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Pharmacy Quality Assurance Self-Assessment

(Sterile Compounding – Hazardous and Non Hazardous)

Date:

Contact information			
Pharmacy:		**CPhM license #:**	
Address:	**City:**		**Postal code:**
Phone #1:	**Fax #1:**	**E-mail address:**	
Phone #2:	**Fax #2:**	**Website:**	
Pharmacy information			
Last inspection date of sterile compounding facilities:			
Hours of operation:			
Pharmacy operational hours: Mon-Fri: Sat: Sun: Holidays: Pharmacist on-call hours:			
Pharmacy staff			
Pharmacy manager:		Manager's licence #:	
Sterile Compounding Supervisor:			

Compounding Personnel:	Pharmacist	Pharmacy Technicians	Other Personnel:
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

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.

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

Pharmacies that undertake sterile compounding are required to be compliant with the items in Part 1 of the Self-Assessment by June 1, 2018.

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.

Notes for discussion or comment: