

Prepublication Requirements

• Issued June 20, 2023 •



Revised Medication Compounding Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online *E-dition*®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives*®. To begin your subscription, call 800-746-6578 or visit <http://www.jcrinc.com>.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO THE MEDICATION COMPOUNDING CERTIFICATION PROGRAM

Effective January 1, 2024

General Responsibilities (MDCGR) Chapter

MDCGR.01

Leaders are responsible for implementing quality standards for medication compounding in the organization.

Element(s) of Performance for MDCGR.01

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|---|--|
| 1. The organization designates an individual(s) who is responsible for the performance and operation of the facility use for and personnel involved in medication compounding. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. The designated person(s) develops policies and procedures that reflect principles outlined in USP chapters <795>, <797>, <800>, and <825> and reviews them annually. The reviews are documented.
Note: USP chapters <795> and <825> are not applicable to HAP and CAH. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 3. The designated person informs staff affected by the policies and procedures of new and revised policies and procedures. The notification and signed attestations of receipt from staff are documented. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 4. The organization has a written quality assurance program for medication compounding that collects and analyzes data on the following, at a minimum:
- Adherence to procedures
- Prevention and detection of errors and other quality problems
- Evaluations of complaints and adverse events
- Appropriate investigations and corrective actions | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 5. The organization evaluates the quality assurance program annually and acts on identified improvement opportunities. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

MDCGR.02

The organization evaluates and minimizes risks associated with the compounding of hazardous drugs.

Element(s) of Performance for MDCGR.02

1. The organization develops a list of hazardous drugs based on the formulary and reviews it at the following times:
 - Annually
 - When products are added or removed
 - When dosage forms are added or removedD

2. The organization performs a risk assessment annually if alternate containment strategies and/or work practices are utilized as allowed by USP chapter <800>. The assessment includes the following, at a minimum:
 - Type of hazardous drug
 - Dosage form
 - Risk of exposure
 - Packaging
 - ManipulationD

3. The organization implements containment strategies for hazardous drugs as described in USP chapter <800>. D

4. The organization develops and implements a written hazardous communication program as described in USP chapter <800> for hazardous drugs used for compounding. D

Competency (MDCC) Chapter

MDCC.01

Compounding staff are provided education, training, and competency assessment consistent with their job descriptions.

Element(s) of Performance for MDCC.01

Key: **D** indicates that documentation is required;

R indicates an identified risk area;

1. **Applicable staff complete testing annually. Competency is assessed and documented prior to compounding independently and every 12 months for the following:** D
 - Cleaning and disinfection
 - Calculations, measuring, and mixing
 - Aseptic technique
 - Achieving and/or maintaining sterility and apyrogenicity
 - Avoidance of touching critical sites
 - Use of equipment
 - Documentation of the compounding process
 - Principles of high-efficiency particulate air (HEPA) filtered unidirectional airflow within the ISO Class 5 area
 - Proper use of primary engineering controls (PECs)
 - Principles of movement of materials and staff within the compounding area
 - Fundamental practices and precautions of hazardous medications

Documentation may be written or electronic.
Note: Applicable staff includes, but is not limited to, the following:

 - Staff who compound category 1, 2, or 3 sterile medications
 - Designated person(s) with oversight
 - Staff with direct oversight of compounding staff

2. **Compounding staff demonstrate competency in proper hand hygiene, as described in USP chapter <797>, at the following times:** D
 - Before they are allowed to compound for patient use
 - Every 6 months when compounding category 1 and 2
 - Every 3 months when compounding category 3

The competency is documented.

3. **Compounding staff demonstrate competency in performing proper garbing procedures, as described in USP chapter <797>, at the following times:** D
 - Before they are allowed to compound for patient use
 - Every 6 months when compounding category 1 and 2
 - Every 3 months when compounding category 3

The competency is documented.

4. **All compounding staff, the designated person(s) with oversight, and staff with direct oversight of compounding staff complete gloved fingertip testing before they are allowed to compound for patient use and on an ongoing basis. The testing is documented and consistent with USP chapter <797> requirements.** D

5. **Staff compounding category 1, 2, or 3 sterile compounds demonstrate competency in proper aseptic technique through media-fill testing, as described in USP chapter <797>. The competency is documented.** D

6. **Compounding staff demonstrate competency in proper cleaning and disinfecting of the compounding area before performing the activities independently and every 12 months. The competency is documented.** D

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 7. Individuals who enter the compounding area but are not compounding or do not have direct oversight of compounding are trained as described in USP chapter <797> and based on their responsibilities and organization's policies. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 8. Compounding staff who fail competency assessments are retrained and reevaluated to address all deficiencies as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |

MDCC.02

Staff who handle or compound hazardous drugs are trained and competent.

Element(s) of Performance for MDCC.02

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| 1. Staff who handle or compound hazardous drugs complete training and demonstrate competency based on job functions as described in USP chapter <800>. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 2. Staff complete training and demonstrated competency for hazardous drugs prior to independently handling hazardous drugs and every 12 months thereafter. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |

MDCC.03

Immediate-use compounding staff complete training and demonstrate competency to conduct immediate-use compounding.

Element(s) of Performance for MDCC.03

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| 1. Immediate-use compounding staff complete training and demonstrate competency in aseptic processes based on the organizations policies and procedures initially and at least every 3 years. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
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Compounding Environment (MDCE) Chapter

MDCE.01

The organization provides an appropriate environment to conduct sterile medication compounding.

Element(s) of Performance for MDCE.01

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| <p>1. Compounding suite surfaces in the classified area meet the following criteria to allow for proper cleaning and disinfection:</p> <ul style="list-style-type: none"> - Surfaces are smooth, impervious, free from cracks and crevices, and nonshedding - If ceilings consist of inlaid panels, these are caulked to the support frame - Junctures between the floor and wall are caulked or coving is used to eliminate cracks and crevices - Penetrations to the ceiling or walls are sealed - If overhangs and ledges are present, they are easily cleanable | <input type="checkbox"/> <input type="checkbox"/> |
| 2. Water sources are not located within the buffer room. Sinks are at least 1 meter away from primary engineering controls in segregated or containment segregated compounding areas. There are no floor drains in the ante room. | <input type="checkbox"/> <input type="checkbox"/> |

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 3. Primary engineering controls are located in the appropriate environment based on compounding activity as described in USP chapters <797> and <800>. | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
| | | | |
| 4. Hazardous drugs are prepared in an appropriate containment primary engineering control (C-PEC) and are externally vented.
Note: A closed-system vial transfer device cannot be used to replace a C-PEC for the preparation of hazardous drugs. | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
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| 5. Primary engineering controls utilized for sterile medication compounding have International Organization of Standardization (ISO) Class 5 or better air quality. | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| 6. Secondary engineering controls utilized for sterile medication compounding meet the following criteria:
- Buffer areas have International Organization of Standardization (ISO) Class 7 or better air quality
- Ante-areas to nonhazardous buffer areas have ISO Class 8 or better air quality
- Ante-areas to hazardous buffer areas have ISO Class 7 or better air quality | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| 7. Air pressure differentials are continually monitored (as well as reviewed and documented daily) and meet the following criteria:
- At a minimum of +0.020 inches of water column between the buffer and ante-area and the ante-area and nonclassified space for nonhazardous compounding areas
- Between -0.01 and -0.03 inches of water column between the buffer and ante-area and the ante-area and nonclassified space for hazardous compounding areas
- Between -0.01 and -0.03 inches of water column between the containment segregated compounding area and the adjoining environment | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| 8. Air exchanges for compounding areas are maintained as described in USP chapters <797> and <800>. | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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MDCE.02

The organization maintains a safe environment for the storage and compounding of hazardous drugs.

Element(s) of Performance for MDCE.02

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| 1. The organization has designated areas for hazardous drug handling that conform to requirements outlined in USP chapter <800> and are located away from breakrooms and refreshment areas for staff, patients, and visitors.
Note: Designated areas for hazardous drug handling include the following:
- Areas for receipt and unpacking of hazardous drugs
- Storage for hazardous drugs used for compounding
- Nonsterile hazardous drug compounding areas, if the organization performs nonsterile hazardous drug compounding
- Sterile hazardous drug compounding areas, if the organization performs sterile hazardous drug compounding | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
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Compounding Operations (MDCO) Chapter

MDCO.01

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

The organization maintains compounding records as described in USP chapter <797>.

Element(s) of Performance for MDCO.01

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| <p>1. The organization develops a master formulation record for all compounded sterile products prepared from nonsterile ingredients or created for more than one patient as described in USP chapter <797>.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black; text-align: center; vertical-align: middle;"/> D |
| <p>2. The organization develops a compounding record for all compounded category 1, 2, and 3 sterile products as described in USP chapter <797>.
 Note: This also applies to immediate-use products when prepared for more than one patient.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black; text-align: center; vertical-align: middle;"/> D |

MDCO.02

The organization 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 MDCO.02

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| <p>1. The organization implements policies and procedures limiting prohibited items as described in USP chapter <797> from entering the compounding area, including, but not limited to, the following:</p> <ul style="list-style-type: none"> - Food and drinks. - Personal outer garments. - Applied cosmetics and eyelash extenders. - Nonessential supplies in the compounding area. - External shipping boxes. - All hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (for example, the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the compounded sterile preparation (CSP). Any jewelry that cannot be removed is covered. - Electronic devices that are not necessary for compounding or other required tasks. - Nail products (for example, polish, artificial nails, and extenders). - Improperly cleaned eyeglasses. <p>Note: The designated person(s) may permit accommodations to staff as long as the quality of the CSP and environment will not be affected. Accommodations are documented.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black; text-align: center; vertical-align: middle;"/> D |
| <p>2. The organization implements policies and procedures that mitigate cross-contamination when manipulating allergenic extracts, biological substances, patient blood-derived material, or other biological material as described in USP chapter <797>.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black; text-align: center; vertical-align: middle;"/> D |
| <p>3. Supplies (for example, beakers, utensils, needles, syringes, filters, and tubing sets) that contact compounding components are not reactive or absorptive. Supplies in direct contact with the compounded sterile preparation must be sterile and depyrogenated.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> |
| <p>4. Carts used to transport compounding components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels to promote mobility and ensure ease of cleaning and disinfection. In a cleanroom suite, carts are not moved from the dirty side to the clean side of the ante-room unless the entire cart, including casters, is cleaned and disinfected.</p> | <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="checkbox"/> |

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

5. The organization implements policies and procedures regarding movement within and through the compounding area as follows: (D)
- All supply items are arranged to provide maximum workflow efficiency and reduce clutter
 - Traffic in the compounding area is minimized and controlled
6. Prior to being introduced into the clean side of the anteroom, the perimeter of the segregated compounding area, or a pass-through, packages are removed from their cartons and wiped down either with a disinfectant, sporicidal, or sterile 70% isopropyl alcohol that does not leave a residue.
- Note: For disinfectants and sporicidals, package labeling must be followed.
7. When introducing items into a primary engineering control (PEC), items are wiped with sterile 70% isopropyl alcohol (IPA) using sterile low-lint wipers and allowed to dry before use.
- Note: When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the PEC without the need to wipe the individual sterile supply items with sterile 70% IPA.

MDCO.03

Equipment used to support sterile compounding activities are safe and functional.

Element(s) of Performance for MDCO.03

1. The organization implements the following procedures for compounding equipment with defined time frames as described in USP chapter <797>: (D)
- Required equipment calibration
 - Routine maintenance of the equipment
 - Monitoring proper function of the equipment
 - Controlled procedures for use of the equipment
 - Use of equipment based on the manufacturer's recommendations

MDCO.04

The organization has a process for recalling compounded sterile preparations.

Element(s) of Performance for MDCO.04

1. For compounded sterile preparations (CSPs) that are dispensed or administered before the results of release testing are known, the organization has procedures for the following: (D)
- Immediately notifying the prescriber of a failure of specifications with the potential to cause patient harm (for example, sterility, strength, purity, bacterial endotoxin, or other quality attributes)
 - Recalling any unused dispensed CSPs and quarantining any stock remaining in the pharmacy
 - Investigating if other lots are affected and if recalling is necessary

2. The organization’s policy for recalling out-of-specification dispensed compounded sterile preparations (CSPs) contains the following: D
- Determine the severity of the problem and the urgency for implementation of recall procedures
 - Determine the distribution of any affected CSP (including the date and quantity of distribution)
 - Identify patients who have received the CSP
 - Dispose and document the recalled CSP
 - Process for investigating and documenting the reason for CSP specification failure

MDCO.05

The organization implements policies and procedures for the use of garbing and hand hygiene in sterile compounding.

Element(s) of Performance for MDCO.05

1. The organization implements policies and procedures for garbing activities to reduce contamination based on the facility design and the category level of sterile compounded products. D
2. Staff entering and exiting the compounding area don and doff appropriate garb based on the category level of the sterile compounded product as described in USP chapters <797> and <800>.
3. Staff entering the compounding area conduct hand hygiene as described in USP chapter <797>.
4. Gloves are disinfected by rubbing sterile 70% isopropyl alcohol (IPA) on all contact surfaces of the gloves and letting the gloves dry thoroughly. Routine disinfection of the gloves occurs throughout the compounding procedure as described in USP chapter <797>.
5. Compounding staff routinely inspect their donned gloves for holes, punctures, or tears and replace them immediately if such are discovered as described in USP chapter <797>.

MDCO.06

The organization ensures appropriate handling of hazardous drugs.

Element(s) of Performance for MDCO.06

1. In accordance with USP chapter <800>, appropriate PPE must be worn and properly disposed of when handling hazardous drugs during the following:
- Receipt
 - Storage
 - Transport
 - Deactivation/decontamination, cleaning, and disinfecting
 - Spill control
 - Waste disposal
2. The organization requires that all individuals who enter the compounding area follow applicable policies and procedures to protect the integrity of the space as described in USP chapter <797>. D

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

MDCO.07

The organization implements policies and procedures for cleaning and disinfecting the compounding environment that are consistent with USP chapters <797> and <800>.

Element(s) of Performance for MDCO.07

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| 1. The organization utilizes the appropriate agent(s) in the proper order for cleaning, disinfecting, sporicidal, decontaminating, and/or deactivating activities based on the organization’s policy and as described in USP chapters <797> and <800>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 2. For primary engineering controls (PECs), staff clean, disinfect, and apply sporicidal agents as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 3. For primary engineering controls (PECs), staff clean, disinfect, and apply sporicidal agents at the minimum frequencies as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 4. For secondary engineering controls (SECs), staff clean, disinfect, and apply sporicidal agents as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 5. For secondary engineering controls (SECs), staff clean, disinfect, and apply sporicidal agents at the minimum frequencies as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 6. For segregated compounding areas, staff clean, disinfect, and apply sporicidal agents as described in USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 7. Sponges, mops, and other cleaning materials are used exclusively in classified areas or segregated compounding areas and are removed only for disposal.
Note: Cleaning supplies used in areas where hazardous compounding is performed may not be used in areas where nonhazardous preparations are completed. | <input type="checkbox"/> <input type="checkbox"/> |

MDCO.08

The organization requires that aseptic technique is followed.

Element(s) of Performance for MDCO.08

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| 1. Compounding staff protect critical sites by preventing physical contact and airborne contamination.
Note: Critical sites include equipment and locations that have any component or fluid pathway surfaces (for example, injection ports, beakers) or openings (for example, opened ampoules) that are at risk of direct contact with air (ambient room), moisture (for example, oral secretions), or touch contamination. See the Glossary for a detailed definition of critical sites. | <input type="checkbox"/> <input type="checkbox"/> |
| 2. Sterile 70% isopropyl alcohol is used to wipe and disinfect the sterile entry point of containers and devices as described in USP chapter <797>. | <input type="checkbox"/> <input type="checkbox"/> |
| 3. For organizations performing compounding using nonsterile ingredients and devices, the designated person (s) implements policies and procedures that address compounding using nonsterile components and devices in accordance with USP chapter <797>. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

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| 4. When weighing or mixing nonsterile product to perform category 2 or 3 compounding activities that precede terminal sterilization, staff perform these activities in an International Organization for Standardization (ISO) Class 8 environment or better, as described in USP chapter <797>. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
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| 5. The organization implements policies and procedures for sterilization of compounded products as described in USP chapter <797>. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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| 6. The organization implements policies and procedures for depyrogenation of compounded products as described in USP chapter <797>. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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MDCO.09

The organization implements procedures to evaluate the accuracy and quality of finished compounded sterile preparations in accordance with USP chapter <797>.

Element(s) of Performance for MDCO.09

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| 1. The organization accurately prepares compounded sterile preparations. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> | | |
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| 2. The organization implements policies and procedures for release inspection and testing, as described in USP chapter <797>, using one or more of the following:
<ul style="list-style-type: none"> - Visual inspection of compounded sterile preparations - Sterility testing of compounded sterile preparations - Bacterial endotoxin testing of compounded sterile preparations | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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MDCO.10

Compounded sterile preparations (CSPs) for immediate use are safely prepared.

Element(s) of Performance for MDCO.10

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| 1. Immediate-use compounded sterile preparations meet the requirements described in USP chapter <797>, including, but not limited to, the following:
<ul style="list-style-type: none"> - Administration begins within 4 hours from the start of preparation - Preparation involves no more than 3 different sterile products | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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MDCO.11

Compounded sterile preparations and associated ingredients are safely stored and assigned beyond-use dates (BUDs) to maintain the sterility, strength, quality, and purity of the CSPs.

Element(s) of Performance for MDCO.11

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| 1. Compounded sterile preparations are assigned beyond-use dates as described in USP chapter <797>. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| 2. Single-dose containers entered or punctured in an International Organization for Standardization (ISO) Class 5 environment or better are stored in accordance with labeling requirements and are used within a 12-hour period (or sooner if required by the manufacturer) from initial entry or puncture. | <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">D</td> </tr> </table> | | D |
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Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

3. Single-dose ampules are not stored for any time period once opened. D
4. Opened multiple-dose containers of injectable medications are stored and used according to manufacturer specifications. D
 Note: Opened multiple-dose containers of injectable medications are used within 28 days unless otherwise specified by the manufacturer.

MDCO.12

Certification testing indicates that the compounding area meets its design and air quality specifications.

Element(s) of Performance for MDCO.12

1. Primary engineering controls (PECs) and secondary engineering controls (SECs) are certified as described in USP chapter <797> at the following times: D
- Before initial use
 - Every 6 months
 - After relocation of PECs
 - After maintenance, repair, or construction
 - After any changes in the configuration of the room affecting air flow or quality
2. Primary engineering control certification includes the following: D
- Airflow testing, including air velocity and air pressure differential, if applicable
 - HEPA filter leak testing
 - Total particle testing
 - Dynamic airflow smoke pattern testing
3. Secondary engineering control certification includes the following: D
- Airflow testing, including air flow velocity, room air pressure, and room air exchanges
 - HEPA filter leak testing
 - Total particle count testing
4. Viable surface testing is conducted under dynamic conditions in the primary engineering control (PEC) at the following times: D
- After relocation of the PEC
 - After maintenance, repair, or construction
 - Monthly for PECs used for category 1 and 2 sterile preparations and for PECs located in a segregated compounding area
 - Weekly starting within 30 days prior to initiating category 3 sterile preparations
 - When issues related to staff technique or work practices are identified
 - When cleaning products are changed
 - In response to patient infections potentially related to compounded sterile preparations

Key: D indicates that documentation is required;

R indicates an identified risk area;

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| <p>5. Viable air testing is conducted under dynamic conditions in the primary engineering control (PEC) at the following times:</p> <ul style="list-style-type: none"> - After relocation of the PEC - After maintenance, repair, or construction - Every 6 months for PECs used for category 1 and 2 sterile preparations and for PECs located in a segregated compounding area - Monthly starting within 30 days prior to initiating category 3 sterile preparations - For issues related to staff technique or work practices or change in cleaning products - In response to patient infections potentially related to compounded sterile preparations | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>6. Viable surface testing is conducted under dynamic conditions in the secondary engineering control (SEC) at the following times:</p> <ul style="list-style-type: none"> - After maintenance, repair, or construction - After changes in the configuration of the room that affect air flow or quality - Monthly for SECs used for category 1 and 2 sterile preparations - Weekly starting within 30 days prior to initiating category 3 sterile preparations - For issues related to staff technique or work practices or change in cleaning products - In response to patient infections potentially related to compounded sterile preparations | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>7. Viable air testing is conducted under dynamic conditions in the secondary engineering control (SEC) at the following times:</p> <ul style="list-style-type: none"> - After maintenance, repair, or construction - After changes in the configuration of the room that affect air flow or quality - Every 6 months for SECs used for category 1 and 2 sterile preparations - Monthly starting within 30 days prior to initiating category 3 sterile preparations - For issues related to staff technique or work practices or change in cleaning products - In response to patient infections potentially related to compounded sterile preparations | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>8. All certification and recertification viable sampling results are reviewed and corrective action taken and documented by the designated person(s) to make certain that the classified environments meet the minimum requirements in USP chapter <797>.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |

MDCO.13

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

Element(s) of Performance for MDCO.13

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|--|--|--|---|
| <p>1. The organization uses packing procedures and materials that protect the integrity, sterility, and stability of the compounded sterile preparations.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>2. Packing procedures and materials protect staff from exposure when transporting compounded sterile preparations.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>3. Compounding staff communicate handling and exposure instructions to each transporter and attach the instructions to the exterior of packages containing compounded sterile preparations.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>4. The organization assesses that the mode of transportation protects the integrity, sterility, and stability of the compounded sterile preparations.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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Key: **D** indicates that documentation is required; **R** indicates an identified risk area;