requiring special precautions such as hazardous and known allergen medications like penicillin.

9. All procedural steps taken in the compounding process are documented; this documentation is readily accessible.

**Standard MDCN.02**

Compounding of nonsterile preparations is performed following defined procedures.

**Element(s) of Performance for MDCN.02**

1. All nonsterile compounding is made in accordance with USP chapter <795>, evidence-based practices, state board of pharmacy requirements, and all applicable laws and regulations.

2. The dose, safety, and intended use of the preparation or device has been evaluated for therapeutic appropriateness, correct dosage form, legal limitation, and the physical and chemical properties of the components.

3. Compounding staff initiate and complete a master formulation and compounding records as follows:
   - A master formulation record is created before proceeding with any nonsterile compounding preparation.
   - The master formulation record is followed every time that specific preparation is made.
   - A compounding record is completed each time a preparation is compounded.

4. Ingredients to be used for nonsterile compounding are purchased or acquired from a source that validates the identity, quality, strength, and purity of the ingredients consistent with laws and regulations.

5. Ingredients used in the nonsterile compounded preparations have their identity, quality, and purity checked per Food and Drug Administration (FDA) requirements such as Good Manufacturing Practice (GMP).

6. Nonsterile compounding is done in a clean and sanitized area dedicated to this activity.

7. Only authorized staff are allowed in the immediate environment of the medication compounding operations.

8. Only one nonsterile preparation is compounded at one time in a specific workspace.

9. Compounding equipment is selected and inspected for cleanliness, correct functioning, maintenance, and calibration and is then properly used.
Requirements for the Medication Compounding Certification

10. The beyond-use date (BUD) is assigned consistent with the accepted potency, purity, quality, and characteristics that the nonsterile preparation must maintain.

11. Compounding staff members use good hand hygiene and wear clean clothing consistent with the type of compounding done (for example, wearing hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons) as needed for protecting staff and preventing medication contamination.

12. Critical process steps such as weighing, measuring, and mixing are verified by the compounding staff for consistency in results and quality of preparation.

13. Final nonsterile compounding preparations are assessed through factors including weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing. This assessment is documented in the compounding record consistent with USP chapter <1163>.

14. Nonsterile compounded preparations are packaged per the Packaging and Drug Preparation Containers section of USP chapter <795>.

15. Nonsterile compounded preparation containers are labeled consistent with board of pharmacy requirements and all applicable laws and regulations.
   - The label of the nonsterile compounded preparation includes the BUD, storage, and handling information.
   - The label states clearly that the contents are a compounded preparation.
   - The compounding record and the master formulation record are checked by the compounding staff to confirm an error-free compounding process.

16. Nonsterile compounded preparations are dispensed to patients or caregivers with registered pharmacist consultation.

17. Quality control procedures for the reproducibility of the intended and specified process are implemented.

18. Procedures designed to prevent errors are implemented.

19. Errors and failures that occur in compounding are investigated and audited, and then corrected in accordance with organization policies and procedures.

Standard MDCN.03
Compounding is conducted in a space that is dedicated and equipped specifically for compounding prescriptions.

Element(s) of Performance for MDCN.03

1. The organization provides compounding space as follows:
   - Is sufficient for the required equipment
   - Supports a work flow that mitigates the risk of cross-contamination or a mix-up of supplies, materials, or preparations
   - Separates areas for sterile preparation from nonsterile preparations
   (See also EC.02.06.01, EP 1)

2. The organization uses purified water for the following:
   - Compounding nonsterile medication preparations when specified in formulations
   - Rinsing equipment and utensils

3. Potable water is used for washing hands and equipment consistent with Environmental Protection Agency regulation 40 CFR Part 141.
4. The organization supports clean, sanitary, and safe practices by providing the following:
   - Staff access to hot and cold water, soap or detergent, and an air drier or single use towels
   - Compounding area that is well lit and maintained in orderly condition, according to USP chapter <795>
   - Prompt repair of equipment and other furniture or furnishings used by staff in compounding
   - A safe, functioning plumbing system
   - Storing all components, equipment, and containers off the floor to prevent soiling and for ease of inspection and cleaning
   - Prompt and sanitary disposal of waste, consistent with laws and regulations

5. Heating, ventilation, and air conditioning systems for the compounding space are as follows:
   - Maintained to mitigate contamination and degradation of compounding materials and chemicals
   - Monitored to sustain appropriate temperature and humidity conditions for certain components and compounded dosages

**Standard MDCN.04**

Compounding supervisors implement policies and procedures addressing selection, handling, and storage of all components used to compound nonsterile preparations.

**Element(s) of Performance for MDCN.04**

1. Selection, handling, and storage policies and procedures for components used to compound nonsterile preparations reflect USP chapter <795>, state board of pharmacy requirements, and all applicable laws and regulations. A USP, National Formulary (NF), or Food Chemicals Codex (FCC) substance is the recommended source of ingredient for compounding.

2. Compounding staff use components manufactured in a facility registered by the Food and Drug Administration (FDA). If components cannot be obtained from an FDA-registered facility, then the following occurs:
   - Compounding staff use professional judgment in selecting an acceptable and reliable source
   - Purity and safety of the components are checked via methods such as certificate of analysis, manufacturer reputation, and reliability of source

3. Ingredients meeting requirements of the USP or NF compendial monographs are used to compound nonsterile compounded preparations; nonsterile compounded preparations are labeled with USP or NF accordingly.

4. If compendial quality components cannot be obtained, the compounding supervisor follows defined procedures, criteria, and authorizations to use alternative high-quality components such as those that are chemically pure, analytical reagent grade, or American Chemical Society certified.

5. If a container is opened, the following three conditions must be met for its original components to be used safely up to the manufacturer’s original expiration date:
   - The component is stored in its original container under conditions to avoid decomposition of the chemicals per USP chapters <1191> and <659>, unless other conditions are noted on the label.
   - There is minimal exposure of the remaining material when material is taken from the original container.
   - All withdrawals from the original container are done by compounding staff trained in the proper handling of the material.

6. For components transferred from their original container to a different container, the new container is as follows:
   - Labeled with the component name, original manufacturer or supplier, lot or control number, transfer date, and expiration date
   - Provides environmental integrity that is equivalent to or greater than the original container
7. For components that do not have expiration dates assigned by the manufacturer or supplier, the compounding staff label the container with the date of receipt and assigns a conservative expiration date not to exceed three years after receipt of the component.

8. If the source of active ingredients is a manufactured medication product, the compounding supervisor(s) verifies the following:
   - The medication product is manufactured in an FDA-registered facility
   - The manufacturer’s product container is labeled with a batch control number and expiration date

9. Nonsterile compounded preparations that are intended for use as dietary or nutritional supplements are prepared in accordance with USP chapter <795>, state board of pharmacy requirements, and all applicable laws and regulations.

10. Compounding supervisors obtain documented assurance from manufacturers and suppliers for all components derived from ruminant animals (for example, bovine, caprine, ovine) stating that components are in compliance with all applicable federal laws governing processing, use, and importation requirements for these components. The documented assurance is kept on file.

11. Compounding staff monitor the list of components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA.

12. All components for nonsterile compounded preparations are stored as directed in terms of clean area, controlled temperature, humidity conditions, and so forth. Components are consistent with manufacturers’ guidelines or USP, NF, or FCC monograph requirements.

13. All components for nonsterile compounded preparations are stored off the floor, handled and stored to prevent contamination, and rotated so the oldest stock is used first.

14. All containers for nonsterile compounded preparations are labeled appropriately per USP chapter <795>, state board of pharmacy requirements, and all applicable laws and regulations.

**Standard MDCN.05**

Compounding is conducted using the correct type and size of equipment to produce drug preparations with safety, accuracy, and integrity.

**Element(s) of Performance for MDCN.05**

1. The equipment and supplies used for compounding medications are designed with the capacity for the quantities and dosage forms to be compounded, consistent with USP chapter <1176> and manufacturers’ instructions.

2. Equipment surfaces do not have reactive, additive, or sorptive properties and do not otherwise affect or alter the purity of the compounded preparations.

3. Equipment used in compounding or testing compounded preparations are inspected and calibrated based on time frames and criteria specified by the organization.

4. Compounding equipment is checked by the compounder immediately before operation for usage suitability and proper performance.

5. Equipment is located and stored in a manner that protects it from contamination and facilitates ease of its use, maintenance, and cleaning.

6. All equipment used in nonsterile compounding is clean and properly maintained, including thoroughly cleaned after use per organization protocol and manufacturers’ instruction. Note: If possible, disposable or dedicated equipment can be used to mitigate the risk of bio-burden and cross-contamination.

7. The organization implements additional cleaning protocols when the same equipment is being used for all medication products, as described in USP chapter <795>.
8. The organization implements additional cleaning protocols for equipment that is used in compounding preparations that require special precautions (for example, antibiotics, cytotoxic, other hazardous materials), as described in USP chapter <795>.

**Standard MDCN.06**

Containers and closures protect the integrity of compounded preparations.

**Element(s) of Performance for MDCN.06**

1. Compounding supervisors verify with container suppliers that containers and closures are performance tested in accordance with USP requirements and any applicable compounding monographs; documentation of this verification is maintained.
   Note: For more information, see USP chapters <795>; <659> (Packaging and Storage requirements); <660> (Containers-Glass); <661> (Plastic Packaging Systems and their Materials of Construction); <671> (Containers-Performance Testing); <1136> (Packaging and Repackaging – Single-Unit Containers).

2. Containers and closures for compounded sterile products are compatible with the physical and chemical properties of the compounded preparation and meet the following requirements:
   - They are made of suitable clean material in order not to alter the quality, strength, or purity of the compounded medication preparation.
   - They do not have sorptive or leaching properties and do not adversely interact with the compounded preparations.

3. Containers and closures for compounded preparations are stored in a manner that assures the safety and quality of the preparations. The manner of storage is as follows:
   - Containers and closures are elevated from the floor and protected from contamination
   - Inspection and cleaning of the storage area is permitted
   - Staff rotate containers and closures so that the oldest stock is used first

4. Containers and closures intended for the compounding of sterile preparations are handled as described in USP chapter <797>.

**Standard MDCN.07**

Compounding supervisors implement policies and procedures addressing nonsterile compounding documentation.

**Element(s) of Performance for MDCN.07**

1. Policies and procedures addressing nonsterile compounding documentation are based on USP <795> standards, state board of pharmacy requirements, and all applicable laws and regulations.

2. Nonsterile compounding documentation is maintained throughout the compounding process so that staff can trace, evaluate, and replicate steps taken to compound each preparation.

3. Compounding staff follow manufacturer’s preparation and labeling instructions; any compounding staff not following manufacturer’s preparation and labeling instructions are required to follow further documentation instructions as described in USP chapter <795>.

4. Documentation records are retained for the time period required for any prescription under state law:
   - The record may be a copy of the prescription in written or machine-readable form
   - The record includes a master formulation record and a compounding record
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5. The master formulation record (MFR), as described in USP chapter <795>, includes but is not limited to:
   - Official or assigned name, strength, and dosage form of the nonsterile compounded preparation
   - Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
   - Description of all ingredients and their quantities
   - Compatibility and stability information, including references when available
   - Equipment used for the preparation, when appropriate
   - Mixing instructions including, but not limited to, order of mixing, temperature, duration of mixing, and related factors important to the replication of the compounded preparation
   - Dispensing container used for nonsterile compounded preparation
   - Packaging and storage requirements
   - Description of final preparation
   - Quality control procedures and expected results

   For sample labeling, in addition to legally required information, the MFR should include generic name, quantity/concentration of each active ingredient; assigned beyond-use date (BUD); storage conditions; prescription or control number

6. The compounding record, as described in USP chapter <795>, includes but is not limited to:
   - Official or assigned name, strength, and dosage of the nonsterile compounded preparation
   - Master formulation record reference for the nonsterile compounded preparation
   - Names and quantities of all components
   - Sources, lot numbers, and expiration dates of all components used in compounding nonsterile preparations
   - Total quantity compounded
   - Name of the staff who compounded the nonsterile preparation, name of the staff who performed the quality control procedures, and name of the staff who approved the preparation
   - Date of preparation
   - Assigned control or prescription number
   - Assigned BUD
   - Duplicate label as described in the master formulation record
   - Description of final preparation
   - Results of quality control procedures (for example, weight range of filled capsules, pH of aqueous liquids)
   - Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver

7. All significant operating procedures performed in the compounding area should be detailed and written as a standard operating procedure (SOP). SOPs are developed for at least the following:
   - The compounding facility
   - The equipment used for nonsterile compounding
   - Preparation of nonsterile compounded medications
   - Packaging of nonsterile compounded preparations
   - Storage of nonsterile compounded preparations
   - Accuracy of nonsterile compounded preparations
   - Quality of nonsterile compounded preparations
   - Safety of nonsterile compounded preparations
   - Uniformity in compounding nonsterile preparations

Standard MDCN.08

The organization implements quality control processes before compounded preparations are dispensed to patients.

Element(s) of Performance for MDCN.08

1. Compounding staff check each procedure at each stage of the process twice.
2. Compounding staff document all deviations from procedures as required in the master formulation record, the compounding record, and any associated written protocols.

3. The compounding supervisor observes the finished preparation for appearance, investigates any discrepancies, and takes appropriate corrective action before the prescription is dispensed to the patient.

4. The compounding supervisor reviews each procedure in the compounding process.

5. The compounding supervisor implements procedures for the tests of uniformity and integrity to be conducted on compounded preparations.

6. Compounding equipment is monitored for output and performance to mitigate variability in final compounded preparations.

7. The organization meets all other responsibilities for quality control procedures as defined in USP chapter <1163>.