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Pharmacy Quality Assurance Self-Assessment

(Sterile Compounding – Hazardous and Non Hazardous)

Date:

Contact information			
Pharmacy:		CPhM license #:	
Address:		City:	Postal code:
Phone #1:	Fax #1:	E-mail address:	
Phone #2:	Fax #2:	Website:	
Pharmacy information			
Last inspection date of sterile compounding facilities:			
Hours of operation:			
Pharmacy operational hours:			
Mon-Fri:	Sat:	Sun:	Holidays:
Pharmacist on-call hours:			
Pharmacy staff			
Pharmacy manager:		Manager's licence #:	
Sterile Compounding Supervisor:			
Compounding Personnel:	Pharmacist	Pharmacy Technicians	Other Personnel:
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other persons:			
Services Overview			
Pharmacy Services	Check if Provided	Comments	
Sterile Non Hazardous Compounding	<input type="checkbox"/>		
Non-Sterile Compounding	<input type="checkbox"/>		
Chemotherapy Preparation	<input type="checkbox"/>		
Home IV	<input type="checkbox"/>		

Please complete the assessment by circling the most accurate response based on the following rating scale:

1	We are confident in our compliance
2	We are not sure if we are compliant
3	We need help to be compliant
N/A	Not applicable at this pharmacy

Note: In an effort to reduce duplication, when the term sterile compound is used without reference to hazardous or non-hazardous, it refers to both hazardous and non-hazardous sterile compounds. Items specific to hazardous sterile compounds will include the word hazardous.

Glossary:

Controlled area: Anteroom and/or cleanroom

PEC: Primary engineering control

CPEC: Containment primary engineering control

BSC: Biological Safety Cabinet

LAFW: Laminar AirFlow Workbench

CAI: Compounding Aseptic Isolator

CACI: Compounding Aseptic Containment Isolator

ACPH: Air Changes Per Hour

If your pharmacy does not compound hazardous sterile compounds, indicate N/A where the item references hazardous sterile compounds.

Pharmacies that undertake sterile compounding are required to be compliant with the items in Part 1 of the Self-Assessment by January 1, 2019.

Pharmacies that undertake sterile compounding are required to be compliant with the items in Part 2 of the Self-Assessment by June 1, 2019.

Pharmacies that undertake sterile compounding are required to be compliant with the items in Part 3 of the Self-Assessment by January 1, 2021.

Part 1:

5.1 Personnel

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A sterile compounding supervisor has been designated and is qualified to perform compounding of sterile preparations.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The sterile compounding supervisor ensures that the pharmacy assistant is supervised by a pharmacist or pharmacy technician according to established protocols.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The sterile compounding supervisor has previous work experience supervising sterile compounding activities.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A pharmacist or pharmacy technician has been designated to support hazardous products management.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All new personnel involved in compounding sterile preparations have successfully completed a workplace training and competency assessment pertinent to the type of preparations to be produced.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>An annual competency assessment program has been put into place.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Personnel involved in compounding sterile preparations are evaluated for compliance with operating procedures and use of appropriate techniques for compounding sterile preparations.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All personnel (pharmacists, pharmacy technicians and pharmacy assistants) know and apply safe-handling procedures for the receipt, storage, distribution and disposal of hazardous products and hazardous waste, as well as the procedures for dealing with accidental exposure and spills.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The assessment results and corrective measures imposed are recorded and these records are retained.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All compounding personnel have the knowledge and skills required to perform quality work.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The initial training and assessment program for compounding personnel has the following components:</p> <ul style="list-style-type: none"> <input type="checkbox"/> reading and understanding the policies and procedures related to sterile preparations <input type="checkbox"/> theoretical training, with assessment <input type="checkbox"/> Individualized practical training and assessment in the workplace clean room.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All compounding personnel have passed a gloved fingertip sampling and a media fill test before working in the compounding area for sterile products</p>

					Cleaning and Disinfecting Personnel
1	2	3	N/A	<input type="checkbox"/>	<p>The initial training and assessment program for cleaning and disinfecting personnel have the following components:</p> <p><input type="checkbox"/> theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment (see Appendix 3 for a list of the elements to cover as part of the theoretical assessment of cleaning and disinfecting personnel);</p> <p><input type="checkbox"/> practical training and assessment in the areas reserved for compounding sterile preparations.</p>
1	2	3	N/A	<input type="checkbox"/>	The sterile compounding supervisor has ensured that cleaning and disinfecting personnel have the appropriate level of training
1	2	3	N/A	<input type="checkbox"/>	The sterile compounding supervisor works closely with the head of environmental services and the head of infection prevention and control to develop joint work and training procedures.
					Other Persons
1	2	3	N/A	<input type="checkbox"/>	Any other person who enters the sterile compounding area or who is involved in sterile compounding processes are adequately trained and follow and comply with specific policies and procedures.

Competency Assessment Program

1	2	3	N/A	<input type="checkbox"/>	The sterile compounding supervisor has successfully completed training (ie. courses) in the compounding of sterile preparations, maintained up-to-date knowledge and demonstrated the required competencies.
1	2	3	N/A	<input type="checkbox"/>	The sterile compounding supervisor has the competency required to manage a safe, high-quality sterile-preparation compounding area.
1	2	3	N/A	<input type="checkbox"/>	The sterile compounding supervisor is evaluated for knowledge and abilities, at the same frequency as compounding personnel, by a third party evaluator.
1	2	3	N/A	<input type="checkbox"/>	The third party evaluator meets the criteria set out in the NAPRA standards, section 5.1.2.4., for third party evaluators.
1	2	3	N/A	<input type="checkbox"/>	A competency assessment program for all compounding personnel (pharmacists, pharmacy technicians, and pharmacy assistants) has been implemented in the workplace.

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The competency assessment program includes the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> a theoretical test measuring required knowledge of policies and procedures and the aseptic compounding process. <input type="checkbox"/> a practical test in the workplace clean room (including Gloved Fingertip Sampling and a media fill test) to evaluate compliance with operating procedures and knowledge of aseptic compounding processes.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All personnel assigned to the compounding of sterile preparations undergo assessment:</p> <ul style="list-style-type: none"> <input type="checkbox"/> At least once a year in the workplace for preparations with low or medium risk level <input type="checkbox"/> At least twice a year in the workplace for preparations with a high risk level
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The results of the assessments of the compounding personnel are retained for 5 years.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A competency assessment program for cleaning and disinfecting personnel has been implemented in the workplace.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All cleaning and disinfecting personnel are evaluated at least once a year.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Compounding personnel who fail the written or practical assessment immediately stop sterile compounding and redo their training.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Cleaning and disinfecting personnel who fail the practical assessment immediately stop sterile compounding and redo their training.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>In case of repeated failures, a decision is made regarding permanent termination of sterile preparation compounding or cleaning and disinfecting activities. (Hazardous sterile compounding only)</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Pharmacists whose activities are limited to supervising a pharmacy technician or pharmacy assistant during sterile preparation compounding</p> <ul style="list-style-type: none"> <input type="checkbox"/> Possess a good understanding of the policies and procedures related to sterile compounding and demonstrated ability to determine whether the pharmacy technicians and pharmacy assistants are complying with aseptic processes, in order to quickly detect any risk of error and possible contamination <input type="checkbox"/> Must pass the practical section of the training program regarding assessment of the aseptic compounding process, the media fill test and Gloved Fingertip Sampling, if there is a possibility that this pharmacist will compound sterile preparations on an occasional basis.

1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Any pharmacist on duty in a health care facility where a pharmacist will be expected to compound sterile preparations receives the same training as a compounding pharmacist and undergoes an annual assessment of competency in sterile-preparation compounding.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>If the sterile compounding supervisor assigns the training and assessment of compounding personnel and cleaning and disinfecting personnel to a third party,</p> <ul style="list-style-type: none"> <input type="checkbox"/> the third party is a pharmacist or pharmacy technician with expertise in compounding sterile preparations; <input type="checkbox"/> the third party is at arm's length from the pharmacy or facility (independence); <input type="checkbox"/> the third party is free of any real or perceived conflict of interest with the individual being evaluated; <input type="checkbox"/> the third-party evaluator has training that covers the compounding of sterile preparations and certification that his or her competencies in this area are being maintained and developed; <input type="checkbox"/> the third-party evaluator's annual competency assessment includes the same elements as those of a competency assessment program for compounding personnel

5.2 Policies and Procedures

1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The content of the policies and procedures are established by the Sterile Compounding supervisor. And include activities outlined in Appendix 1 of the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The sterile compounding supervisor ensures compliance with the policies and procedures.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The procedures are clear and follow a standard format which includes an index for easy access to information.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The policies and procedures are promptly updated whenever there is a change in practice or standards.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Policies and procedures are reviewed at least every three years.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The date of each change, the names of the authors and reviewers are included in each revised policy and procedure.

6.2 Compounded Sterile Preparation Protocols

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Protocols for compounded sterile preparations include all of the information required to prepare the compound:</p> <ul style="list-style-type: none"> <input type="checkbox"/> name of preparation <input type="checkbox"/> pharmaceutical form <input type="checkbox"/> ingredients required <input type="checkbox"/> quantity, concentration and source of ingredients <input type="checkbox"/> necessary equipment <input type="checkbox"/> compounding procedure <input type="checkbox"/> storage method <input type="checkbox"/> BUD <input type="checkbox"/> references <input type="checkbox"/> draft and revision date <input type="checkbox"/> pharmacist's signature
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All protocols for pharmacy compounded sterile products are stored together and are ready available for quick consultation.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All protocols are reviewed and approved by the sterile compounding supervisor or designate.</p>

6.3 Compounded Sterile Preparation Log

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A compounded sterile preparation log is completed during the compounding process.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A compounded sterile preparation log is kept for each individual patient, as well as for sterile preparations made in batches.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The Compounded sterile preparation log for individual patients is filed and retained for 5 years.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The compounded sterile preparation log for sterile preparations prepared in batches is filed and retained for 5 years.</p>

6.4 Patient File

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	For any compounded sterile preparation that has already been dispensed, all information required for review and assessment of the preparation by pharmacists and for subsequent treatment of the patient is recorded in the patient file.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	Information recorded in the patient file allows users to accurately reproduce the prescribed preparation at a later date and identify the compounding personnel, if necessary.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	The origin of the compounded sterile preparation dispensed to the patient is recorded in the patient file in cases where the preparation was made by another pharmacy.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	The pharmacy is able to track information related to preparations that it dispenses, even if those preparations were made by another pharmacy.

6.7 Packaging

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	Appropriate packaging is used for all preparations that are to be delivered to patients or other health care providers.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	Preparations to be delivered are packaged and labelled to ensure the safety of both the patient and the shipper
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel put all final compounded sterile preparations in packaging that maintains each preparation's stability, integrity and storage conditions
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel put each final hazardous compounded sterile preparation in a clear plastic bag (or an amber bag, if the preparation must be protected from light);
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel place items with an attached needle in a second rigid container.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel indicate storage requirements on the final package (e.g., temperature, protection from light).
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel indicate additional precautions on the final packaging (e.g., if product is an irritant).
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	During packaging, compounding personnel indicate transport precautions (e.g., temperature, fragility, safety) and instructions (name and address of patient) on the outside packaging of each item.

<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The packaging procedure specifies the following details:</p> <ul style="list-style-type: none"> <input type="checkbox"/> equipment to be used to prevent breakage, contamination, spills or degradation of the compounded sterile preparation during transport and to protect the carrier; <input type="checkbox"/> equipment to be used to ensure that packaging protects compounded sterile preparations against freezing and excessive heat. <input type="checkbox"/> method to be used to confirm whether the temperature of compounded sterile preparations has been maintained during transport (e.g., temperature maintenance indicator, min/max thermometer, certified cooler); <input type="checkbox"/> packaging to be used to protect against extreme temperatures (i.e., excessive heat or freezing) during transport of compounded sterile preparations, unless information is available demonstrating the product's stability at these temperatures.
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>For compounded sterile preparations requiring refrigeration, the packaging maintains a temperature between 2°C and 8°C.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>For compounded sterile preparations to be kept at room temperature, the packaging maintains a temperature between 19°C and 25°C.</p>

6.8 Receipt and Storage of Non-Hazardous products:

<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The sterile compounding supervisor has developed a storage procedure which is followed at all times.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All commercial products used for preparations are properly stored immediately upon receipt.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>All commercial products used for preparations are handled and stored so as to prevent cross-contamination and incompatibilities.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Product storage conditions specified by the manufacturer are strictly observed.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>For final compounded sterile preparations or products used for preparations, the storage temperature is controlled and remains within the limits specified in Appendix 10 of the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations, regardless of the season.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Information on monitoring of room, refrigerator and other temperatures and controls related to implementation of the storage procedure are recorded in the general maintenance log.</p>

1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	A biomedical refrigerator or freezer is available for storing products, ingredients and final compounded sterile preparations that need to be refrigerated or frozen.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Alternative storage is provided when conditions are beyond acceptable temperature variations and when refrigerators and freezers are being cleaned.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Products that have been stored are inspected before use for evidence of deterioration.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	A procedure for verifying the beyond use dates of stored compounded sterile preparations and the expiration dates of commercial products has been developed and implemented to ensure that products and compounded sterile preparations that have become unusable are quickly discarded.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Products used for preparations of hazardous products are unpacked outside of controlled areas (clean room and anteroom).
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	If a spill has occurred inside the container, box or outside bag, then all packaging materials are considered chemically contaminated and are discarded in a hazardous (cytotoxic) waste container.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	When unpacking intact hazardous products that have been received from the supplier sealed in impervious plastic, two pairs of ASTM International–approved gloves are used.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	When unpacking potentially damaged hazardous products, the following garb is used: <input type="checkbox"/> two pairs of ASTM International–approved gloves <input type="checkbox"/> gown approved for the compounding of hazardous sterile preparations <input type="checkbox"/> hair, face, beard and shoe covers <input type="checkbox"/> eye protection (goggles) and a face shield or full face-piece respirator <input type="checkbox"/> chemical cartridge respirator
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	When receiving a container for hazardous drugs that appears to be damaged, either: <input type="checkbox"/> the package is sealed without opening it, the supplier is contacted, and the package is returned or disposed of as hazardous waste; or <input type="checkbox"/> the container is sealed in an impervious container, which is unpacked in a C-PEC used for compounding of non-sterile hazardous preparations.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Damaged hazardous drugs are unpacked in a C-PEC used for compounding of non-sterile hazardous preparations.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor has developed a storage procedure, and this procedure is followed at all times.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored separately from non-hazardous products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Product storage conditions specified by the manufacturer are strictly observed, regardless of where the products are stored (warehouse, pharmacy, delivery vehicle, delivery loading dock, etc.).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored in a well-ventilated room (about 12 ACPH) or in a dedicated biomedical refrigerator or freezer.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored within a negative pressure room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored in a room with all air exhausted to the exterior.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For final hazardous compounded sterile preparations or hazardous products used for such preparations, the storage temperature is controlled and remains within the limits specified in Appendix 10 of NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For final hazardous compounded sterile preparations or hazardous products used for such preparations, the storage temperature is within the range specified by the BUDs of final preparations and products regardless of the season.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Information on monitoring of temperature in the storage area for hazardous products and the refrigerator or freezer are recorded in the general maintenance log.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Alternative storage is provided if the storage temperature exceeds acceptable variations and when refrigerators and freezers are being cleaned.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Products that have been stored are inspected before use, for evidence of deterioration.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Preparations that have exceeded their BUDs are discarded promptly.

6.9 Transport and Delivery of compounded sterile preparations:

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Policies and procedures have been developed and implemented for the transport of compounded sterile preparations and their delivery to patient care units, pharmacists and patients.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A policy for return of expired or unused compounded sterile preparations from the patient's home or the patient care unit in a health care facility has been developed.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The transport and delivery procedures identify the delivery person.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The transport and delivery procedures identify the times when the min/max thermometer must be checked during transport.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The steps to be followed in the event of non-maintenance of target storage temperature during transport are indicated in the procedure.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The transport and delivery procedures include any precautions to be taken by the delivery person, especially during delivery (e.g., personal delivery of the compounded sterile preparation, rather than delegation to another person) and during return of medications, waste, and sharp or pointed items.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The sterile compounding supervisor ensures that personnel involved in preparation and delivery of products (pharmacist, pharmacy technician, pharmacy assistant and driver) receive training on the transport and delivery procedures, including the procedure for dealing with accidental exposure or spills.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Any unused compounded sterile preparation returned from a patient's home is disposed of by the pharmacist or pharmacy technician.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Hazardous compounded sterile preparations are transported in rigid containers marked "Cytotoxic".</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Hazardous compounded sterile preparations are transported in rigid containers designed to minimize the risk of cracking or failure of the preparation containers.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>When a private delivery carrier is used, the sterile compounding supervisor has verified the steps taken to ensure maintenance of the cold chain throughout transport and storage of compounded sterile preparations.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>When a private delivery carrier is used to deliver compounded sterile preparations to a patient, the sterile compounding supervisor has ensured that the transport conditions will comply with the required storage conditions.</p>

1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Policies and procedures have been developed and implemented for the transport of compounded sterile preparations and their delivery to patient care units, pharmacists and patients.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The sterile compounding supervisor ensures that the private carrier knows the procedures to be followed in the event of a spill, that a spill kit is available and that transport personnel have received appropriate training. (for Hazardous compounded sterile preparations).
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Where compounding is undertaken by another pharmacy, the compounding personnel ensures that the preparation is transported to the dispensing pharmacy under conditions that maintain stability of the preparation.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Where compounding is undertaken by another pharmacy, the receiving pharmacy ensures that transport conditions are maintained until the product is delivered to the patient.

6.12 Waste Management

1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Medications and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Medications to be destroyed are safely stored in a location separate from other medications in inventory.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	A procedure has been developed and implemented for the destruction of pharmaceutical waste.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Hazardous products are destroyed in accordance with regulations governing such products.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	A list of hazardous products in use is available in the pharmacy.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Policies and procedures for the management of hazardous waste have been developed and followed.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Policies and procedures for the management of hazardous waste comply with local, provincial/territorial and federal requirements.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	All personnel involved in the management of hazardous waste receive appropriate training on destruction procedures to ensure their own protection and to prevent contamination of the premises or the environment.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	All equipment, products and vials used in the compounding of hazardous sterile preparations are discarded in a hazardous waste container.

1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Hazardous waste containers are identified with a self-adhesive label marked "Hazardous waste – cytotoxic"
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Sharps containers removed from the C-PEC are decontaminated and then discarded into a hazardous waste container and sent for destruction.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Non-sharps waste used in the compounding of hazardous sterile preparations are placed in a hazardous waste container inside the C-PEC or placed in a sealable plastic bag before removal from the C-PEC and then discarded in a hazardous waste container.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Outer gloves are removed inside the C-PEC and placed in a hazardous waste container inside the C-PEC or placed in a sealable plastic bag before removal from the C-PEC and then discarded in a hazardous waste container.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	All PPE used in the compounding of hazardous sterile products are discarded in a hazardous waste container.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Bins used for hazardous waste comply with local, provincial/territorial and federal requirements. These bins are incinerated. (Decontamination by autoclave and subsequent burial is prohibited).

6.10 Recall of sterile products or final compounded sterile products

1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	When information obtained by a community or hospital pharmacy as a result of internal control, a complaint or a product recall shows that the grade or quality of a product or preparation does not meet requirements, the pharmacist or pharmacy technician is able to: <input type="checkbox"/> identify patients who have received the compounded sterile preparation; <input type="checkbox"/> notify patients or their caregivers that there is a problem with the preparation; <input type="checkbox"/> perform the necessary follow-up if the preparation has been administered.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	The information about individual units or batches of compounded sterile preparations recorded in the patient file and the preparation log is sufficient to allow users to track recipients of compounded sterile preparations.

1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	The sterile compounding supervisor ensures that a procedure for the recall of compounded sterile preparations has been developed and approved.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	The causes of the problem leading to the recall have been reviewed, and corrective and preventive measures have been identified and implemented.

6.11 Incident and Accident Management

1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	When an incident or accident involving a compounded sterile preparation occurs, the compounding personnel complete an event report and explanation form.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Complaints, accidents, incidents and reported side effects are evaluated to determine their cause, and the necessary steps are taken to prevent re-occurrence.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	The organization has a process to evaluate complaints, accidents, incidents and reported side effects to determine their cause and necessary steps to prevent a re-occurrence.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	The organization maintains a log of complaints, accidents, incidents and reported side effects.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Policies and procedures to be followed in case of accidental exposure of personnel to hazardous products have been established.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Material safety data sheets are accessible in the workplace.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	If a hazardous product comes into contact with skin or clothing, the person immediately removes all PPE and contaminated clothing and washes the affected area with plenty of water and soap.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	If a hazardous product comes into contact with the eyes, the eyes should be rinsed with water or saline for at least 15 minutes. An appropriate eyewash station is available for this purpose. Persons wearing contact lenses remove them promptly after exposure.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Accidental exposure to hazardous products is documented in the appropriate logs.
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Policies and procedures for managing spills have been established
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/>	Employees who clean up hazardous product spills have received adequate training,

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Employees who clean up spills, wear appropriate garb while cleaning up a spill.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Employees who clean up spills use a chemical cartridge respirator for organic vapours equipped with a pre-filter.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The respirator has been properly fitted to provide maximum protection in the presence of aerosolized or powdered products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Spill kits are available in locations where hazardous products are handled.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Spill kits are present on carts used for transporting hazardous products.

7.0 Quality Assurance Program

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor has established a quality assurance program to ensure the clear definition, application and verification of all activities that will affect the quality of hazardous compounded sterile preparations and the protection of personnel.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The quality assurance program has the following four components: <input type="checkbox"/> verification of equipment, including the PEC; <input type="checkbox"/> verification of controlled areas (clean room and anteroom); <input type="checkbox"/> verification of aseptic compounding processes; <input type="checkbox"/> verification of final preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Each component of the quality assurance program and its activities are documented.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For each of the specified components of the quality assurance program, the sterile compounding supervisor has established a verification process, the results of which are assigned one of three levels: 1. Compliance (no action required): mandatory specifications have been attained. 2. Alert (tendency toward non-compliance): increased vigilance is required to prevent non-compliance. 3. Action required (non-compliant): more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non-compliance.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, have been certified with respect to its installation.

<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, have been calibrated before being put into service and thereafter as recommended by the manufacturer.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>A regular maintenance plan has been established, taking into account the manufacturer's recommendations for each device. If no manufacturer's recommendations are available, maintenance activities are performed at least once a year by a qualified technician.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The maintenance report is saved in the general maintenance log.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>At least once a day, compounding personnel check the temperature log of equipment with an integrated recording device (e.g., refrigerator, freezer, incubator), to review temperatures over the previous 24 hours</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Compounding personnel take corrective actions in case of substantial variance with respect to specified parameters of temperature log of equipment with an integrated recording device.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>When a thermometer is used as a verification instrument, the temperature is read twice a day (at specified but different times of day; e.g., morning and night).</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The pharmacist or pharmacy technician records and retains proof of calibration of the thermometer.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>If a computerized temperature monitoring system is used, the system offers features to record and store temperature at least twice a day.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>If a computerized temperature monitoring system is used, the system triggers an alarm if the temperature readings deviate from the acceptable range.</p>
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The controlled areas of facilities and the PEC are certified by a recognized organization</p> <ul style="list-style-type: none"> <input type="checkbox"/> at least every 6 months <input type="checkbox"/> during installation of new equipment or a new controlled area; <input type="checkbox"/> during maintenance or repair of equipment (repair of PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall, etc.) that might alter environmental or operational parameters; <input type="checkbox"/> when investigation of a contamination problem or a problem involving non-compliance in the aseptic compounding process requires exclusion of malfunctioning facilities.
<p>1 2 3 N/A</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The program for monitoring facilities and the PEC includes a plan for sampling viable and nonviable particles.</p>

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	An environmental verification program has been established to ensure that facilities maintain established specifications and uphold the quality and safety standards set by the industry.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor ensures that all personnel on site <input type="checkbox"/> have full knowledge of the measuring instruments used for verification; <input type="checkbox"/> know the specifications for each parameter being verified; <input type="checkbox"/> know the procedure to be followed in case of non-compliance with respect to air pressure and temperature.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The temperature of ISO Class 7 and ISO Class 8 areas are verified and documented at least once a day.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The differential pressure between controlled areas is kept constant according to the specifications described in section 5.3.2.5 of NAPRA Model standards for Pharmacy Compounding of Hazardous and Non-Hazardous Preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Pressure is measured continuously, and an alarm system is in place to immediately advise personnel of non-compliance with specifications.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A procedure has been developed to outline and explain the actions to be taken should the pressure differential between controlled areas deviate from specifications.
Surface and Air Sampling				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A written surface sampling plan of viable, non-viable and surface particles in controlled areas and the PEC has been established.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The plan for sampling air (for viable and non-viable particles) and surfaces has been established according to the specifications of a recognized standard, such as CETA application guide CAG-002, CAG-003 or CAG-008.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The air and surface sampling plan includes, for each controlled area (clean room and anteroom), <input type="checkbox"/> sampling site diagram; <input type="checkbox"/> type of sampling to be done; <input type="checkbox"/> sampling methods to be used; <input type="checkbox"/> number of samples to be obtained at each site; <input type="checkbox"/> frequency of sampling; <input type="checkbox"/> number of colony-forming units (CFUs) triggering action.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sampling plan allows for three types of samples: <input type="checkbox"/> non-viable particles per cubic metre of air; <input type="checkbox"/> viable particles per cubic metre of air; <input type="checkbox"/> viable surface particles.

<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Samples are obtained at least every 6 months from the air in controlled areas and in the PEC <i>and</i> every time that the following conditions are present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> during installation of new equipment or a new controlled area; <input type="checkbox"/> during maintenance or repair of equipment (repair of PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall); <input type="checkbox"/> during investigation of a contamination problem or a problem involving non-compliance of personnel with aseptic processes.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Samples for determining the number of non-viable particles per cubic metre of air, viable particles per cubic metre of air and viable surface particles are always obtained under <i>dynamic</i> operating conditions during each facility and PEC certification.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Non-viable particles in the air in controlled areas and the PEC are sampled at least every 6 months under <i>dynamic</i> operating conditions, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> by the qualified certifier, during certification of facilities; or <input type="checkbox"/> by employees of the community or health care facility pharmacy, provided the employees have been trained within the framework of an internal verification program (including training in use of a calibrated particle meter), to ensure proper operation of facilities and equipment.
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The sterile compounding supervisor has ensured the competency of the certifier and the personnel chosen to conduct the sampling. (Appendix 5 of the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non hazardous preparations describes certification activities).</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>The values obtained by the certifier comply with the specifications established for each controlled area. (ISO 14644-1 classification for air quality).</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Calibration certificates for the equipment used to conduct the certification accompany the report prepared after each certification.</p>
<p>1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	<p>Sampling for viable particles includes:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sampling of viable particles per cubic metre of air for each established sampling site, using an air sampler (1000 L for ISO Class 5 and 500 L for all other areas); <input type="checkbox"/> surface sampling of each established sampling site, whereby a 55-mm agar surface is used to gently touch the sample site, with a new agar plate being used for each sampling site (the agar will leave behind a residue, and the sampled area must be disinfected immediately after sampling).

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sampled area is disinfected immediately after sampling.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sampling of viable air and surface particles is performed by a qualified individual.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	An established sampling procedure is followed and personnel have received and successfully completed the proper training for this procedure.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A calibration certificate for the viable air sampler has been obtained.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The appropriate nutrient medium for plating of samples is used. <input type="checkbox"/> tryptic soy agar (low sulphur content) or soybean-casein digest medium for air samples <input type="checkbox"/> tryptic soy agar with lecithin and polysorbate for surface samples <input type="checkbox"/> for high-risk compounding, in addition to the above, malt extract agar or other media that support the growth of fungi.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The microbial proliferation capacity of each batch of nutrient medium used has been verified. The certificate used for this test, provided by the manufacturer is retained.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The samples obtained are either <input type="checkbox"/> sent to a certified external laboratory; or <input type="checkbox"/> incubated in the community or health care facility pharmacy
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The incubator used in the community or health care facility pharmacy is certified periodically.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Procedures are in place for use and maintenance of the incubator and for surveillance of temperatures
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel are properly trained and are competent to read and interpret the results of the incubated samples and to take appropriate preventive or corrective actions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism is identified.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Surface contamination by hazardous antineoplastic drugs, as determined by environmental monitoring, is recorded in the general maintenance log
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Gloved Fingertip Sampling (GFS) includes: <input type="checkbox"/> a sample obtained after sterile gloves are put on (after aseptic washing of hands and forearms) but before application of sterile 70% isopropyl alcohol <input type="checkbox"/> a sample obtained after the media fill test, making sure that the employee has not applied sterile 70% isopropyl alcohol to his or her gloves in the minutes before sampling.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When the sampling is complete, the gloves are taken off and thrown away, and hand and forearm hygiene is performed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The GFS samples are incubated between 30°C and 35°C
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The GFS results are read within 48 to 72 hours.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For each employee, a negative result (0 CFU) is obtained three times for the first GFS (obtained after sterile gloves are put on) before the employee can be permitted to compound sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For each employee, GFS after the media fill test is completed annually for low- and medium-risk sterile compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For each employee, GFS after the media fill test is completed every 6 months for high-risk sterile compounding
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For the GFS after the media fill test, the total CFU count for both hands is no more than 3 CFUs. <i>(If the result on any GFS after a media fill test is more than 3 CFUs, the sterile compounding supervisor is prompted to investigate the employee's work practices, procedures, use of disinfectants, etc.)</i>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For the media fill test, the simulation chosen is representative of activities performed under real compounding conditions in the particular environment and represents the most complex preparations according to the microbiological risk level of preparations made there.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A tryptic soy agar (low sulphur content) or soybean-casein digest nutrient medium is used for the media fill test.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For compounded sterile preparations with low or medium risk of microbial contamination, the nutrient medium is sterile.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For compounded sterile preparations with a high risk of microbial contamination, the nutrient medium is non-sterile and includes simulation of sterilization by filtration.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The proliferation capacity of every batch of nutrient medium used has been tested by the manufacturer, and the certificate for this test result is retained by the compounding pharmacy.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The containers filled with nutrient medium for use in the media fill test are incubated between 20°C and 25°C or between 30°C and 35°C for 14 consecutive days.

				Documentation of Quality Control Activities
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Written documentation related to the quality assurance program has been verified, analyzed and signed by the sterile compounding supervisor and retained for 5 years.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The sterile compounding supervisor:</p> <ul style="list-style-type: none"> <input type="checkbox"/> investigates missing documentation, situations of non-compliance (where action is required) and deviations from protocols; <input type="checkbox"/> identifies trends concerning microbial load in controlled areas and types of microorganisms found; <input type="checkbox"/> consults with a microbiology specialist, if necessary; <input type="checkbox"/> takes corrective and preventive actions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All completed documentation concerning components of environmental verification of controlled areas, the PEC and supporting equipment is filed and retained with other compounding records for 5 years.

Part 2:

6.5 Conduct of personnel in areas reserved for the compounding of sterile preparations.

				Conduct of Personnel
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel behave in a professional manner, following pertinent policies and procedures.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel afflicted with the following conditions are excluded from sterile compounding activities and sterile compounding areas until the condition has been remedied: <ul style="list-style-type: none"> <input type="checkbox"/> Uncontrolled weeping skin condition <input type="checkbox"/> Burns to the skin, including sunburns <input type="checkbox"/> Cold sores (active herpes simplex viral infection) <input type="checkbox"/> Conjunctivitis (viral or bacterial) <input type="checkbox"/> Active respiratory infection with coughing, sneezing or runny nose <input type="checkbox"/> Fresh piercings <input type="checkbox"/> Other fresh wounds
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel with a recent tattoo on the face, neck or arms have ceased sterile compounding activities and do not resume activities until the skin is completely healed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel remove personal outer garments (e.g., coat, hat, jacket, scarf, sweater, vest, boots and outdoor shoes)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel remove all cosmetics, including makeup, false eyelashes, perfume, hair products, henna tattoos, and paper tattoos.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel tie up long hair.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel remove nail polish and other nail applications (nail extensions and other synthetic nail-lengthening products are prohibited);
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel ensure that natural nails are kept short and trimmed (0.6mm).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel ensure that skin of hands and forearms is undamaged.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel change into dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel wear pants that fully cover the legs.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel wear closed shoes and socks.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before entering the anteroom, personnel wash their hands.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Food items, drinks, chewing gum, candy and cigarettes (or other smoking products) are prohibited in the clean room and anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All access doors to the clean room and anteroom are kept closed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All personnel in the clean room and anteroom follow specified hand hygiene and garbing procedures.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel have developed work techniques to minimize the risk of cross-contamination and microbial contamination, to avoid errors and to maximize performance of the PEC.

6.6 Aseptic compounding of hazardous sterile preparations

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The number of people in the clean room and anteroom is limited to the minimum number required to perform aseptic compounding activities.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before the compounding of sterile preparations begins, the pharmacist or pharmacy technician ensures that calculations are accurate and that the appropriate drugs, equipment and devices have been selected.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pharmacist or pharmacy technician ensures that compounding personnel follow the protocol for compounding the sterile preparation.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pharmacist or pharmacy technician validates the preparations log.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Exposure of critical sites is limited to a PEC that maintains ISO Class 5 air quality requirements.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hand and forearm hygiene is performed by anyone entering the cleanroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	After donning head and facial hair covers and face masks and dedicated shoes or shoe covers, personnel wash and disinfect hands and forearms in the following sequence:

	<input type="checkbox"/> Under warm running water, use a nail pick to remove debris from underneath fingernails. <input type="checkbox"/> Wash hands and forearms up to the elbows with soap and water, for at least 30 seconds. Do not use brushes. <input type="checkbox"/> Rinse with water. <input type="checkbox"/> Dry hands and forearms with disposable, lint-free towel. <input type="checkbox"/> Dispense ABHR (Alcohol-based hand rub) with persistent activity onto one palm. <input type="checkbox"/> Immerse fingertips of the other hand into the ABHR. <input type="checkbox"/> Cover the forearm of the other hand with ABHR until the ABHR evaporates. <input type="checkbox"/> Repeat with other hand and other forearm. <input type="checkbox"/> Don gown. <input type="checkbox"/> Enter the clean room. <input type="checkbox"/> Dispense ABHR onto palm of one hand. Rub both hands with ABHR, making sure that all surfaces of the hands are covered. <input type="checkbox"/> Continue to rub until the ABHR has evaporated. <input type="checkbox"/> Allow hands to dry. <input type="checkbox"/> Don sterile gloves. The gloves must cover the cuffs of the non-shedding gown.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	When compounding hazardous preparations, two pairs of gloves are donned.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	When compounding hazardous preparations, the inner pair of gloves goes under the sleeves of the gown, while the outer pair of gloves is pulled up over the gown cuffs. The outer gloves are sterile.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The hand-washing sequence is documented in the policies and procedures and updated as appropriate.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Personal Protective Equipment is worn during sterile compounding, regardless of the type of PEC that is used.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Compounding personnel don garb in the sequence described in the policies and procedures.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Shoe covers or dedicated shoes are used at all times in the clean area of the anteroom and the clean room when compounding non-hazardous preparations.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Two pairs of shoe covers are used at all times in the clean area of the anteroom and the clean room when compounding hazardous preparations.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	If dedicated shoes are used, they are closed, dry, clean and easy to maintain.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If dedicated shoes are used, they are cleaned and disinfected once a week.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When compounding of hazardous sterile preparations is complete, personnel remove the PPE following an established technique and sequence, as set out in a detailed procedure developed by the facility.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel who compound hazardous sterile preparation dispose of soiled PPE in a container for cytotoxic waste and wash their hands before exiting the compounding area.
Introducing products and equipment into the clean room				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before any product is introduced into the anteroom, it is removed from its cardboard shipping box
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Before any product is introduced into the anteroom, the product is wiped with a sporicidal agent.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Where packaging allows, compounding equipment and products are disinfected with sterile 70% isopropyl alcohol just before being introduced into the clean room or the antechamber of the CACI.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Non-shedding wipes or swabs are used for disinfection.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Sterile 70% isopropyl alcohol is not sprayed onto compounding equipment or products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The wipes or swabs are changed regularly during disinfection of equipment and products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For introduction of compounding equipment and products into the clean room, the items are placed in a plastic or stainless steel bin.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Plastic or stainless steel bins used for transferring product into the clean room are disinfected before use.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a pass-through is available, equipment and products that are to be introduced into the clean room are placed in plastic or stainless steel bins and then placed in the pass-through for transfer to the clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If there is no pass-through, the equipment and products are transferred from the “dirty” cart or bin to the “clean” cart or bin at the demarcation line in the anteroom and are then introduced into the clean room. The equipment and products are disinfected while being transferred to the clean cart or bin.
Cleaning and disinfecting the primary engineering control				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel comply with the following requirements when cleaning and disinfecting the PEC:

	<input type="checkbox"/> Disinfect non-powdered sterile gloves with sterile 70% isopropyl alcohol and allow to dry before starting to clean and disinfect the PEC. <input type="checkbox"/> Avoid having the head and upper body enter the PEC. <input type="checkbox"/> Use non-shedding, disposable wipes. <input type="checkbox"/> Avoid contaminating the surface of wipes used for cleaning and disinfecting. <input type="checkbox"/> Change wipes after disinfection of each section of the PEC. <input type="checkbox"/> Clean and disinfect the PEC with clean wipes and germicidal disinfectant detergent, followed by sterile 70% isopropyl alcohol, at the start and end of the day or shift (minimum twice per day). <input type="checkbox"/> Follow the cleaning method described in the pharmacy's procedures. <input type="checkbox"/> Follow the disinfecting method described in the pharmacy's procedures (with regard to equipment, sequence and movements). <input type="checkbox"/> Follow the manufacturer's directions concerning dwell time for the disinfectant. <input type="checkbox"/> Wait until the disinfectant has dried before compounding the first preparation in the PEC. <input type="checkbox"/> Record cleaning and disinfecting activities in the maintenance log.(non hazardous)
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Sterile water is used for diluting concentrated disinfectant solutions used inside any ISO Class 5 device.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Decontamination, deactivation and disinfection tasks (Hazardous sterile preparation) are recorded in the general maintenance log.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Sterile 70% isopropyl alcohol alone is not used to decontaminate hazardous drugs.
1 2 3 N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	For daily activities such as disinfecting the inside of a C-PEC, a surface decontamination step using an appropriate agent precedes the usual disinfection step with sterile 70% isopropyl alcohol.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All surfaces of LAFW are cleaned and disinfected at the start of each workday and at the end of each workday.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A germicidal disinfecting detergent followed by a sterile 70% isopropyl alcohol are used to clean and disinfect all surfaces of LAFW. (Laminar Airflow workbench)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The work surface of LAFW is cleaned and disinfected using sterile 70% isopropyl alcohol <input type="checkbox"/> before starting any sterile product preparation. <input type="checkbox"/> At each shift change <input type="checkbox"/> Whenever surface contamination is suspected <input type="checkbox"/> If there has been non compliance with aseptic techniques
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The work surface of the LAFW and any surface that has been splashed is cleaned and disinfected when there is a spill using sterile water for cleaning followed by sterile 70% isopropyl alcohol.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All surfaces and subfloor of the LAFW are cleaned and disinfected weekly (at the end of the workday)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The work surface of the BSC or CACI is disinfected before the start of hazardous preparation compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The work surface of the BSC or CACI is decontaminated and disinfected: <input type="checkbox"/> On each preparation change, upon removal from the BSC or CACI <input type="checkbox"/> At the start or end of each shift. <input type="checkbox"/> When surface contamination is suspected <input type="checkbox"/> If there has been non compliance with aseptic techniques
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All surfaces inside the BSC or CACI are decontaminated and disinfected: <input type="checkbox"/> At the start of the workday. <input type="checkbox"/> At the start of the workday if the BSC or CACI has not been used for one or more days. <input type="checkbox"/> When there has been a spill. <input type="checkbox"/> Before and after certification. <input type="checkbox"/> After service interruption (ie power outage) <input type="checkbox"/> If the C-PEC is moved
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All surfaces and subfloor of the BSC or CACI are decontaminated, deactivated, and disinfected weekly (at the end of a workday or as recommended by the manufacturer).

				Aseptic technique for compounding sterile preparations
1	2	3	N/A	Compounding personnel use meticulous aseptic technique when preparing compounded sterile preparations.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Compounding occurs in the critical area of the PEC, such that critical sites are exposed to first air.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Each preparation is completed from start to finish before compounding of another preparation is begun.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	In the event of non-compliance with aseptic technique, the preparation is discarded.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	In the event of non-compliance with aseptic technique, new supplies are used, and the surface of the PEC is disinfected before another preparation is started.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Gloved hands are disinfected with sterile 70% isopropyl alcohol before re-introduction into the PEC or after gloves have come into contact with a microbiologically contaminated surface.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	If gloves are torn, they are removed and hand and forearm hygiene performed before new gloves are donned.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Even without tearing, gloves are changed regularly
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The frequency and circumstances of glove changes are defined in a procedure.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Products and supplies are intact, dry and unsoiled.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	All containers (e.g., bags of solution, vials and ampoules) are examined before use.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Products exhibiting turbidity, cloudiness or particulates are not used.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	All equipment with surfaces that can be disinfected are disinfected with sterile 70% isopropyl alcohol before being introduced into the PEC.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Non-shedding wipes or sterile swabs are changed regularly during disinfection of equipment.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To reduce the risk of errors and to decrease turbulent air flow from the PEC, vials are not allowed to accumulate in the PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>Personnel who compound hazardous preparations adhere to the following requirements when working in the C-PEC:</p> <ul style="list-style-type: none"> <input type="checkbox"/> When diluting powder or withdrawing liquids, use a ventilated system equipped with a 0.22-µm hydrophobic filter. <input type="checkbox"/> When withdrawing a hazardous solution, comply with the maximum fill limit of the syringe, i.e.,75% (3/4) of total syringe capacity. <input type="checkbox"/> When dispensing a hazardous preparation in a syringe, use a protective Luer-Lok safety tip system. <input type="checkbox"/> If possible, use a closed-transfer system (since the steps described above do not completely eliminate the risk of exposure to the hazardous preparation). <input type="checkbox"/> Discard all materials used during compounding into a marked waste container specifically designated for hazardous products. <input type="checkbox"/> Before removing a container holding a final hazardous compounded sterile preparation from the C-PEC, follow the surface decontamination procedure on all surfaces of the container. <input type="checkbox"/> While the final container is still inside the C-PEC, compounding personnel must label it and place it in a sealable plastic bag.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All final hazardous compounded sterile preparations are marked “cytotoxic”.
				Verification of final compounded sterile preparations
				Role of personnel in verification
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The sterile compounding supervisor performs the following activities:</p> <ul style="list-style-type: none"> <input type="checkbox"/> ensure that all compounded sterile preparations comply with compounding protocols; <input type="checkbox"/> verify the identity of the ingredients (drug and diluent); <input type="checkbox"/> verify the volume of the ingredients (drug and diluent); <input type="checkbox"/> regularly verify the quality of the manipulations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>When compounding a preparation, compounding personnel undertake the following activities:</p> <ul style="list-style-type: none"> <input type="checkbox"/> perform a visual inspection of each unit for evidence of particulates, to verify the clarity, colour and volume of the solution, to check the container for possible leaks and to verify the integrity of the container; <input type="checkbox"/> verify the information on the label; <input type="checkbox"/> place final compounded sterile preparations that require storage at 2°C to 8°C in the refrigerator pending verification and delivery to patients or the patient care unit.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Final compounded sterile preparations are cooled in the refrigerator before being placed in a cooler.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Verification may be conducted by capturing images of the critical site (in the PEC) with a camera connected to a monitor. Such verification is performed before the compounded sterile preparation is delivered to the patient.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When verification is conducted by capturing images of the critical site (in the PEC) with a camera connected to a monitor, and the verifying pharmacist or pharmacy technician notices that one or more procedures have not been followed correctly, all sterile preparations compounded during this period are destroyed, and the destruction of preparations is entered in the preparations log.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the person performing verification duties enters the clean room, he or she is garbed exactly the same as the compounding personnel.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If verification occurs in the anteroom (via camera or image capture), the person performing verification duties wears a hair cover, gown, two pairs of ASTM rated gloves and shoe covers.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Ophthalmic drops are verified at each stage of the compounding process. The vehicle used and product taken from the vial is checked before insertion into the dispenser bottle.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Diluted Cassettes are verified at each stage of compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Preparations made using a volumetric pump are verified at each stage of compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	With all preparations the equipment and products used are verified before and after compounding
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	An additional verification method, by counting vials, ampoules and remaining material, has been implemented.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Each preparation is inspected by a person other than the individual who performed the aseptic compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The person inspecting the preparation inspects each unit for evidence of particulates and verifies the clarity, colour and volume of the solution. The container is also checked for possible leaks and the integrity of the product is verified.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The verifier signs the preparation log.

				Labelling of final compounded sterile preparations
1	2	3	N/A	The sterile compounding supervisor establishes a policy for the labelling of compounded sterile preparations and ensures that it is followed.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The information on labels follows federal/provincial legislation and regulations for drugs prepared or sold with or without a prescription
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The labels for compounded sterile preparations meet the requirements of the applicable legislation and regulation
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	All active ingredients are identified on the label.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The label includes the concentration of each ingredient.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Each container for a compounded sterile preparation is labelled.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	A label is affixed to each prepared unit, accompanied, if necessary, by a supplementary document to complete the required information.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	Compounding personnel label the following items: final compounded sterile preparations; <input type="checkbox"/> each unit of a compounded sterile preparation for an individual patient, along with required auxiliary labels; <input type="checkbox"/> each unit of sterile preparations compounded in batches (with, at a minimum, drug name, concentration, route of administration, batch number and BUD); <input type="checkbox"/> each package containing final preparation units, along with auxiliary labels indicating required storage conditions and special precautions.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The compounding pharmacist or pharmacy technician labels sterile preparations that have been compounded at the request of another pharmacy, where permitted by provincial legislation.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	At the pharmacy where the compounded sterile preparations will be dispensed to the patient, another label is added containing all information required by the respective provincial regulatory authority. A supplementary document is prepared if required and both labels are retained on the preparations.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1	2	3	N/A	The computer-generated self-adhesive label printed by the prescription and file management software may be too small to carry all relevant information to ensure safe, appropriate use of the
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	compounded sterile preparation by the patient. In that situation, an insert has been prepared.			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Together, the label and insert provides all information required for proper use of the drug by the patient or for safe administration by a third party.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The label contains the following information, at a minimum: <input type="checkbox"/> pharmacy identification (name, address and telephone number of the compounder's or dispenser's pharmacy); <input type="checkbox"/> drug identification (active ingredients, source, concentration, form, <input type="checkbox"/> route of administration, volume, solute, amount prepared); <input type="checkbox"/> overfill volume, when overfilling has occurred; <input type="checkbox"/> special precautions (e.g., if product is an irritant); <input type="checkbox"/> storage method; <input type="checkbox"/> date when the sterile preparation was compounded; <input type="checkbox"/> BUD; <input type="checkbox"/> preparation batch number.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The package insert includes the following information: <input type="checkbox"/> all information required by federal/provincial legislation and regulations regarding the labelling of medications that could not be included on the main label; <input type="checkbox"/> details concerning mode of administration; <input type="checkbox"/> special precautions related to drug storage (e.g., "Caution: contents must be refrigerated upon receipt — store between 2°C and 8°C. Do not freeze"; "Do not store medication in the refrigerator door"; "Keep out of reach of children"); <input type="checkbox"/> special precautions for disposal or destruction of the preparation; <input type="checkbox"/> emergency contact information of the compounding pharmacy.
References				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor has available a recent edition of the following publications: <input type="checkbox"/> Standards, guidelines and policies of the pharmacy regulatory authority <input type="checkbox"/> Trissel LA. Handbook on injectable drugs. Bethesda, MD: American Society of Health-System Pharmacists. <input type="checkbox"/> United States Pharmacopeial Convention (USP). USP pharmacists' pharmacopeia. Rockville, MD: USP; current version (contains all USP chapters useful to pharmacists, including General Chapter <797>: Pharmaceutical Compounding — Sterile Preparations).

Part 3:

6.1 Beyond-use date and dating methods

				Beyond Use dates for preparations
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Administration of the compounded sterile preparation begins before the BUD has passed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>Where no specific sterility testing is performed for a preparation or batch, the sterile compounding supervisor assigns a BUD on the basis of the following criteria:</p> <p><i>The BUD must not exceed the earliest of the dates established by the following two criteria:</i></p> <p><input type="checkbox"/> expiration date based on chemical and physical stability according to reference texts.</p> <p><input type="checkbox"/> storage time related to risk of microbial contamination.</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To establish a longer BUD, sterility tests are performed for a given preparation or batch.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Preparations are quarantined while awaiting the results of the sterility test.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pharmacy's operating procedures describe the risk assessment process used to establish the BUD and the storage conditions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	During compounding, the use of commercially available products have priority.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a sterile product is commercially available, compounding personnel do not use non-sterile ingredients to compound a sterile preparation.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When a single use vial is punctured in a PEC that maintains ISO Class 5 air quality, the BUD is 6 hours
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Six hours after an initial needle puncture, the single use vial is no longer used.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When the single use vial is removed from the ISO Class 5 PEC, it is discarded.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To properly manage risk, a label is affixed to the vial indicating the time of initial needle puncture.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The contents of a vial are not divided for the sole purpose of extending stability.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the vial or another single-dose container is opened or punctured in an environment with air quality worse than ISO Class 5, the BUD is 1 hour.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Storage of an open ampoule is not permitted. (no BUD applies).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The BUD of a multiple dose container (eg vial) is 28 days, unless otherwise specified by the manufacturer.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If there is visible contamination of the multiple dose container (eg vial) before 28 days (or the manufacturer's expiry date), the container is discarded.
Beyond Use Date for Low Risk Compounded Sterile Preparations				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with low risk of contamination at controlled room temperature is 48 hours.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with low risk of contamination with storage in refrigerator is 14 days.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with low risk of contamination with storage in freezer is 45 days.
Beyond Use Date for Medium Risk Compounded Sterile Preparations				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with medium risk of contamination at controlled room temperature is 30 hours.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with medium risk of contamination with storage in refrigerator is 9 days.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with medium risk of contamination with storage in freezer is 45 days.
Beyond Use Date for High Risk Compounded Sterile Preparations				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with high risk of contamination at controlled room temperature is 24 hours.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with high risk of contamination with storage in the refrigerator is 3 days.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The Beyond Use Date (BUD) for compounded sterile preparations with high risk of contamination with storage in freezer is 45 days.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	High-risk preparations are always sterilized
Sterility Test and Bacterial endotoxin test				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A sterility test via membrane filtration and a bacterial endotoxin test is performed for high-risk sterile preparations when sterile preparations are compounded in batches of over 25 identical units;
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A sterility test via membrane filtration and a bacterial endotoxin test is performed for high-risk sterile preparations when there has been more than 12 hours of exposure time at a temperature between 2°C and 8°C before sterilization.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A sterility test via membrane filtration and a bacterial endotoxin test is performed for high-risk sterile preparations when there has been more than 6 hours of exposure time at a temperature above 8°C before sterilization.
Beyond Use dates for immediate use preparations				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous sterile preparations do not qualify as immediate use preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>Compounded non-hazardous sterile preparations prepared for immediate use in the patient's room or on patient care units comply with the following conditions:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Compounding is performed only when the situation is critical, with a requirement for immediate administration to the patient. <input type="checkbox"/> The preparation does not exceed 3 "sterile units". <input type="checkbox"/> The preparation does not contain any hazardous drugs (e.g., chemotherapeutic agents). <input type="checkbox"/> For each sterile unit used, there are no more than two entries into any one container, package or administration container/device. <input type="checkbox"/> Aseptic technique does not require more than 1 hour of continuous preparation. <input type="checkbox"/> Aseptic technique is rigorously applied
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Administration of the preparation begins within 1 hour after the start of compounding; otherwise the preparation is discarded.
Beyond Use times of 12 hours or less for Non-Hazardous preparations compounded in segregated areas				
Note: The self-assessment statements below refer to compounded sterile preparations made in an LAFW that is not placed in an environment meeting the standards for ISO Class 7 air quality, or in a CAI that does not meet the requirements described in section 5.3.3.1 of NAPRA Model standards.				

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The PEC is certified every 6 months and maintains ISO Class 5 air quality or better
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Only low-risk preparations are compounded.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Only one preparation is compounded at a time.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sink is not directly adjacent to the PEC and is separated from the immediate area of the PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparation area has no unsealed windows or doors leading to the exterior of the building.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparation area in a segregated compounding area is not in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Administration of the preparation begins within 12 hours after the start of compounding
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If administration of the preparation begins within 12 hours after the start of compounding the preparation is discarded.
				Beyond Use times of 12 hours or less for Hazardous preparations compounded in segregated areas
Note:				The self-assessment statements below refer to compounded sterile preparations made in a BSC that is not placed in an environment meeting the standards for ISO Class 7 air quality, or in a CACI that does not meet the requirements described in section 5.3.3.1 of NAPRA Model standards.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The segregated area has walls to separate the room from other areas.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The C-PEC is certified every 6 months and maintains ISO Class 5 air quality or better
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The room has a minimum of 12 ACPH.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The room maintains negative pressure of at least -2.5 Pa relative to adjacent spaces.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Only low or medium risk preparations are compounded.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Only one preparation is compounded at a time.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sink is 1 metre away from the C-PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparation area has no unsealed windows or doors leading to the exterior of the building.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The preparation area in a segregated compounding area is not in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Administration of the preparation begins within 12 hours after the start of compounding
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If administration of the preparation begins within 12 hours after the start of compounding the preparation is discarded.

5.3 Facilities and equipment

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The NIOSH list of hazardous drugs has been used to develop the pharmacies own list of hazardous drugs that require special handling precautions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A list of hazardous drugs used in the pharmacy is available at the pharmacy and is reviewed at least every 12 months.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Each drug on the hazardous drug list is handled and disposed of properly.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Areas reserved for the compounding of sterile preparations are large enough to: <ul style="list-style-type: none"> <input type="checkbox"/> Facilitate compounding <input type="checkbox"/> Allow cleaning and disinfecting without constraint <input type="checkbox"/> Ensure good flow of people, equipment and materials
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The lighting in compounding area is sufficient so as to: <ul style="list-style-type: none"> <input type="checkbox"/> Facilitate the sterile compounding process <input type="checkbox"/> Allow verification at all stages of compounding.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The facility's heating, ventilation and air conditioning (HVAC) system has been designed to achieve and maintain the appropriate ISO class for clean rooms and anterooms.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In a facility compounding hazardous drugs, the facility's heating, ventilation and air conditioning (HVAC) system has been designed to minimize the exposure of personnel to hazardous products in the work environment.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The air supplied to areas used for compounding sterile preparations passes through a high-efficiency particulate air (HEPA) filter.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The intake air comes from the ceiling via diffusers, each fitted with a terminal HEPA filter.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All sources that generate particles are controlled to achieve and maintain the ISO class for clean rooms and anterooms used to compound sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The air quality in controlled rooms complies with ISO 14644-1, according to the specifications listed in Table 1 of the NAPRA model standards, under dynamic operating conditions, as follows: the number of particles $\geq 0.5 \mu\text{m}$ diameter per cubic metre of air is verified while compounding personnel perform or simulate a typical sterile-product preparation (e.g., media fill).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The particle count is performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and the primary engineering control (PEC/C-PEC)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For hazardous sterile compounding, the return air from the clean room is exhausted to the exterior of the building.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In older facilities, an airflow analysis is performed under dynamic operating conditions (using the air speed achieved at the front of the PEC/C-PEC) to ensure that the location of the return air intakes does not hinder the compounding process.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	An air conditioning system is included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment (PPE).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Controlled rooms do not have windows or doors opening directly to the exterior of the building.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If any windows are present in controlled rooms, they are sealed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Any doors leading to the outside or to a non-controlled area (other than the doors designated for accessing the room), are sealed.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	An environmental control procedure and a housekeeping procedure, including the cleaning of sealed windows and doors, has been implemented by cleaning and disinfecting personnel
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Compounding areas for non-hazardous sterile preparation have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the PEC (e.g., laminar airflow workbench [LAFW], compounding aseptic isolator [CAI]) is located, and an anteroom, located next to the clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For non-hazardous sterile preparation: In the absence of a wall between the ante-area and the clean area, there is displacement airflow with a velocity of at least 40 feet per minute (12.2 metres per minute) from the clean area to the ante-area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The principle of displacement airflow is not applied for high-risk compounding of non-hazardous sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Compounding areas for hazardous sterile preparation have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the C-PEC (e.g., BSC or CACI) is located, and an anteroom, located next to the clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The clean room is physically separated from the rest of the pharmacy and from other non-controlled areas. (both hazardous and non hazardous compounding)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The clean room is physically separated from adjacent areas by walls, doors and pass-throughs.
				Functional Parameter of Clean room and Anteroom – Non Hazardous
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The clean room for the compounding of non-hazardous sterile preparations is kept under positive pressure relative to the anteroom and adjacent areas.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pressure differential is at least 5.0 Pa (ideally between 5.0 Pa and 12.5 Pa, equivalent to 0.02 to 0.05 inch water column) relative to the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	ISO Class 7 air quality is maintained in the clean room under dynamic operating conditions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The clean room has at least 30 or more air changes per hour (ACPH).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The temperature of the clean room is less than or equal to 20°C.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Medication storage temperatures in the clean room do not exceed 25°C.
Anteroom for non-hazardous sterile compounding				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The anteroom is located between the clean room and the non-controlled areas of the pharmacy.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The anteroom is kept under positive pressure relative to the non-controlled area adjacent to the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pressure differential is at least 5.0 Pa (equivalent to 0.02 to 0.05 inch water column) relative to the non-controlled area adjacent to the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A notification system is installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	ISO Class 8 air quality is maintained in the anteroom under dynamic operating conditions, unless the anteroom is also supporting a hazardous drug clean room, in which case ISO Class 7 air quality is maintained.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	There are at least 20 air changes per hour (ACPH).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The temperature of the anteroom is less than or equal to 20°C, taking into account employees' comfort once all clean room garb (including PPE) has been donned.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Medication storage temperatures do not exceed 25°C.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The anteroom is separated into two spaces by a visible demarcation line.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Access of supplies, equipment and personnel into the clean room is through the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Supplies, equipment and personnel do not enter the clean room from a non-controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The contents of the anteroom are limited to facilitate maintenance and to maintain the target ISO air quality classification.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The anteroom contains the following items:</p> <ul style="list-style-type: none"> <input type="checkbox"/> PPE, placed in the correct order to allow users to follow the correct garbing sequence <input type="checkbox"/> hands-free sink, ideally made of stainless steel or other material not harmed by cleaning products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing; <input type="checkbox"/> soap dispenser (cartridge or disposable, non-refillable unit); <input type="checkbox"/> nail picks; <input type="checkbox"/> alcohol-based hand rub (ABHR) with persistent activity and its dispenser; <input type="checkbox"/> hand-drying system:

					<ul style="list-style-type: none"> - lint-free towels (preferred) with a dispenser - air hand dryer designed specifically for use in a controlled area <input type="checkbox"/> mirror or other means to verify garbing; <input type="checkbox"/> clock; <input type="checkbox"/> waste container; <ul style="list-style-type: none"> - Cytotoxic waste container for hazardous <input type="checkbox"/> eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby); <input type="checkbox"/> pass-through for transferring products into the clean room and/or a cart reserved for use in the “clean” area of the anteroom and the clean room.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The supplies, drugs, labels and other items required for each preparation or batch are gathered and assembled in the anteroom and placed in a bin or tray for entry into the clean room at the time of compounding.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The anteroom has two doors.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The pharmacy has a process that allows only one door to be open at a time.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The door between the clean room and the anteroom and the door between the anteroom and the non-controlled area has windows.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Horizontal surfaces in the anteroom are cleaned daily.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Supplies are removed from cardboard boxes outside the anteroom and disinfected with a sporicidal agent before being moved into the anteroom.
					Anteroom for Hazardous Sterile Compounding
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The pharmacy has a process that allows only one door to be open at a time (i.e., to prevent both doors from being open at the same time).
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The door between the clean room and the anteroom and the door between the anteroom and the non-controlled area has windows.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The anteroom is adjacent to the clean room, separate from the rest of the pharmacy and fully enclosed.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Horizontal surfaces in the anteroom are kept to a minimum.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Horizontal surfaces in the anteroom are cleaned daily.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	The anteroom is separated into two spaces by a visible demarcation line, identifying the “clean side” and the “dirty side”.
1	2	3	N/A	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Activity in the clean room is kept to a minimum and are limited to those activities that are essential to or that directly support the work undertaken in the clean room.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Access of supplies, equipment and personnel into the clean room is through the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	No supplies, equipment or personnel enter the clean room from a non-controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The contents of the anteroom is limited to facilitate maintenance and to maintain ISO air quality.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The anteroom contains the following items:</p> <ul style="list-style-type: none"> <input type="checkbox"/> PPE and storage space for PPE, placed in the correct order to allow users to follow the correct garbing sequence <input type="checkbox"/> hands-free sink, ideally made of stainless steel or other material not harmed by cleaning products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing; <input type="checkbox"/> soap dispenser (cartridge or disposable, non-refillable unit); <input type="checkbox"/> nail picks; <input type="checkbox"/> alcohol-based hand rub (ABHR) with persistent activity and its dispenser; <input type="checkbox"/> hand-drying system: <ul style="list-style-type: none"> - lint-free towels (preferred) with a dispenser or air hand dryer, designed specifically for use in a controlled area. <input type="checkbox"/> mirror or other means to verify garbing; <input type="checkbox"/> clock; <input type="checkbox"/> cytotoxic waste container; <input type="checkbox"/> eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby); <input type="checkbox"/> pass-through for transferring products into the clean room and/or a cart reserved for use in the “clean” area of the anteroom and the clean room
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The supplies, drugs, labels and other items required for each preparation or batch are gathered and assembled in the anteroom and placed in a bin or tray for entry into the clean room at the time of compounding
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	One or more observation windows has been installed in the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Supplies are removed from cardboard boxes outside the anteroom and disinfected with a sporicidal agent before being moved into the anteroom.
				Functional Parameters of clean room and anteroom - Hazardous
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pressure in the cleanroom is negative.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pressure in the anteroom is positive.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The pressure differential is at least 5.0Pa relative to the pharmacy adjacent to the anteroom.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	ISO Class 7 air quality is maintained in the clean room and the anteroom under dynamic operating conditions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	There are at least 30 air changes per hour (ACPH) in the clean room and the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The return air from the clean room is externally vented.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The temperature in the controlled rooms is less than or equal to 20°C.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Medication storage temperatures in the clean room and anteroom do not exceed 25°C.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The clean room has one or more observation windows.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Access to the clean room is restricted to personnel with specific responsibilities in the clean room.
				Storing hazardous products
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are grouped and stored in a properly ventilated room with all air completely exhausted to the exterior.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The storage area for hazardous products has negative pressure relative to adjacent rooms.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The storage area for hazardous products has at least 12 Air Changes per Hour (ACPH).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The storage area for hazardous products is identified with proper signage indicating the presence of hazardous products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the refrigerator containing hazardous drugs is located in the clean room, the air exhausts are placed in such a way as to remove particles generated by the refrigerator within the storage area. The placement of the refrigerator ensures sufficient air changes per hour (ACPH) to maintain an ISO 7 clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The area for storing hazardous drugs is separate from the unpacking area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored in a negative pressure environment (-2.5 Pa) relative to surrounding areas.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored in an environment with at least 12 air changes per hour (ACPH) with all air exhausted to the exterior.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored on shelves with lips to prevent drug containers from falling off and breaking.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous products are stored in an environment with sufficient ventilation to prevent contamination from spreading to adjoining rooms.
				Shared facilities
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Separate clean rooms are used when compounding hazardous and non-hazardous sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	No drugs are stored in a shared anteroom.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When there is a shared anteroom for compounding of hazardous and non hazardous sterile preparations: <input type="checkbox"/> The anteroom is under positive pressure <input type="checkbox"/> The pressure differential is at least 5 Pa relative to adjacent areas <input type="checkbox"/> A notification system is installed in each pressure monitor to alert pharmacy personnel when pressure differential deviate from specifications. <input type="checkbox"/> ISO Class 7 air quality is maintained in the anteroom under dynamic operating conditions. <input type="checkbox"/> There are at least 30 air changes per hour (ACPH) <input type="checkbox"/> The temperature of the anteroom is less than or equal to 20°C. <input type="checkbox"/> Medication storage temperature does not exceed 25°C.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The anteroom is separated into two spaces by a demarcation line.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The air diffusers are positioned such that the particle stream is directed toward the “dirty” area of the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Air flowing into the anteroom is not recycled.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Air flowing within a shared anteroom is exhausted to the exterior of the building.
				Materials and finishes
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The surfaces of ceilings, walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas are smooth, impervious, non-friable, free from cracks and crevices, non-porous and resistant to damage from cleaning and disinfecting products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Dust-collecting overhangs are avoided. (E.g. door sills, utility pipes, windowsills, window curtains and window blinds).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Ceilings have been constructed of smooth, impervious, non-friable, non-porous, waterproof materials resistant to damage from cleaning and disinfecting products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All joints in the ceiling have been sealed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In the clean room and the anteroom, joints between the ceiling and walls are free of sharp corners where foreign substances could accumulate.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a conventional recessed panel ceiling is installed, the panels have been impregnated with polymer to make them impermeable and hydrophobic, and the edges have been coated with clean room silicone to seal them to the support frame.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Facilities with conventional recessed panel ceilings that undergo certification have this type of ceiling tested for tightness.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in ceilings are repaired and sealed at the earliest opportunity.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The walls have been constructed of smooth, impervious, non-friable, non-porous, waterproof materials resistant to damage from cleaning and disinfecting products, such as gypsum board coated with epoxy paint, thick polymer panels or glass panels.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All joints in the walls have been sealed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in walls are repaired and sealed at the earliest opportunity.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Flooring is flat, smooth, impervious, non-friable, non-porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage is repaired and sealed immediately.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In the clean room and anteroom, the floor is covered up the side wall, at least 10–15 cm.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	There are no carpets, rugs, “sticky mats” or anti-fatigue mats in the clean room or anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In controlled areas (clean room and anteroom), ceiling fixtures are recessed and flush-mounted.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	In controlled areas, external surfaces of ceiling fixtures, whether made of glass or other material, are washable, smooth and sealed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Water sources, sinks and drains are not located in a clean room (but are permitted in the anteroom).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Control systems are connected to a notification system to alert personnel when operating parameters are outside pre-set limits.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For hazardous sterile compounding, BSCs and CACIs are connected to a notification system to alert personnel to any unscheduled interruption or any alert related to the operation of the device outside compounding periods.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Instruments for measuring differential pressure between controlled areas are calibrated at least once a year or as recommended by the manufacturer.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Work surfaces and furniture are constructed of smooth, impervious, non-friable and non-porous materials, preferably stainless steel.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Any material used for work surfaces is able to withstand repeated cleaning and disinfecting and is resistant to damage from cleaning and disinfecting products.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Any breakage in work surfaces and furniture is repaired and sealed at the earliest opportunity.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Gloves are not donned within the ISO Class 5 PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All furniture in the clean room and anteroom, as well as the floor and wall surfaces, has been designed and placed to facilitate cleaning and disinfecting.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All movable furniture is cleaned and disinfected before it is placed in the clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Chairs used in controlled areas is made of smooth, non-friable, non-porous, washable materials that are resistant to damage from cleaning and disinfecting products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Each room is identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, hazards, restricted access, dress code).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Maintenance is performed on equipment within the facility.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Facility maintenance activities are recorded in the general maintenance log.
				Equipment
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The same personal protective equipment (PPE) that is worn for compounding of hazardous sterile preparations is worn for any type of facility and equipment maintenance.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The efficiency of HEPA filters in the ventilation system is tested during facility certification (at least every 6 months), and filters are replaced periodically as recommended by the manufacturer.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Filters used to exhaust air from hazardous clean rooms or C-PECs are considered contaminated are handled appropriately with respect to personnel and the environment.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The PEC has been installed according to the manufacturer's recommendations and certified by a qualified certifier.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfection is performed according to specifications in section 6.6.4 of the NAPRA Model Standards for hazardous and non hazardous sterile compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor ensures that the certification is completed according to certification standards currently in force.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous sterile preparations are compounded inside a C-PEC.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The C-PEC for hazardous sterile preparations is externally vented.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A PEC (non hazardous) operates continuously during every sterile compounding activity.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A C-PEC (hazardous) operates continuously, 24 hours a day.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the PEC or C-PEC has been turned off, it is allowed to run for at least 30 minutes, or as recommended by the manufacturer, before decontamination (if applicable), cleaning, disinfection, and compounding of sterile preparations are undertaken.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The PEC provides a work area with unidirectional airflow and quality meeting ISO Class 5 or better under dynamic operating conditions.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The working surface of the PEC is resistant to damage from cleaning, disinfecting, deactivation, decontamination (if applicable) products and is changed if it becomes damaged.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a CAI or CACI is in use, the recovery time recommended by the manufacturer (i.e., the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started) is observed when transferring products from the clean room to the manipulation area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To facilitate cleaning and disinfecting activities, such as cleaning the exterior of the PEC, and to avoid interfering with the operation of the PEC, there is sufficient clearance around the PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When positioning a PEC, the manufacturer's recommendations are strictly followed to avoid interfering with normal operation.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	During certification, a smoke test under dynamic conditions is used to validate proper operation.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The LAFW is positioned in an ISO Class 7 clean room that is adjacent to an ISO Class 8 anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The LAFW is not placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If multiple LAFWs are used, they are positioned to prevent interference with one another.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The BSC is positioned in an ISO Class 7 clean room or better.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The BSC is positioned in a room under negative pressure.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The BSC is positioned in a room adjoining an ISO 7 anteroom.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The BSC is not placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If multiple BSCs are used, they are positioned to prevent interference with one another.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CAI is positioned in an ISO Class 7 clean room adjacent to an ISO Class 8 anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CAI is positioned in an environment where the air particles exceed ISO Class 7 where all of the following conditions are met: <input type="checkbox"/> The CAI maintains an ISO Class 5 environment (see Table 1) at all times during compounding, including when ingredients, equipment and devices are being transferred into and out of the CAI. <input type="checkbox"/> Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CAI shows ISO Class 5 air quality during compounding <input type="checkbox"/> Particulate sampling conducted as close as possible to the doors when materials are being transferred, without obstructing the passageway, shows no more than 3520 particles (0.5 µm diameter or larger) per cubic metre of air (ISO Class 5) in the CAI.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor obtains the following information from the manufacturer: <input type="checkbox"/> documentation indicating that the CAI meets established standards when installed in an environment where the number of particles exceeds ISO Class 7 specifications; <input type="checkbox"/> the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started (i.e., the recovery time).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CACI is positioned in an ISO Class 7 clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CACI is positioned in a room under negative pressure.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CACI is positioned in a room adjoining an ISO Class 7 anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The CACI is positioned in an environment where the air particles exceed ISO Class 7 where all of the following conditions are met: <input type="checkbox"/> The room has negative pressure. <input type="checkbox"/> The room has at least 12 ACPH. <input type="checkbox"/> The CACI maintains an ISO Class 5 environment at all times during compounding, including when ingredients, equipment and devices are being transferred into and out of the CACI. <input type="checkbox"/> Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CACI shows ISO Class 5 air quality during compounding

				<input type="checkbox"/> Particulate sampling conducted as close as possible to the doors when materials are being transferred, without obstructing the passageway, shows no more than 3520 particles (0.5 µm diameter or larger) per cubic metre of air (ISO Class 5) in the CACI.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The sterile compounding supervisor obtains the following information from the manufacturer:</p> <input type="checkbox"/> documentation indicating that the CACI meets established standards when installed in an environment where the number of particles exceeds ISO Class 7 specifications; <input type="checkbox"/> the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started (i.e., the recovery time).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>The compounding personnel working in a CACI comply with the garbing procedure for compounding hazardous sterile preparations.</p>
Maintenance of Primary Engineering Controls and Containment				
Primary Engineering Controls				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>PECs/CPECs are maintained in accordance with the manufacturer's recommendations but certified according to the testing standards detailed in the Controlled Environment Testing Association (CETA) application guide CAG-003 (current version).</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>PECs/CPECs must be certified:</p> <input type="checkbox"/> every 6 months; <input type="checkbox"/> when relocated; <input type="checkbox"/> after major repairs; <input type="checkbox"/> when viable air sampling indicates that the PEC may not be in compliance with specifications.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>PEC/CPEC pre-filters are accessible.</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>Washable pre-filters are not used.</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>HEPA filters are verified during installation and certification to ensure there are no leaks or damage to the filters after they have been transported or installed.</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>Preventive maintenance for PECs/CPECs and other equipment is performed when no compounding is in progress, before cleaning and disinfection operations.</p>
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	<p>All PEC/CPEC maintenance and certification, including maintenance of filters and pre-filters, is documented in the general maintenance log (paper-based or computerized).</p>

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor has ensured that PEC/CPEC maintenance and certification has been performed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor reviews the results or ensures that the results have been reviewed and corrective measures taken, as appropriate.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor signs the maintenance form or log.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment used to compound sterile preparations are clean and disinfected with germicidal detergent, followed by a sterile disinfectant such as 70% isopropyl alcohol
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment used to compound sterile preparations are made of materials resistant to damage from cleaning and disinfecting products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	All necessary devices, instruments and accessories are cleaned and disinfected before being placed in a controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a device, instrument, or accessory used in the hazardous clean room or anteroom is removed, it is decontaminated.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Maintenance of devices, instruments and accessories is recorded in the general maintenance log.
				Automated compounding Device and balance
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The automated compounding device (ACD) is positioned in the PEC/CPEC such that compounding occurs while critical sites are exposed to first air.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the ACD is a peristaltic pump, this device is calibrated between batches.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The ACD is calibrated at least once a day (after cleaning), then as needed, according to the manufacturer's recommendations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The balance is calibrated before each use, after it is moved, after cleaning and as needed, according to the manufacturer's recommendations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The results of calibration are entered in the preparation log, general maintenance log or some other form of documentation (e.g., mix check report) for each batch, at a minimum.
				Carts
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If carts are used, one cart is reserved for the "dirty" area of the anteroom and remains there.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For hazardous sterile compounding, a second cart is reserved for use in the "clean" area of the anteroom and in the cleanroom.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Carts used to bring supplies into the anteroom from outside the controlled area do not cross the demarcation line.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Carts taken into the anteroom from the clean room are not moved beyond the clean side of the demarcation line.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the anteroom is shared, one cart is reserved for the “clean but chemically contaminated” area and another for the “clean and not chemically contaminated” area.
				Refrigerator and freezer
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The refrigerator and freezer used to store medications are commercial biomedical grade units.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Domestic refrigerators and freezers are not used.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Refrigerators and freezers designated for hazardous drugs are used only for this purpose.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Refrigerators and freezers used for storing medications are not used to store food.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous sterile preparations and hazardous sterile drugs and the refrigerator and freezer in which they are stored may be placed in the clean room for compounding hazardous sterile preparations. In this case, the exhaust is placed behind the refrigerator or freezer.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a refrigerator or freezer is placed in the hazardous clean room, there are sufficient air changes per hour in the clean room to maintain ISO Class 7 air.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The tested storage temperature in the refrigerator and freezer units meet the following parameters: <input type="checkbox"/> controlled refrigeration temperature: 2°C to 8°C <input type="checkbox"/> controlled freezing temperature: –25°C to –10°C
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Accurate temperature probes (gauges or sensors) have been installed to indicate the actual temperature.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A notification system is installed in each refrigerator and freezer to alert pharmacy personnel when temperatures deviate from specifications.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Refrigerator and freezer temperature readings are recorded on a form stored in the general maintenance log, unless the units are equipped with a continuous temperature recorder.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the refrigerator and freezer unit is equipped with a continuous temperature recorder, the data recorded by this device is verified and stored.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Temperature probes are maintained and calibrated at least once a year or in accordance with the manufacturer’s instructions.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Calibration of these instruments is noted in the general maintenance log.
Incubator				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The incubator temperature is controlled (20°C to 25°C or 30°C to 35°C, depending on the culture medium and incubation period).
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When the incubator is in operation, the incubator temperature is read and recorded in the general maintenance log at least once a day.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The incubator is calibrated and maintained according to the manufacturer's recommendations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The incubator is not placed in the clean room or the anteroom.
Camera and computer equipment				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Preference is given to audiovisual and computer equipment that features "hands-free" operation and that is made of smooth, nonporous, cleanable materials with low particulate emission and resistance to damage from cleaning and disinfecting products.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment cables are covered to facilitate cleaning.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Personal electronic devices or accessories (cell phone, iPods, earbuds) are not permitted in the anteroom or clean room.
Waste containers				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A sufficient number of easy-to-clean waste containers of suitable size and made of materials resistant to damage from cleaning, disinfecting, and decontaminating (if applicable) products are available.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For hazardous sterile compounding, waste containers are closable to limit the spread of vapors.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For hazardous sterile compounding, the exterior of each waste container is decontaminated before it is removed from the controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	For non-hazardous sterile compounding, the waste is collected in plastic bags and removed with minimal agitation.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The waste containers are emptied and cleaned at least once a day, at a time when no compounding is occurring.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Hazardous waste containers are identified with appropriate hazardous materials symbols.
Personal protective equipment and clothing – Non-hazardous				
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Compounding personnel and anyone else who accesses controlled areas wears appropriate protective clothing,

. 1	2	3	N/A	<p>PPE worn for the compounding of non-hazardous sterile preparations and when accessing facilities for the compounding of non-hazardous sterile preparations includes the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> pair of shoe covers or dedicated shoes <input type="checkbox"/> hair cover <input type="checkbox"/> beard cover (if applicable) <input type="checkbox"/> surgical mask <input type="checkbox"/> non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) <input type="checkbox"/> pair of non-powdered sterile gloves, which must cover the cuffs of the non-shedding gown
				Personal protective equipment and clothing - Hazardous
1	2	3	N/A	<p>Personal protective equipment adapted and approved for the compounding of hazardous sterile preparations are worn during compounding activities.</p>
1	2	3	N/A	<p>Gloves used in the clean room, in the clean area of the anteroom and during aseptic processes in all CPECs are:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Non-powdered <input type="checkbox"/> Compliant with ASTM standards <input type="checkbox"/> Sterile (outer glove only)
1	2	3	N/A	<p>Personnel wear two pairs of gloves for the following activities:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Unpacking <input type="checkbox"/> Cleaning and disinfecting the clean room <input type="checkbox"/> Disinfecting the CPEC <input type="checkbox"/> Compounding hazardous preparations <input type="checkbox"/> Managing a spill <input type="checkbox"/> Disposing of hazardous products
1	2	3	N/A	<p>Both pairs of gloves are discarded and replaced every 30 minutes or immediately following a tear, puncture or contamination.</p>
1	2	3	N/A	<p>The gown has been tested by the manufacturer for resistance to permeability by hazardous drugs.</p>
1	2	3	N/A	<p>The gown closes in the back, has long sleeves with fitted cuffs to the wrists.</p>
1	2	3	N/A	<p>The gown is discarded and replaced after 2-3 hours of continuous compounding work, or after each removal or after a contamination has occurred.</p>
1	2	3	N/A	<p>A gown is used for unpacking a damaged hazardous drug.</p>
1	2	3	N/A	<p>A gown is used if a spill of a hazardous material has occurred.</p>
1	2	3	N/A	<p>A disposable hair cover is worn during the compounding of hazardous sterile preparations.</p>
1	2	3	N/A	<p>The disposable hair cover is changed after each removal or if it becomes contaminated.</p>

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If a hazardous drug shipment has been damaged before receipt, a chemical cartridge respirator is used during unpacking.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A chemical cartridge respirator with a pre-filter is worn in the presence of vapours, gas and particles or if there has been a spill.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Masks, including N95, N100, and chemical cartridge respirators are fit tested.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The mask is changed at the earliest of 3.5 hours of continuous compounding work, or after each removal or if contamination has occurred.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	N95 or N100 masks are specific for health care workers.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Goggles and a face shield or full face-piece respirator are worn when working at or above eye level when deactivating, decontaminating and cleaning underneath the work surface of a C-PEC.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Goggles and a face shield or full face-piece respirator are worn when cleaning up a spill.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Goggles and a face shield or full face-piece respirator are worn when unpacking suspected damaged drugs.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Two pairs of disposable shoe covers are worn at all times in the clean area of the anteroom and in the clean room, even if dedicated shoes are worn.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The shoe covers are changed after each removal or in the event of a contamination, spill or breakage.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Shoe covers are not worn outside of the controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If the compounder has facial hair, a disposable beard cover is worn while compounding hazardous sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The beard cover is changed at the earliest of 3.5 hours of continuous compounding work, or after each removal or if contamination has occurred
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Compounding personnel wear clean room scrubs, not street clothes.
				Cleaning and disinfecting
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfecting (housekeeping) in the controlled area is performed to ensure the cleanliness required for the quality and integrity of final sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfecting procedures are strictly adhered to in the clean room and the anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Policies and procedures for cleaning and disinfecting tasks have been developed.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfecting personnel have been trained and assessed on correct application of policies and procedures.

	Decontamination, deactivation and disinfection			
	Decontamination			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	When compounding hazardous sterile preparations, cleaning of the premises and equipment must involve decontamination, deactivation and disinfection.
	Deactivation			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If sodium hypochlorite is used for deactivation of hazardous sterile preparations, it is neutralized with sodium thiosulphate or removed with a germicidal detergent.
	Disinfectant			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A germicidal disinfectant detergent is used to disinfect all surfaces in a clean room and anteroom.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The sterile compounding supervisor: <ul style="list-style-type: none"> <input type="checkbox"/> selects an appropriate disinfecting agent for controlled areas, considering mainly its effectiveness and compatibility with materials used for facilities and equipment; <input type="checkbox"/> in health care facilities, takes into account the organization's disinfection policies and procedures, following the manufacturer's directions to dilute the disinfectant properly; <input type="checkbox"/> follows the manufacturer's directions regarding required contact time between the disinfectant and the surface to be cleaned.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The daily use of a germicidal disinfectant should be augmented with weekly (or monthly) use of a sporicidal agent.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	The material safety data sheets for disinfectants used in the facility are available on site and easily accessible.
	Equipment used for cleaning and disinfection and its storage – Non-hazardous			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To avoid cross-contamination and to protect cleaning and disinfecting personnel, equipment is specifically designated for cleaning areas used for compounding non-hazardous sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Non-shedding equipment is used for cleaning controlled areas.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment used for cleaning controlled areas (mop heads, towels, etc.) should be disposable. If reusable accessories are used, they are washed and dried after each use and are stored in a clean cabinet dedicated to storing this equipment.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	If reusable accessories are used, one set of accessories is dedicated to cleaning ISO Class 5 areas and a separate set dedicated to cleaning ISO Class 7 and 8 areas.

1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning equipment and supplies (mop handle, outside of bottles, etc.) are disinfected before each entry into a controlled area.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A cabinet located in the anteroom or nearby is provided for storing equipment (mop handle, etc.), refills (mop heads, towels) and cleaning products used for cleaning and disinfecting.
				Equipment used for cleaning and disinfection and its storage - Hazardous
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	To avoid cross-contamination and to protect cleaning and disinfecting personnel, equipment is specifically designated for cleaning areas used for compounding hazardous sterile preparations.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Non-shedding equipment is used for cleaning controlled areas.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Equipment used for cleaning controlled areas (mop heads, towels, etc.) should be disposable.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning equipment and supplies (mop handle, outside of bottles, etc) are disinfected before entry into the clean room.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	A cabinet located in the anteroom or nearby is provided for storing equipment (mop handle, etc.), refills (mop heads, towels) and cleaning products used for cleaning and disinfecting.
				Garbing of cleaning and disinfecting personnel (housekeeping personnel)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfecting personnel comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties/
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Housekeeping personnel don gloves before starting work in non-hazardous controlled rooms.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Housekeeping personnel don two pairs of ASTM approved gloves before starting work in hazardous controlled rooms, and the outer gloves are sterile.
				Cleaning frequency
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning and disinfecting procedures include surface decontamination followed by disinfection at regular intervals and at specific locations for hazardous sterile compounding.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Daily cleaning and disinfecting are performed for the following surfaces and areas for non-hazardous sterile compounding: <input type="checkbox"/> PEC <input type="checkbox"/> counters <input type="checkbox"/> carts <input type="checkbox"/> floors <input type="checkbox"/> surfaces that are touched frequently (e.g., doorknobs, switches,

	chairs)			
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Daily cleaning, decontamination and disinfecting are performed for the following surfaces and areas for hazardous sterile compounding: <input type="checkbox"/> CPEC <input type="checkbox"/> counters <input type="checkbox"/> carts <input type="checkbox"/> floors <input type="checkbox"/> surfaces that are touched frequently (e.g., doorknobs, switches, chairs)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Monthly cleaning and disinfecting are performed for the following surfaces and areas: <input type="checkbox"/> walls <input type="checkbox"/> ceiling <input type="checkbox"/> shelves <input type="checkbox"/> outer surfaces of the PEC/CPEC
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Waste and garbage is removed daily.
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Cleaning should be performed from the “cleanest” area to the “dirtiest” area (i.e., from the closed end of the clean room toward the anteroom exit)
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	N/A <input type="checkbox"/>	Forms or schedules used to document cleaning and disinfecting activities, as per established policy, are retained in the general maintenance log.

Notes for discussion or comment:

