College of Pharmacists of Manitoba

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Sterile Compounding
Pharmacy Quality Assurance Self-Assessment

(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:
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Other persons:

Services Overview		
Pharmacy Services	Check if Provided	Comments
Sterile Non Hazardous Compounding	☐	
Non-Sterile Compounding	☐	
Chemotherapy Preparation	☐	
Home IV	☐	

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.

Part 1 and 2 of the Sterile Compounding Pharmacy Quality Assurance Self-Assessment are now in effect.

Pharmacies that undertake sterile compounding are required to be compliant with the items in Part 3 of the Self-Assessment by January 1, 2022.

Part 1:

5.1 Personnel

1 2 3 N/A ☐ ☐ ☐ ☐	A sterile compounding supervisor has been designated and is qualified to perform compounding of sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor ensures that the pharmacy assistant is supervised by a pharmacist or pharmacy technician according to established protocols.
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor has previous work experience supervising sterile compounding activities.
1 2 3 N/A ☐ ☐ ☐ ☐	A pharmacist or pharmacy technician has been designated to support hazardous products management.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	An annual competency assessment program has been put into place.
1 2 3 N/A ☐ ☐ ☐ ☐	Personnel involved in compounding sterile preparations are evaluated for compliance with operating procedures and use of appropriate techniques for compounding sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	The assessment results and corrective measures imposed are recorded and these records are retained.
1 2 3 N/A ☐ ☐ ☐ ☐	All compounding personnel have the knowledge and skills required to perform quality work.
1 2 3 N/A ☐ ☐ ☐ ☐	The initial training and assessment program for compounding personnel has the following components: ❑ reading and understanding the policies and procedures related to sterile preparations ❑ theoretical training, with assessment ❑ Individualized practical training and assessment in the workplace clean room.
1 2 3 N/A ☐ ☐ ☐ ☐	All compounding personnel have passed a gloved fingertip sampling and a media fill test before working in the compounding area for sterile products

	Cleaning and Disinfecting Personnel
1 2 3 N/A ☐ ☐ ☐ ☐	The initial training and assessment program for cleaning and disinfecting personnel have the following components: ❑ 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); ❑ practical training and assessment in the areas reserved for compounding sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor has ensured that cleaning and disinfecting personnel have the appropriate level of training
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	The sterile compounding supervisor has the competency required to manage a safe, high-quality sterile-preparation compounding area.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	A competency assessment program for **all compounding personnel** (pharmacists, pharmacy technicians, and pharmacy assistants) has been implemented in the workplace.

1 2 3 N/A ☐ ☐ ☐ ☐	The competency assessment program includes the following: ❑ a theoretical test measuring required knowledge of policies and procedures and the aseptic compounding process. ❑ 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.
1 2 3 N/A ☐ ☐ ☐ ☐	All personnel assigned to the compounding of sterile preparations undergo assessment: ❑ At least once a year in the workplace for preparations with **low or medium risk level** ❑ At least twice a year in the workplace for preparations with a **high risk level**
1 2 3 N/A ☐ ☐ ☐ ☐	The results of the assessments of the compounding personnel are retained for 5 years.
1 2 3 N/A ☐ ☐ ☐ ☐	A competency assessment program for **cleaning and disinfecting personnel** has been implemented in the workplace.
1 2 3 N/A ☐ ☐ ☐ ☐	All cleaning and disinfecting personnel are evaluated at least once a year.
1 2 3 N/A ☐ ☐ ☐ ☐	Compounding personnel who fail the written or practical assessment immediately stop sterile compounding and redo their training.
1 2 3 N/A ☐ ☐ ☐ ☐	Cleaning and disinfecting personnel who fail the practical assessment immediately stop sterile compounding and redo their training.
1 2 3 N/A ☐ ☐ ☐ ☐	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)
1 2 3 N/A ☐ ☐ ☐ ☐	Pharmacists whose activities are limited to supervising a pharmacy technician or pharmacy assistant during sterile preparation compounding ❑ 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 ❑ 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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	If the sterile compounding supervisor assigns the training and assessment of compounding personnel and cleaning and disinfecting personnel to a third party, ❑ the third party is a pharmacist or pharmacy technician with expertise in compounding sterile preparations; ❑ the third party is at arm's length from the pharmacy or facility (independence); ❑ the third party is free of any real or perceived conflict of interest with the individual being evaluated; ❑ 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; ❑ 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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	The sterile compounding supervisor ensures compliance with the policies and procedures.
1 2 3 N/A ☐ ☐ ☐ ☐	The procedures are clear and follow a standard format which includes an index for easy access to information.
1 2 3 N/A ☐ ☐ ☐ ☐	The policies and procedures are promptly updated whenever there is a change in practice or standards.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures are reviewed at least every three years.
1 2 3 N/A ☐ ☐ ☐ ☐	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

1 2 3 N/A ☐ ☐ ☐ ☐	Protocols for compounded sterile preparations include all of the information required to prepare the compound: ❑ name of preparation ❑ pharmaceutical form ❑ ingredients required ❑ quantity, concentration and source of ingredients ❑ necessary equipment ❑ compounding procedure ❑ storage method ❑ BUD ❑ references ❑ draft and revision date ❑ pharmacist's signature
1 2 3 N/A ☐ ☐ ☐ ☐	All protocols for pharmacy compounded sterile products are stored together and are ready available for quick consultation.
1 2 3 N/A ☐ ☐ ☐ ☐	All protocols are reviewed and approved by the sterile compounding supervisor or designate.

6.3 Compounded Sterile Preparation Log

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

6.4 Patient File

1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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

1 2 3 N/A ☐ ☐ ☐ ☐	Appropriate packaging is used for all preparations that are to be delivered to patients or other health care providers.
1 2 3 N/A ☐ ☐ ☐ ☐	Preparations to be delivered are packaged and labelled to ensure the safety of both the patient and the shipper
1 2 3 N/A ☐ ☐ ☐ ☐	During packaging, compounding personnel put all final compounded sterile preparations in packaging that maintains each preparation's stability, integrity and storage conditions
1 2 3 N/A ☐ ☐ ☐ ☐	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);
1 2 3 N/A ☐ ☐ ☐ ☐	During packaging, compounding personnel place items with an attached needle in a second rigid container.
1 2 3 N/A ☐ ☐ ☐ ☐	During packaging, compounding personnel indicate storage requirements on the final package (e.g., temperature, protection from light).
1 2 3 N/A ☐ ☐ ☐ ☐	During packaging, compounding personnel indicate additional precautions on the final packaging (e.g., if product is an irritant).
1 2 3 N/A ☐ ☐ ☐ ☐	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.

1 2 3 N/A ☐ ☐ ☐ ☐	The packaging procedure specifies the following details: ❑ equipment to be used to prevent breakage, contamination, spills or degradation of the compounded sterile preparation during transport and to protect the carrier; ❑ equipment to be used to ensure that packaging protects compounded sterile preparations against freezing and excessive heat. ❑ 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); ❑ 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.
1 2 3 N/A ☐ ☐ ☐ ☐	For compounded sterile preparations requiring refrigeration, the packaging maintains a temperature between 2°C and 8°C.
1 2 3 N/A ☐ ☐ ☐ ☐	For compounded sterile preparations to be kept at room temperature, the packaging maintains a temperature between 19°C and 25°C.

6.8 Receipt and Storage of Non-Hazardous products:

1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor has developed a storage procedure which is followed at all times.
1 2 3 N/A ☐ ☐ ☐ ☐	All commercial products used for preparations are properly stored immediately upon receipt.
1 2 3 N/A ☐ ☐ ☐ ☐	All commercial products used for preparations are handled and stored so as to prevent cross-contamination and incompatibilities.
1 2 3 N/A ☐ ☐ ☐ ☐	Product storage conditions specified by the manufacturer are strictly observed.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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.

1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	Alternative storage is provided when conditions are beyond acceptable temperature variations and when refrigerators and freezers are being cleaned.
1 2 3 N/A ☐ ☐ ☐ ☐	Products that have been stored are inspected before use for evidence of deterioration.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	Products used for preparations of hazardous products are unpacked outside of controlled areas (clean room and anteroom).
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	When unpacking potentially damaged hazardous products, the following garb is used: ❑ two pairs of ASTM International–approved gloves ❑ gown approved for the compounding of hazardous sterile preparations ❑ hair, face, beard and shoe covers ❑ eye protection (goggles) and a face shield or full face-piece respirator ❑ chemical cartridge respirator
1 2 3 N/A ☐ ☐ ☐ ☐	When receiving a container for hazardous drugs that appears to be damaged, either: ❑ the package is sealed without opening it, the supplier is contacted, and the package is returned or disposed of as hazardous waste; or ❑ 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 ☐ ☐ ☐ ☐	Damaged hazardous drugs are unpacked in a C-PEC used for compounding of non-sterile hazardous preparations.

1 ☐ 2 ☐ 3 ☐ N/A ☐	The sterile compounding supervisor has developed a storage procedure, and this procedure is followed at all times.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous products are stored separately from non-hazardous products.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous products are stored in a well-ventilated room (about 12 ACPH) or in a dedicated biomedical refrigerator or freezer.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous products are stored within a negative pressure room.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous products are stored in a room with all air exhausted to the exterior.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	Alternative storage is provided if the storage temperature exceeds acceptable variations and when refrigerators and freezers are being cleaned.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Products that have been stored are inspected before use, for evidence of deterioration.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Preparations that have exceeded their BUDs are discarded promptly.

6.9 Transport and Delivery of compounded sterile preparations:

1 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐	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.
1 ☐ 2 ☐ 3 ☐ N/A ☐	The transport and delivery procedures identify the delivery person.
1 ☐ 2 ☐ 3 ☐ N/A ☐	The transport and delivery procedures identify the times when the min/max thermometer must be checked during transport.
1 ☐ 2 ☐ 3 ☐ N/A ☐	The steps to be followed in the event of non-maintenance of target storage temperature during transport are indicated in the procedure.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Any unused compounded sterile preparation returned from a patient's home is disposed of by the pharmacist or pharmacy technician.
1 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous compounded sterile preparations are transported in rigid containers marked "Cytotoxic".
1 ☐ 2 ☐ 3 ☐ N/A ☐	Hazardous compounded sterile preparations are transported in rigid containers designed to minimize the risk of cracking or failure of the preparation containers.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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.

1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	Medications and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws.
1 2 3 N/A ☐ ☐ ☐ ☐	Medications to be destroyed are safely stored in a location separate from other medications in inventory.
1 2 3 N/A ☐ ☐ ☐ ☐	A procedure has been developed and implemented for the destruction of pharmaceutical waste.
1 2 3 N/A ☐ ☐ ☐ ☐	Hazardous products are destroyed in accordance with regulations governing such products.
1 2 3 N/A ☐ ☐ ☐ ☐	A list of hazardous products in use is available in the pharmacy.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures for the management of hazardous waste have been developed and followed.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures for the management of hazardous waste comply with local, provincial/territorial and federal requirements.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	All equipment, products and vials used in the compounding of hazardous sterile preparations are discarded in a hazardous waste container.

1 2 3 N/A ☐ ☐ ☐ ☐	Hazardous waste containers are identified with a self-adhesive label marked “Hazardous waste – cytotoxic”
1 2 3 N/A ☐ ☐ ☐ ☐	Sharps containers removed from the C-PEC are decontaminated and then discarded into a hazardous waste container and sent for destruction.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	All PPE used in the compounding of hazardous sterile products are discarded in a hazardous waste container.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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: ❑ identify patients who have received the compounded sterile preparation; ❑ notify patients or their caregivers that there is a problem with the preparation; ❑ perform the necessary follow-up if the preparation has been administered.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor ensures that a procedure for the recall of compounded sterile preparations has been developed and approved.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	When an incident or accident involving a compounded sterile preparation occurs, the compounding personnel complete an event report and explanation form.
1 2 3 N/A ☐ ☐ ☐ ☐	Complaints, accidents, incidents and reported side effects are evaluated to determine their cause, and the necessary steps are taken to prevent re-occurrence.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The organization maintains a log of complaints, accidents, incidents and reported side effects.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures to be followed in case of accidental exposure of personnel to hazardous products have been established.
1 2 3 N/A ☐ ☐ ☐ ☐	Material safety data sheets are accessible in the workplace.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Accidental exposure to hazardous products is documented in the appropriate logs.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures for managing spills have been established
1 2 3 N/A ☐ ☐ ☐ ☐	Employees who clean up hazardous product spills have received adequate training,

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

7.0 Quality Assurance Program

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The quality assurance program has the following four components: ❑ verification of equipment, including the PEC; ❑ verification of controlled areas (clean room and anteroom); ❑ verification of aseptic compounding processes; ❑ verification of final preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	Each component of the quality assurance program and its activities are documented.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, have been certified with respect to its installation.

1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	The maintenance report is saved in the general maintenance log.
1 2 3 N/A ☐ ☐ ☐ ☐	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
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	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).
1 2 3 N/A ☐ ☐ ☐ ☐	The pharmacist or pharmacy technician records and retains proof of calibration of the thermometer.
1 2 3 N/A ☐ ☐ ☐ ☐	If a computerized temperature monitoring system is used, the system offers features to record and store temperature at least twice a day.
1 2 3 N/A ☐ ☐ ☐ ☐	If a computerized temperature monitoring system is used, the system triggers an alarm if the temperature readings deviate from the acceptable range.
1 2 3 N/A ☐ ☐ ☐ ☐	The controlled areas of facilities and the PEC are certified by a recognized organization ❑ at least every 6 months ❑ during installation of new equipment or a new controlled area; ❑ 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; ❑ when investigation of a contamination problem or a problem involving non-compliance in the aseptic compounding process requires exclusion of malfunctioning facilities.
1 2 3 N/A ☐ ☐ ☐ ☐	The program for monitoring facilities and the PEC includes a plan for sampling viable and nonviable particles.

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor ensures that all personnel on site ❑ have full knowledge of the measuring instruments used for verification; ❑ know the specifications for each parameter being verified; ❑ know the procedure to be followed in case of non-compliance with respect to air pressure and temperature.
1 2 3 N/A ☐ ☐ ☐ ☐	The temperature of ISO Class 7 and ISO Class 8 areas are verified and documented at least once a day.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Pressure is measured continuously, and an alarm system is in place to immediately advise personnel of non-compliance with specifications.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	A written surface sampling plan of viable, non-viable and surface particles in controlled areas and the PEC has been established.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The air and surface sampling plan includes, for each controlled area (clean room and anteroom), ❑ sampling site diagram; ❑ type of sampling to be done; ❑ sampling methods to be used; ❑ number of samples to be obtained at each site; ❑ frequency of sampling; ❑ number of colony-forming units (CFUs) triggering action.
1 2 3 N/A ☐ ☐ ☐ ☐	The sampling plan allows for three types of samples: ❑ non-viable particles per cubic metre of air; ❑ viable particles per cubic metre of air; ❑ viable surface particles.

1 2 3 N/A ☐ ☐ ☐ ☐	Samples are obtained at least every 6 months from the air in controlled areas and in the PEC *and* every time that the following conditions are present: ❑ during installation of new equipment or a new controlled area; ❑ during maintenance or repair of equipment (repair of PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall); ❑ during investigation of a contamination problem or a problem involving non-compliance of personnel with aseptic processes.
1 2 3 N/A ☐ ☐ ☐ ☐	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 *dynamic* operating conditions during each facility and PEC certification.
1 2 3 N/A ☐ ☐ ☐ ☐	Non-viable particles in the air in controlled areas and the PEC are sampled at least every 6 months under *dynamic* operating conditions, as follows: ❑ by the qualified certifier, during certification of facilities; or ❑ 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.
1 2 3 N/A ☐ ☐ ☐ ☐	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).
1 2 3 N/A ☐ ☐ ☐ ☐	The values obtained by the certifier comply with the specifications established for each controlled area. (ISO 14644-1 classification for air quality).
1 2 3 N/A ☐ ☐ ☐ ☐	Calibration certificates for the equipment used to conduct the certification accompany the report prepared after each certification.
1 2 3 N/A ☐ ☐ ☐ ☐	Sampling for viable particles includes: ❑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); ❑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 2 3 N/A ☐ ☐ ☐ ☐	The sampled area is disinfected immediately after sampling.
1 2 3 N/A ☐ ☐ ☐ ☐	The sampling of viable air and surface particles is performed by a qualified individual.
1 2 3 N/A ☐ ☐ ☐ ☐	An established sampling procedure is followed and personnel have received and successfully completed the proper training for this procedure.
1 2 3 N/A ☐ ☐ ☐ ☐	A calibration certificate for the viable air sampler has been obtained.
1 2 3 N/A ☐ ☐ ☐ ☐	The appropriate nutrient medium for plating of samples is used. ❑ tryptic soy agar (low sulphur content) or soybean-casein digest medium for air samples ❑ tryptic soy agar with lecithin and polysorbate for surface samples ❑ for high-risk compounding, in addition to the above, malt extract agar or other media that support the growth of fungi.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The samples obtained are either ❑ sent to a certified external laboratory; or ❑ incubated in the community or health care facility pharmacy
1 2 3 N/A ☐ ☐ ☐ ☐	The incubator used in the community or health care facility pharmacy is certified periodically.
1 2 3 N/A ☐ ☐ ☐ ☐	Procedures are in place for use and maintenance of the incubator and for surveillance of temperatures
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism is identified.
1 2 3 N/A ☐ ☐ ☐ ☐	Surface contamination by hazardous antineoplastic drugs, as determined by environmental monitoring, is recorded in the general maintenance log
1 2 3 N/A ☐ ☐ ☐ ☐	Gloved Fingertip Sampling (GFS) includes: ❑ a sample obtained after sterile gloves are put on (after aseptic washing of hands and forearms) but before application of sterile 70% isopropyl alcohol ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	When the sampling is complete, the gloves are taken off and thrown away, and hand and forearm hygiene is performed.
1 2 3 N/A ☐ ☐ ☐ ☐	The GFS samples are incubated between 30°C and 35°C
1 2 3 N/A ☐ ☐ ☐ ☐	The GFS results are read within 48 to 72 hours.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	For each employee, GFS after the media fill test is completed annually for **low- and medium-risk** sterile compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	For each employee, GFS after the media fill test is completed every 6 months for **high-risk** sterile compounding
1 2 3 N/A ☐ ☐ ☐ ☐	For the GFS after the media fill test, the total CFU count for both hands is no more than 3 CFUs. *(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.)*
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	A tryptic soy agar (low sulphur content) or soybean-casein digest nutrient medium is used for the media fill test.
1 2 3 N/A ☐ ☐ ☐ ☐	For compounded sterile preparations with **low or medium risk** of microbial contamination, the nutrient medium is sterile.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	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 ☐ 2 ☐ 3 ☐ N/A ☐	The sterile compounding supervisor: ❑ investigates missing documentation, situations of non-compliance (where action is required) and deviations from protocols; ❑ identifies trends concerning microbial load in controlled areas and types of microorganisms found; ❑ consults with a microbiology specialist, if necessary; ❑ takes corrective and preventive actions.
1 ☐ 2 ☐ 3 ☐ N/A ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Personnel behave in a professional manner, following pertinent policies and procedures.
1 2 3 N/A ☐ ☐ ☐ ☐	Personnel afflicted with the following conditions are excluded from sterile compounding activities and sterile compounding areas until the condition has been remedied: ❑ Uncontrolled weeping skin condition ❑ Burns to the skin, including sunburns ❑ Cold sores (active herpes simplex viral infection) ❑ Conjunctivitis (viral or bacterial) ❑ Active respiratory infection with coughing, sneezing or runny nose ❑ Fresh piercings ❑ Other fresh wounds
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel remove personal outer garments (e.g., coat, hat, jacket, scarf, sweater, vest, boots and outdoor shoes)
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel remove all cosmetics, including makeup, false eyelashes, perfume, hair products, henna tattoos, and paper tattoos.
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel tie up long hair.
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel remove nail polish and other nail applications (nail extensions and other synthetic nail-lengthening products are prohibited);
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel ensure that natural nails are kept short and trimmed (0.6mm).
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel ensure that skin of hands and forearms is undamaged.

1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel change into dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs)
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel wear pants that fully cover the legs.
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel wear closed shoes and socks.
1 2 3 N/A ☐ ☐ ☐ ☐	Before entering the anteroom, personnel wash their hands.
1 2 3 N/A ☐ ☐ ☐ ☐	Food items, drinks, chewing gum, candy and cigarettes (or other smoking products) are prohibited in the clean room and anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	All access doors to the clean room and anteroom are kept closed.
1 2 3 N/A ☐ ☐ ☐ ☐	All personnel in the clean room and anteroom follow specified hand hygiene and garbing procedures.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The number of people in the clean room and anteroom is limited to the minimum number required to perform aseptic compounding activities.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The pharmacist or pharmacy technician ensures that compounding personnel follow the protocol for compounding the sterile preparation.
1 2 3 N/A ☐ ☐ ☐ ☐	The pharmacist or pharmacy technician validates the preparations log.
1 2 3 N/A ☐ ☐ ☐ ☐	Exposure of critical sites is limited to a PEC that maintains ISO Class 5 air quality requirements.
1 2 3 N/A ☐ ☐ ☐ ☐	Hand and forearm hygiene is performed by anyone entering the cleanroom.
1 2 3 N/A ☐ ☐ ☐ ☐	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:

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

1 2 3 N/A ☐ ☐ ☐ ☐	If dedicated shoes are used, they are cleaned and disinfected once a week.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Before any product is introduced into the anteroom, it is removed from its cardboard shipping box
1 2 3 N/A ☐ ☐ ☐ ☐	Before any product is introduced into the anteroom, the product is wiped with a sporicidal agent.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Non-shedding wipes or swabs are used for disinfection.
1 2 3 N/A ☐ ☐ ☐ ☐	Sterile 70% isopropyl alcohol is not sprayed onto compounding equipment or products.
1 2 3 N/A ☐ ☐ ☐ ☐	The wipes or swabs are changed regularly during disinfection of equipment and products.
1 2 3 N/A ☐ ☐ ☐ ☐	For introduction of compounding equipment and products into the clean room, the items are placed in a plastic or stainless steel bin.
1 2 3 N/A ☐ ☐ ☐ ☐	Plastic or stainless steel bins used for transferring product into the clean room are disinfected before use.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Personnel comply with the following requirements when cleaning and disinfecting the PEC:

	❑ Disinfect non-powdered sterile gloves with sterile 70% isopropyl alcohol and allow to dry before starting to clean and disinfect the PEC. ❑ Avoid having the head and upper body enter the PEC. ❑ Use non-shedding, disposable wipes. ❑ Avoid contaminating the surface of wipes used for cleaning and disinfecting. ❑ Change wipes after disinfection of each section of the PEC. ❑ 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). ❑ Follow the cleaning method described in the pharmacy's procedures. ❑ Follow the disinfecting method described in the pharmacy's procedures (with regard to equipment, sequence and movements). ❑ Follow the manufacturer's directions concerning dwell time for the disinfectant. ❑ Wait until the disinfectant has dried before compounding the first preparation in the PEC. ❑ Record cleaning and disinfecting activities in the maintenance log.(non hazardous)
1 2 3 N/A ☐ ☐ ☐ ☐	Sterile water is used for diluting concentrated disinfectant solutions used inside any ISO Class 5 device.
1 2 3 N/A ☐ ☐ ☐ ☐	Decontamination, deactivation and disinfection tasks (Hazardous sterile preparation) are recorded in the general maintenance log.
1 2 3 N/A ☐ ☐ ☐ ☐	Sterile 70% isopropyl alcohol alone is not used to decontaminate hazardous drugs.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	All surfaces of LAFW are cleaned and disinfected at the start of each workday and at the end of each workday.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The work surface of LAFW is cleaned and disinfected using sterile 70% isopropyl alcohol ❑ before starting any sterile product preparation. ❑ At each shift change ❑ Whenever surface contamination is suspected ❑ If there has been non compliance with aseptic techniques
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	All surfaces and subfloor of the LAFW are cleaned and disinfected weekly (at the end of the workday)
1 2 3 N/A ☐ ☐ ☐ ☐	The work surface of the BSC or CACI is disinfected before the start of hazardous preparation compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	The work surface of the BSC or CACI is decontaminated and disinfected: ❑ On each preparation change, upon removal from the BSC or CACI ❑ At the start or end of each shift. ❑ When surface contamination is suspected ❑ If there has been non compliance with aseptic techniques
1 2 3 N/A ☐ ☐ ☐ ☐	All surfaces inside the BSC or CACI are decontaminated and disinfected: ❑ At the start of the workday. ❑ At the start of the workday if the BSC or CACI has not been used for one or more days. ❑ When there has been a spill. ❑ Before and after certification. ❑ After service interruption (ie power outage) ❑ If the C-PEC is moved
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	Compounding occurs in the critical area of the PEC, such that critical sites are exposed to first air.
1 2 3 N/A ☐ ☐ ☐ ☐	Each preparation is completed from start to finish before compounding of another preparation is begun.
1 2 3 N/A ☐ ☐ ☐ ☐	In the event of non-compliance with aseptic technique, the preparation is discarded.
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.
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.
1 2 3 N/A ☐ ☐ ☐ ☐	If gloves are torn, they are removed and hand and forearm hygiene performed before new gloves are donned.
1 2 3 N/A ☐ ☐ ☐ ☐	Even without tearing, gloves are changed regularly
1 2 3 N/A ☐ ☐ ☐ ☐	The frequency and circumstances of glove changes are defined in a procedure.
1 2 3 N/A ☐ ☐ ☐ ☐	Products and supplies are intact, dry and unsoiled.
1 2 3 N/A ☐ ☐ ☐ ☐	All containers (e.g., bags of solution, vials and ampoules) are examined before use.
1 2 3 N/A ☐ ☐ ☐ ☐	Products exhibiting turbidity, cloudiness or particulates are not used.
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.
1 2 3 N/A ☐ ☐ ☐ ☐	Non-shedding wipes or sterile swabs are changed regularly during disinfection of equipment.

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Personnel who compound hazardous preparations adhere to the following requirements when working in the C-PEC: ❑ When diluting powder or withdrawing liquids, use a ventilated system equipped with a 0.22-µm hydrophobic filter. ❑ When withdrawing a hazardous solution, comply with the maximum fill limit of the syringe, i.e.,75% (3/4) of total syringe capacity. ❑ When dispensing a hazardous preparation in a syringe, use a protective Luer-Lok safety tip system. ❑ If possible, use a closed-transfer system (since the steps described above do not completely eliminate the risk of exposure to the hazardous preparation). ❑ Discard all materials used during compounding into a marked waste container specifically designated for hazardous products. ❑ 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. ❑ While the final container is still inside the C-PEC, compounding personnel must label it and place it in a sealable plastic bag.
1 2 3 N/A ☐ ☐ ☐ ☐	All final hazardous compounded sterile preparations are marked “cytotoxic”.
	Verification of final compounded sterile preparations
	Role of personnel in verification
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor performs the following activities: ❑ ensure that all compounded sterile preparations comply with compounding protocols; ❑ verify the identity of the ingredients (drug and diluent); ❑ verify the volume of the ingredients (drug and diluent); ❑ regularly verify the quality of the manipulations.
1 2 3 N/A ☐ ☐ ☐ ☐	When compounding a preparation, compounding personnel undertake the following activities: ❑ 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; ❑ verify the information on the label; ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	Final compounded sterile preparations are cooled in the refrigerator before being placed in a cooler.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	If the person performing verification duties enters the clean room, he or she is garbed exactly the same as the compounding personnel.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Diluted Cassettes are verified at each stage of compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	Preparations made using a volumetric pump are verified at each stage of compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	With all preparations the equipment and products used are verified before and after compounding
1 2 3 N/A ☐ ☐ ☐ ☐	An additional verification method, by counting vials, ampoules and remaining material, has been implemented.
1 2 3 N/A ☐ ☐ ☐ ☐	Each preparation is inspected by a person other than the individual who performed the aseptic compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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.
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
1 2 3 N/A ☐ ☐ ☐ ☐	The labels for compounded sterile preparations meet the requirements of the applicable legislation and regulation
1 2 3 N/A ☐ ☐ ☐ ☐	All active ingredients are identified on the label.
1 2 3 N/A ☐ ☐ ☐ ☐	The label includes the concentration of each ingredient.
1 2 3 N/A ☐ ☐ ☐ ☐	Each container for a compounded sterile preparation is labelled.
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.
1 2 3 N/A ☐ ☐ ☐ ☐	Compounding personnel label the following items: final compounded sterile preparations; ❑ each unit of a compounded sterile preparation for an individual patient, along with required auxiliary labels; ❑ each unit of sterile preparations compounded in batches (with, at a minimum, drug name, concentration, route of administration, batch number and BUD); ❑ each package containing final preparation units, along with auxiliary labels indicating required storage conditions and special precautions.
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.
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.
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

	compounded sterile preparation by the patient. In that situation, an insert has been prepared.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The label contains the following information, at a minimum: ❑ pharmacy identification (name, address and telephone number of the compounder's or dispenser's pharmacy); ❑ drug identification (active ingredients, source, concentration, form, ❑ route of administration, volume, solute, amount prepared); ❑ overfill volume, when overfilling has occurred; ❑ special precautions (e.g., if product is an irritant); ❑ storage method; ❑ date when the sterile preparation was compounded; ❑ BUD; ❑ preparation batch number.
1 2 3 N/A ☐ ☐ ☐ ☐	The package insert includes the following information: ❑ all information required by federal/provincial legislation and regulations regarding the labelling of medications that could not be included on the main label; ❑ details concerning mode of administration; ❑ 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"); ❑ special precautions for disposal or destruction of the preparation; ❑ emergency contact information of the compounding pharmacy.
	References
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor has available a recent edition of the following publications: ❑ Standards, guidelines and policies of the pharmacy regulatory authority ❑ Trissel LA. Handbook on injectable drugs. Bethesda, MD: American Society of Health-System Pharmacists. ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	Administration of the compounded sterile preparation begins before the BUD has passed.
1 2 3 N/A ☐ ☐ ☐ ☐	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: ***The BUD must not exceed the earliest of the dates established by the following two criteria:*** ❑ expiration date based on chemical and physical stability according to reference texts. ❑ storage time related to risk of microbial contamination.
1 2 3 N/A ☐ ☐ ☐ ☐	To establish a longer BUD, sterility tests are performed for a given preparation or batch.
1 2 3 N/A ☐ ☐ ☐ ☐	Preparations are quarantined while awaiting the results of the sterility test.
1 2 3 N/A ☐ ☐ ☐ ☐	The pharmacy's operating procedures describe the risk assessment process used to establish the BUD and the storage conditions.
1 2 3 N/A ☐ ☐ ☐ ☐	During compounding, the use of commercially available products have priority.
1 2 3 N/A ☐ ☐ ☐ ☐	If a sterile product is commercially available, compounding personnel do not use non-sterile ingredients to compound a sterile preparation.
1 2 3 N/A ☐ ☐ ☐ ☐	When a single use vial is punctured in a PEC that maintains ISO Class 5 air quality, the BUD is 6 hours
1 2 3 N/A ☐ ☐ ☐ ☐	Six hours after an initial needle puncture, the single use vial is no longer used.
1 2 3 N/A ☐ ☐ ☐ ☐	When the single use vial is removed from the ISO Class 5 PEC, it is discarded.
1 2 3 N/A ☐ ☐ ☐ ☐	To properly manage risk, a label is affixed to the vial indicating the time of initial needle puncture.

1 2 3 N/A ☐ ☐ ☐ ☐	The contents of a vial are not divided for the sole purpose of extending stablility.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Storage of an open ampoule is not permitted. (no BUD applies).
1 2 3 N/A ☐ ☐ ☐ ☐	The BUD of a multiple dose container (eg vial) is 28 days, unless otherwise specified by the manufacturer.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **low risk** of contamination at controlled room temperature is 48 hours.
1 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **low risk** of contamination with storage in refrigerator is 14 days.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **medium risk** of contamination at controlled room temperature is 30 hours.
1 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **medium risk** of contamination with storage in refrigerator is 9 days.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **high risk** of contamination at controlled room temperature is 24 hours.
1 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **high risk** of contamination with storage in the refrigerator is 3 days.
1 2 3 N/A ☐ ☐ ☐ ☐	The Beyond Use Date (BUD) for compounded sterile preparations with **high risk** of contamination with storage in freezer is 45 days.

1 2 3 N/A ☐ ☐ ☐ ☐	High-risk preparations are always sterilized
	Sterility Test and Bacterial endotoxin test
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Hazardous sterile preparations do not qualify as immediate use preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	Compounded non-hazardous sterile preparations prepared for immediate use in the patient's room or on patient care units comply with the following conditions: ❑ Compounding is performed only when the situation is critical, with a requirement for immediate administration to the patient. ❑ The preparation does not exceed 3 "sterile units". ❑ The preparation does not contain any hazardous drugs (e.g., chemotherapeutic agents). ❑ For each sterile unit used, there are no more than two entries into any one container, package or administration container/device. ❑ Aseptic technique does not require more than 1 hour of continuous preparation. ❑ Aseptic technique is rigorously applied
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The PEC is certified every 6 months and maintains ISO Class 5 air quality or better
1 2 3 N/A ☐ ☐ ☐ ☐	Only low-risk preparations are compounded.
1 2 3 N/A ☐ ☐ ☐ ☐	Only one preparation is compounded at a time.
1 2 3 N/A ☐ ☐ ☐ ☐	The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.
1 2 3 N/A ☐ ☐ ☐ ☐	The sink is not directly adjacent to the PEC and is separated from the immediate area of the PEC.
1 2 3 N/A ☐ ☐ ☐ ☐	The preparation area has no unsealed windows or doors leading to the exterior of the building.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.
1 2 3 N/A ☐ ☐ ☐ ☐	Administration of the preparation begins within 12 hours after the start of compounding
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The segregated area has walls to separate the room from other areas.
1 2 3 N/A ☐ ☐ ☐ ☐	The C-PEC is certified every 6 months and maintains ISO Class 5 air quality or better
1 2 3 N/A ☐ ☐ ☐ ☐	The room has a minimum of 12 ACPH.
1 2 3 N/A ☐ ☐ ☐ ☐	The room maintains negative pressure of at least -2.5 Pa relative to adjacent spaces.
1 2 3 N/A ☐ ☐ ☐ ☐	Only low or medium risk preparations are compounded.

1 2 3 N/A ☐ ☐ ☐ ☐	Only one preparation is compounded at a time.
1 2 3 N/A ☐ ☐ ☐ ☐	The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.
1 2 3 N/A ☐ ☐ ☐ ☐	The sink is 1 metre away from the C-PEC.
1 2 3 N/A ☐ ☐ ☐ ☐	The preparation area has no unsealed windows or doors leading to the exterior of the building.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.
1 2 3 N/A ☐ ☐ ☐ ☐	Administration of the preparation begins within 12 hours after the start of compounding
1 2 3 N/A ☐ ☐ ☐ ☐	If administration of the preparation begins within 12 hours after the start of compounding the preparation is discarded.

5.3 Facilities and equipment

1 2 3 N/A ☐ ☐ ☐ ☐	The NIOSH list of hazardous drugs has been used to develop the pharmacies own list of hazardous drugs that require special handling precautions.
1 2 3 N/A ☐ ☐ ☐ ☐	A list of hazardous drugs used in the pharmacy is available at the pharmacy and is reviewed at least every 12 months.
1 2 3 N/A ☐ ☐ ☐ ☐	Each drug on the hazardous drug list is handled and disposed of properly.
1 2 3 N/A ☐ ☐ ☐ ☐	Areas reserved for the compounding of sterile preparations are large enough to: ❑ Facilitate compounding ❑ Allow cleaning and disinfecting without constraint ❑ Ensure good flow of people, equipment and materials
1 2 3 N/A ☐ ☐ ☐ ☐	The lighting in compounding area is sufficient so as to: ❑ Facilitate the sterile compounding process ❑ Allow verification at all stages of compounding.

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The air supplied to areas used for compounding sterile preparations passes through a high-efficiency particulate air (HEPA) filter.
1 2 3 N/A ☐ ☐ ☐ ☐	The intake air comes from the ceiling via diffusers, each fitted with a terminal HEPA flter.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 ≥ 0.5 µm diameter per cubic metre of air is verified while compounding personnel perform or simulate a typical sterile-product preparation (e.g., media fill).
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	For hazardous sterile compounding, the return air from the clean room is exhausted to the exterior of the building.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	An air conditioning system is included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment (PPE).
1 2 3 N/A ☐ ☐ ☐ ☐	Controlled rooms do not have windows or doors opening directly to the exterior of the building.
1 2 3 N/A ☐ ☐ ☐ ☐	If any windows are present in controlled rooms, they are sealed.
1 2 3 N/A ☐ ☐ ☐ ☐	Any doors leading to the outside or to a non-controlled area (other than the doors designated for accessing the room), are sealed.

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	**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 2 3 N/A ☐ ☐ ☐ ☐	The principle of displacement airflow is not applied for high-risk compounding of non-hazardous sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The clean room for the compounding of non-hazardous sterile preparations is kept under positive pressure relative to the anteroom and adjacent areas.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	ISO Class 7 air quality is maintained in the clean room under dynamic operating conditions.
1 2 3 N/A ☐ ☐ ☐ ☐	The clean room has at least 30 or more air changes per hour (ACPH).
1 2 3 N/A ☐ ☐ ☐ ☐	The temperature of the clean room is less than or equal to 20ºC.

1 2 3 N/A ☐ ☐ ☐ ☐	Medication storage temperatures in the clean room do not exceed 25ºC.
	Anteroom for **non-hazardous** sterile compounding
1 2 3 N/A ☐ ☐ ☐ ☐	The anteroom is located between the clean room and the non-controlled areas of the pharmacy.
1 2 3 N/A ☐ ☐ ☐ ☐	The anteroom is kept under positive pressure relative to the non-controlled area adjacent to the anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	A notification system is installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	There are at least 20 air changes per hour (ACPH).
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Medication storage temperatures do not exceed 25°C.
1 2 3 N/A ☐ ☐ ☐ ☐	The anteroom is separated into two spaces by a visible demarcation line.
1 2 3 N/A ☐ ☐ ☐ ☐	Access of supplies, equipment and personnel into the clean room is through the anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	Supplies, equipment and personnel do not enter the clean room from a non-controlled area.
1 2 3 N/A ☐ ☐ ☐ ☐	The contents of the anteroom are limited to facilitate maintenance and to maintain the target ISO air quality classification.
1 2 3 N/A ☐ ☐ ☐ ☐	The anteroom contains the following items: ❑ PPE, placed in the correct order to allow users to follow the correct garbing sequence ❑ 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; ❑ soap dispenser (cartridge or disposable, non-refillable unit); ❑ nail picks; ❑ alcohol-based hand rub (ABHR) with persistent activity and its dispenser; ❑ hand-drying system:

	- lint-free towels (preferred) with a dispenser - air hand dryer designed specifically for use in a controlled area ❑ mirror or other means to verify garbing; ❑ clock; ❑ waste container; - Cytotoxic waste container for hazardous ❑ eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby); ❑ 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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	The anteroom has two doors.
1 2 3 N/A ☐ ☐ ☐ ☐	The pharmacy has a process that allows only one door to be open at a time.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	Horizontal surfaces in the anteroom are cleaned daily.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	The anteroom is adjacent to the clean room, separate from the rest of the pharmacy and fully enclosed.
1 2 3 N/A ☐ ☐ ☐ ☐	Horizontal surfaces in the anteroom are kept to a minimum.
1 2 3 N/A ☐ ☐ ☐ ☐	Horizontal surfaces in the anteroom are cleaned daily.
1 2 3 N/A ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Access of supplies, equipment and personnel into the clean room is through the anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	No supplies, equipment or personnel enter the clean room from a non-controlled area.
1 2 3 N/A ☐ ☐ ☐ ☐	The contents of the anteroom is limited to facilitate maintenance and to maintain ISO air quality.
1 2 3 N/A ☐ ☐ ☐ ☐	The anteroom contains the following items: ❑ PPE and storage space for PPE, placed in the correct order to allow users to follow the correct garbing sequence ❑ 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; ❑ soap dispenser (cartridge or disposable, non-refillable unit); ❑ nail picks; ❑ alcohol-based hand rub (ABHR) with persistent activity and its dispenser; ❑ hand-drying system: - lint-free towels (preferred) with a dispenser or air hand dryer, designed specifically for use in a controlled area. ❑ mirror or other means to verify garbing; ❑ clock; ❑ cytotoxic waste container; ❑ eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby); ❑ 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 ☐ ☐ ☐ ☐	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 ☐ ☐ ☐ ☐	One or more observation windows has been installed in the anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The pressure in the cleanroom is negative.
1 2 3 N/A ☐ ☐ ☐ ☐	The pressure in the anteroom is positive.
1 2 3 N/A ☐ ☐ ☐ ☐	The pressure differential is at least 5.0Pa relative to the pharmacy adjacent to the anteroom.

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

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

1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	All joints in the walls have been sealed.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	In the clean room and anteroom, the floor is coved up the side wall, at least 10–15 cm.
1 2 3 N/A ☐ ☐ ☐ ☐	There are no carpets, rugs, “sticky mats” or anti-fatigue mats in the clean room or anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	In controlled areas (clean room and anteroom), ceiling fixtures are recessed and flush-mounted.
1 2 3 N/A ☐ ☐ ☐ ☐	In controlled areas, external surfaces of ceiling fixtures, whether made of glass or other material, are washable, smooth and sealed.
1 2 3 N/A ☐ ☐ ☐ ☐	Water sources, sinks and drains are not located in a clean room (but are permitted in the anteroom).
1 2 3 N/A ☐ ☐ ☐ ☐	Control systems are connected to a notification system to alert personnel when operating parameters are outside pre-set limits.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Instruments for measuring differential pressure between controlled areas are calibrated at least once a year or as recommended by the manufacturer.
1 2 3 N/A ☐ ☐ ☐ ☐	Work surfaces and furniture are constructed of smooth, impervious, non-friable and non-porous materials, preferably stainless steel.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Any breakage in work surfaces and furniture is repaired and sealed at the earliest opportunity.
1 2 3 N/A ☐ ☐ ☐ ☐	Gloves are not donned within the ISO Class 5 PEC.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	All movable furniture is cleaned and disinfected before it is placed in the clean room.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Each room is identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, hazards, restricted access, dress code).
1 2 3 N/A ☐ ☐ ☐ ☐	Maintenance is performed on equipment within the facility.
1 2 3 N/A ☐ ☐ ☐ ☐	Facility maintenance activities are recorded in the general maintenance log.
	Equipment
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The PEC has been installed according to the manufacturer's recommendations and certified by a qualified certifier.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor ensures that the certification is completed according to certification standards currently in force.
1 2 3 N/A ☐ ☐ ☐ ☐	Hazardous sterile preparations are compounded inside a C-PEC.

1 2 3 N/A ☐ ☐ ☐ ☐	The C-PEC for hazardous sterile preparations is externally vented.
1 2 3 N/A ☐ ☐ ☐ ☐	A PEC (non hazardous) operates continuously during every sterile compounding activity.
1 2 3 N/A ☐ ☐ ☐ ☐	A C-PEC (hazardous) operates continuously, 24 hours a day.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The PEC provides a work area with unidirectional airflow and quality meeting ISO Class 5 or better under dynamic operating conditions.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	When positioning a PEC, the manufacturer's recommendations are strictly followed to avoid interfering with normal operation.
1 2 3 N/A ☐ ☐ ☐ ☐	During certification, a smoke test under dynamic conditions is used to validate proper operation.
1 2 3 N/A ☐ ☐ ☐ ☐	The LAFW is positioned in an ISO Class 7 clean room that is adjacent to an ISO Class 8 anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	The LAFW is not placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
1 2 3 N/A ☐ ☐ ☐ ☐	If multiple LAFWs are used, they are positioned to prevent interference with one another.
1 2 3 N/A ☐ ☐ ☐ ☐	The BSC is positioned in an ISO Class 7 clean room or better.
1 2 3 N/A ☐ ☐ ☐ ☐	The BSC is positioned in a room under negative pressure.
1 2 3 N/A ☐ ☐ ☐ ☐	The BSC is positioned in a room adjoining an ISO 7 anteroom.

1 2 3 N/A ☐ ☐ ☐ ☐	The BSC is not placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
1 2 3 N/A ☐ ☐ ☐ ☐	If multiple BSCs are used, they are positioned to prevent interference with one another.
1 2 3 N/A ☐ ☐ ☐ ☐	The CAI is positioned in an ISO Class 7 clean room adjacent to an ISO Class 8 anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	The CAI is positioned in an environment where the air particles exceed ISO Class 7 where all of the following conditions are met: ❑ 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. ❑ Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CAI shows ISO Class 5 air quality during compounding ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor obtains the following information from the manufacturer: ❑ documentation indicating that the CAI meets established standards when installed in an environment where the number of particles exceeds ISO Class 7 specifications; ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	The CACI is positioned in an ISO Class 7 clean room.
1 2 3 N/A ☐ ☐ ☐ ☐	The CACI is positioned in a room under negative pressure.
1 2 3 N/A ☐ ☐ ☐ ☐	The CACI is positioned in a room adjoining an ISO Class 7 anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	The CACI is positioned in an environment where the air particles exceed ISO Class 7 where all of the following conditions are met: ❑ The room has negative pressure. ❑ The room has at least 12 ACPH. ❑ 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. ❑ Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CACI shows ISO Class 5 air quality during compounding

	❑ 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 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor obtains the following information from the manufacturer: ❑ documentation indicating that the CACI meets established standards when installed in an environment where the number of particles exceeds ISO Class 7 specifications; ❑ 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 2 3 N/A ☐ ☐ ☐ ☐	The compounding personnel working in a CACI comply with the garbing procedure for compounding hazardous sterile preparations.
	Maintenance of Primary Engineering Controls and Containment Primary Engineering Controls
1 2 3 N/A ☐ ☐ ☐ ☐	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).
1 2 3 N/A ☐ ☐ ☐ ☐	PECs/CPECs must be certified: ❑ every 6 months; ❑ when relocated; ❑ after major repairs; ❑ when viable air sampling indicates that the PEC may not be in compliance with specifications.
1 2 3 N/A ☐ ☐ ☐ ☐	PEC/CPEC pre-filters are accessible.
1 2 3 N/A ☐ ☐ ☐ ☐	Washable pre-filters are not used.
1 2 3 N/A ☐ ☐ ☐ ☐	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.
1 2 3 N/A ☐ ☐ ☐ ☐	Preventive maintenance for PECs/CPECs and other equipment is performed when no compounding is in progress, before cleaning and disinfection operations.
1 2 3 N/A ☐ ☐ ☐ ☐	All PEC/CPEC maintenance and certification, including maintenance of filters and pre-filters, is documented in the general maintenance log (paper-based or computerized).

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

1 2 3 N/A ☐ ☐ ☐ ☐	Carts used to bring supplies into the anteroom from outside the controlled area do not cross the demarcation line.
1 2 3 N/A ☐ ☐ ☐ ☐	Carts taken into the anteroom from the clean room are not moved beyond the clean side of the demarcation line.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The refrigerator and freezer used to store medications are commercial biomedical grade units.
1 2 3 N/A ☐ ☐ ☐ ☐	Domestic refrigerators and freezers are not used.
1 2 3 N/A ☐ ☐ ☐ ☐	Refrigerators and freezers designated for hazardous drugs are used only for this purpose.
1 2 3 N/A ☐ ☐ ☐ ☐	Refrigerators and freezers used for storing medications are not used to store food.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The tested storage temperature in the refrigerator and freezer units meet the following parameters: ❑ controlled refrigeration temperature: 2°C to 8°C ❑ controlled freezing temperature: –25°C to –10°C
1 2 3 N/A ☐ ☐ ☐ ☐	Accurate temperature probes (gauges or sensors) have been installed to indicate the actual temperature.
1 2 3 N/A ☐ ☐ ☐ ☐	A notification system is installed in each refrigerator and freezer to alert pharmacy personnel when temperatures deviate from specifications.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	If the refrigerator and freezer unit is equipped with a continuous temperature recorder, the data recorded by this device is verified and stored.
1 2 3 N/A ☐ ☐ ☐ ☐	Temperature probes are maintained and calibrated at least once a year or in accordance with the manufacturer’s instructions.

1 2 3 N/A ☐ ☐ ☐ ☐	Calibration of these instruments is noted in the general maintenance log.
	Incubator
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	When the incubator is in operation, the incubator temperature is read and recorded in the general maintenance log at least once a day.
1 2 3 N/A ☐ ☐ ☐ ☐	The incubator is calibrated and maintained according to the manufacturer's recommendations.
1 2 3 N/A ☐ ☐ ☐ ☐	The incubator is not placed in the clean room or the anteroom.
	Camera and computer equipment
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Equipment cables are covered to facilitate cleaning.
1 2 3 N/A ☐ ☐ ☐ ☐	Personal electronic devices or accessories (cell phone, iPods, earbuds) are not permitted in the anteroom or clean room.
	Waste containers
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	For hazardous sterile compounding, waste containers are closable to limit the spread of vapors.
1 2 3 N/A ☐ ☐ ☐ ☐	For hazardous sterile compounding, the exterior of each waste container is decontaminated before it is removed from the controlled area.
1 2 3 N/A ☐ ☐ ☐ ☐	For non-hazardous sterile compounding, the waste is collected in plastic bags and removed with minimal agitation.
1 2 3 N/A ☐ ☐ ☐ ☐	The waste containers are emptied and cleaned at least once a day, at a time when no compounding is occurring.
1 2 3 N/A ☐ ☐ ☐ ☐	Hazardous waste containers are identified with appropriate hazardous materials symbols.
	Personal protective equipment and clothing – **Non-hazardous**
1 2 3 N/A ☐ ☐ ☐ ☐	Compounding personnel and anyone else who accesses controlled areas wears appropriate protective clothing,

. 1 2 3 N/A ☐ ☐ ☐ ☐	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: ❑ pair of shoe covers or dedicated shoes ❑ hair cover ❑ beard cover (if applicable) ❑ surgical mask ❑ non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) ❑ 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 ☐ ☐ ☐ ☐	Personal protective equipment adapted and approved for the compounding of hazardous sterile preparations are worn during compounding activities.
1 2 3 N/A ☐ ☐ ☐ ☐	Gloves used in the clean room, in the clean area of the anteroom and during aseptic processes in all CPECs are: ❑ Non-powdered ❑ Compliant with ASTM standards ❑ Sterile (outer glove only)
1 2 3 N/A ☐ ☐ ☐ ☐	Personnel wear two pairs of gloves for the following activities: ❑Unpacking ❑Cleaning and disinfecting the clean room ❑Disinfecting the CPEC ❑Compounding hazardous preparations ❑Managing a spill ❑Disposing of hazardous products
1 2 3 N/A ☐ ☐ ☐ ☐	Both pairs of gloves are discarded and replaced every 30 minutes or immediately following a tear, puncture or contamination.
1 2 3 N/A ☐ ☐ ☐ ☐	The gown has been tested by the manufacturer for resistance to permeability by hazardous drugs.
1 2 3 N/A ☐ ☐ ☐ ☐	The gown closes in the back, has long sleeves with fitted cuffs to the wrists.
1 2 3 N/A ☐ ☐ ☐ ☐	The gown is discarded and replaced after 2-3 hours of continuous compounding work, or after each removal or after a contamination has occurred.
1 2 3 N/A ☐ ☐ ☐ ☐	A gown is used for unpacking a damaged hazardous drug.
1 2 3 N/A ☐ ☐ ☐ ☐	A gown is used if a spill of a hazardous material has occurred.
1 2 3 N/A ☐ ☐ ☐ ☐	A disposable hair cover is worn during the compounding of hazardous sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	The disposable hair cover is changed after each removal or if it becomes contaminated.

1 2 3 N/A ☐ ☐ ☐ ☐	If a hazardous drug shipment has been damaged before receipt, a chemical cartridge respirator is used during unpacking.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Masks, including N95, N100, and chemical cartridge respirators are fit tested.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	N95 or N100 masks are specific for health care workers.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Goggles and a face shield or full face-piece respirator are worn when cleaning up a spill.
1 2 3 N/A ☐ ☐ ☐ ☐	Goggles and a face shield or full face-piece respirator are worn when unpacking suspected damaged drugs.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	The shoe covers are changed after each removal or in the event of a contamination, spill or breakage.
1 2 3 N/A ☐ ☐ ☐ ☐	Shoe covers are not worn outside of the controlled area.
1 2 3 N/A ☐ ☐ ☐ ☐	If the compounder has facial hair, a disposable beard cover is worn while compounding hazardous sterile preparations.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Compounding personnel wear clean room scrubs, not street clothes.
	Cleaning and disinfecting
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Cleaning and disinfecting procedures are strictly adhered to in the clean room and the anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	Policies and procedures for cleaning and disinfecting tasks have been developed.
1 2 3 N/A ☐ ☐ ☐ ☐	Cleaning and disinfecting personnel have been trained and assessed on correct application of policies and procedures.

	Decontamination, deactivation and disinfection
	Decontamination
1 2 3 N/A ☐ ☐ ☐ ☐	When compounding hazardous sterile preparations, cleaning of the premises and equipment must involve decontamination, deactivation and disinfection.
	Deactivation
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	A germicidal disinfectant detergent is used to disinfect all surfaces in a clean room and anteroom.
1 2 3 N/A ☐ ☐ ☐ ☐	The sterile compounding supervisor: ❑ selects an appropriate disinfecting agent for controlled areas, considering mainly its effectiveness and compatibility with materials used for facilities and equipment; ❑ in health care facilities, takes into account the organization's disinfection policies and procedures, following the manufacturer's directions to dilute the disinfectant properly; ❑ follows the manufacturer's directions regarding required contact time between the disinfectant and the surface to be cleaned.
1 2 3 N/A ☐ ☐ ☐ ☐	The daily use of a germicidal disinfectant should be augmented with weekly (or monthly) use of a sporicidal agent.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Non-shedding equipment is used for cleaning controlled areas.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Cleaning equipment and supplies (mop handle, outside of bottles, etc.) are disinfected before each entry into a controlled area.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Non-shedding equipment is used for cleaning controlled areas.
1 2 3 N/A ☐ ☐ ☐ ☐	Equipment used for cleaning controlled areas (mop heads, towels, etc.) should be disposable.
1 2 3 N/A ☐ ☐ ☐ ☐	Cleaning equipment and supplies (mop handle, outside of bottles, etc) are disinfected before entry into the clean room.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Cleaning and disinfecting personnel comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties/
1 2 3 N/A ☐ ☐ ☐ ☐	Housekeeping personnel don gloves before starting work in non-hazardous controlled rooms.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	Cleaning and disinfecting procedures include surface decontamination followed by disinfection at regular intervals and at specific locations for hazardous sterile compounding.
1 2 3 N/A ☐ ☐ ☐ ☐	Daily cleaning and disinfecting are performed for the following surfaces and areas for non-hazardous sterile compounding: ❑ PEC ❑ counters ❑ carts ❑ floors ❑ surfaces that are touched frequently (e.g., doorknobs, switches,

	chairs)
1 2 3 N/A ☐ ☐ ☐ ☐	Daily cleaning, decontamination and disinfecting are performed for the following surfaces and areas for hazardous sterile compounding: ❑ CPEC ❑ counters ❑ carts ❑ floors ❑ surfaces that are touched frequently (e.g., doorknobs, switches, chairs
1 2 3 N/A ☐ ☐ ☐ ☐	Monthly cleaning and disinfecting are performed for the following surfaces and areas: ❑ walls ❑ ceiling ❑ shelves ❑ outer surfaces of the PEC/CPEC
1 2 3 N/A ☐ ☐ ☐ ☐	Waste and garbage is removed daily.
1 2 3 N/A ☐ ☐ ☐ ☐	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 2 3 N/A ☐ ☐ ☐ ☐	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: