College of Pharmacists of Manitoba

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Non-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						
Hours of Operation						
Pharmacy Department Hours: Mon-Fri: Sat: Sun: Holidays: **Pharmacist On-Call Hours:**						
Pharmacy Staff						
Pharmacy manager:				Manager's licence #:		
	Licence number				Pharmacy technicians:	Other personnel:
Compounding Supervisor						
Compounding Personnel						

MISSION: To protect the health and well being of the public by ensuring and promoting safe, patient-centred and progressive pharmacy practice.

Other persons:

Level of Risk

PHARMACY SERVICES	Check if Provided	Comments
Level A Compounding	☐	
Level B Compounding	☐	
Level C Compounding	☐	

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

Part 1:

Risk Assessment

1 2 3 N/A ❑ ❑ ❑ ❑	For each compounded product, a risk assessment has been undertaken to identify appropriate level of requirements to minimize contamination and to provide adequate protection for personnel.
1 2 3 N/A ❑ ❑ ❑ ❑	The cumulative risk associated with all preparations compounded in the pharmacy has been assessed.
1 2 3 N/A ❑ ❑ ❑ ❑	Documentation specifies potential risks of compounding the product and extra steps that must be taken to mitigate the risk.
1 2 3 N/A ❑ ❑ ❑ ❑	If a small quantity of a hazardous product is used in compounding, there is documentation of alternative containment strategies and/or work practices employed to minimize occupational exposure.
1 2 3 N/A ❑ ❑ ❑ ❑	For each compound, safety data sheets and other applicable references are consulted.
1 2 3 N/A ❑ ❑ ❑ ❑	For each compound, appropriate procedures for safe compounding are documented on the Master Formulation Record.
1 2 3 N/A ❑ ❑ ❑ ❑	For each compound, additional laws and regulations governing the compounding of hazardous preparations and the handling of hazardous products are consulted.
1 2 3 N/A ❑ ❑ ❑ ❑	The risk assessment is reviewed at least every 12 months to ensure that it is still valid.
1 2 3 N/A ❑ ❑ ❑ ❑	If several different high-risk or low-risk preparations are being compounded, the cumulative risk is considered, even if they are compounded on different days.
1 2 3 N/A ❑ ❑ ❑ ❑	Consideration of cumulative risk is documented in the risk assessment.
1 2 3 N/A	WHIMIS safety data sheets are available to all employees.

❑ ❑ ❑ ❑	

Compounding Personnel

1 2 3 N/A ❑ ❑ ❑ ❑	A non-sterile compounding supervisor has been assigned.
1 2 3 N/A ❑ ❑ ❑ ❑	Assignment of tasks by the non-sterile compounding supervisor is a formal delegation process or under supervision in accordance with the regulations.
1 2 3 N/A ❑ ❑ ❑ ❑	The non-sterile compounding supervisor ensures the following requirements are met: ❑ Measures are in place (i.e., personnel training and assessment program) to ensure that personnel are competent to perform compounding, which includes training for any specific populations (e.g., pediatric, geriatric, veterinary). ❑ Personnel know and fully comply with policies and procedures. ❑ The existing compounding process yields high-quality non-sterile preparations. ❑ A risk assessment is performed to determine appropriate requirements for each compounded preparation. ❑ Appropriate measures are taken to ensure the safety of personnel during each preparation. ❑ Procedures for incident/accident reporting and follow-up, as well as recall procedures, are in place. ❑ Policies and procedures covering all activities are developed, regularly reviewed and updated. ❑ The facilities and equipment used to compound non-sterile preparations meet requirements and are maintained, calibrated or certified according to manufacturers' specifications or standards, whichever are more stringent. ❑ The available, recognized scientific literature is used to determine stability and to establish the BUD for each non-sterile preparation. ❑ Master Formulation Records are developed, reviewed and updated. ❑ An ongoing quality assurance program, designed to ensure that preparation activities are performed in accordance with standards of

	practice, scientific standards, existing data and relevant information, is implemented, followed, evaluated and updated as required. ❑ Current editions of mandatory and supplementary references, which should be in compliance with provincial/territorial requirements, are available. Safety data sheets are available and updated regularly, or are readily accessible in an electronic format. ❑ All records of decisions, activities or specifications required by the Model Standards are completed, and any changes are documented and traceable. The records are retained and readily available for audit and inspection purposes, as required by the provincial/territorial pharmacy regulatory authority.
1 2 3 N/A ❑ ❑ ❑ ❑	Non-regulated pharmacy personnel are supervised by a pharmacist or pharmacy technician according to established supervision protocols and appropriate quality measures.
	Conduct of Personnel in compounding areas
1 2 3 N/A ❑ ❑ ❑ ❑	Personnel behave in a professional manner and follow all pertinent policies and procedures.
1 2 3 N/A ❑ ❑ ❑ ❑	Personnel follow the procedures on the Master Formulation Record.
1 2 3 N/A ❑ ❑ ❑ ❑	Appropriate hand hygiene is performed, before and after compounding.
1 2 3 N/A ❑ ❑ ❑ ❑	Powder free gloves are donned after proper hand hygiene
1 2 3 N/A ❑ ❑ ❑ ❑	A clean lab coat reserved for compounding or a disposable gown is worn.
1 2 3 N/A ❑ ❑ ❑ ❑	If a clean laboratory coat is worn, it is reserved for making non-sterile preparations and not worn outside the compounding area.
1 2 3 N/A ❑ ❑ ❑ ❑	When employees leave the compounding area, lab coats are left behind.
1 2 3 N/A ❑ ❑ ❑ ❑	Used laboratory coats are put on again when the employees return to the compounding area, only when the coats are **clean and unsoiled**.
1 2 3 N/A ❑ ❑ ❑ ❑	Laboratory coats are changed as soon as they become soiled or according to established protocols.
1 2 3 N/A ❑ ❑ ❑ ❑	Disposable gowns are changed every day or as soon as they become soiled.

1 2 3 N/A ❑ ❑ ❑ ❑	Other sources that might contaminate the preparation are avoided, such as: ❑ loose hair ❑ long or false nails ❑ jewellery on hands and wrists ❑ chewing gum ❑ consuming food or drink ❑ using tobacco in the compounding area
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding supervisor is notified if the compounder has an active respiratory tract infection, an eye or skin infection, a hand lesion or other ailment.
1 2 3 N/A ❑ ❑ ❑ ❑	If indicated on the Master Formulation Record, a cap and mask, eye protection and, a beard guard is worn.
1 2 3 N/A ❑ ❑ ❑ ❑	Any other reasonable measures are taken to prevent cross-contamination and to ensure protection from chemical exposure.
	Food or drink is not stored or consumed in the compounding area.

Training and Skills Assessment

1 2 3 N/A ❑ ❑ ❑ ❑	All personnel involved in compounding possess expertise commensurate with their responsibilities.
1 2 3 N/A ❑ ❑ ❑ ❑	Before compounding personnel undertake non-sterile compounding, they have received the proper orientation, training and a skills assessment concerning their work and the type of compounding to be done.
1 2 3 N/A ❑ ❑ ❑ ❑	A skills assessment program, which considers the type and complexity of operations performed, is established for all personnel involved in non-sterile compounding.
1 2 3 N/A ❑ ❑ ❑ ❑	Compliance with operating procedures and application of non-sterile compounding techniques are evaluated regularly and are included in the skills assessment program for compounding personnel.
	Cleaning personnel
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning personnel know all policies and procedures related to: ❑ cleaning and decontaminating the equipment ❑ cleaning and decontaminating furniture and facilities

	❑ policies and procedures related to hygiene ❑ policies and procedures related to personal protective equipment ❑ cleaning and disinfecting tasks.
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning personnel know and use personal protective equipment specifically for handling hazardous products.
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning personnel know and use the emergency measures to be applied in case of accidental exposure, accidents or spills.

Policies and Procedures

1 2 3 N/A ❑ ❑ ❑ ❑	Established policies and procedures provide detailed descriptions of all activities, including cleaning; regarding the pharmacy's compounding of non-sterile preparations
1 2 3 N/A ❑ ❑ ❑ ❑	The non-sterile supervisor ensures application of and compliance with these policies and procedures.
1 2 3 N/A ❑ ❑ ❑ ❑	Established policies and procedures are promptly updated whenever there is a change in practice or in standards.
1 2 3 N/A ❑ ❑ ❑ ❑	At a minimum, policies and procedures are reviewed every 3 years to ensure currency..
1 2 3 N/A ❑ ❑ ❑ ❑	For handling or compounding hazardous drugs or materials, additional policies and procedures have been developed; including the safe receipt, storage, handling, compounding, labelling, transport and disposal of hazardous drugs and materials
1 2 3 N/A ❑ ❑ ❑ ❑	When compounding is undertaken by another pharmacy, the dispensing facility has included in its general procedures manual information about policies and procedures for acquiring compounded non-sterile preparations for patients (originating pharmacy, entry in the file, delivery, etc.).

Facilities and Equipment

1 2 3 N/A ❑ ❑ ❑ ❑	If a pharmacy or healthcare facility compounds any sterile preparations, the area of the pharmacy reserved for this purpose is separate and distinct from the area of the pharmacy set aside for nonsterile compounding.
1 2 3 N/A ❑ ❑ ❑ ❑	All compounding is performed in a separate space specifically designated for compounding of prescriptions.
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding space is located away from parts of the pharmacy where there is a considerable amount of traffic (aisles, entrance and exit doors, etc.)
1 2 3 N/A ❑ ❑ ❑ ❑	Compounding areas are large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner, in clean and secure surroundings.
1 2 3 N/A ❑ ❑ ❑ ❑	All components, equipment, and containers are stored off the floor, in a manner that prevents contamination and allows for inspection and cleaning of the compounding and storage area.
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding area is conducive to necessary cleaning, containing no areas that are difficult to clean.
1 2 3 N/A ❑ ❑ ❑ ❑	The areas used for non-sterile compounding is maintained in clean, orderly and sanitary conditions with appropriate and sanitary waste disposal, and is maintained in a good state of repair.
1 2 3 N/A ❑ ❑ ❑ ❑	The lighting fixtures are located so as to provide a well-lit area facilitating the compounding process and allowing verification at all stages of compounding.
1 2 3 N/A ❑ ❑ ❑ ❑	The heating, ventilation and air conditioning system is controlled in such a way as to avoid decomposition and contamination of chemicals, to maintain the quality and efficacy of stored products and to ensure the safety and comfort of compounding personnel
1 2 3 N/A ❑ ❑ ❑ ❑	Air vents are not located directly over work areas, to avoid contamination of the products.
1 2 3 N/A ❑ ❑ ❑ ❑	A clean water supply, with hot and cold running water, is available in or close to the compounding area or, for Level B and Level C requirements, in the compounding room.
1 2 3 N/A ❑ ❑ ❑ ❑	Work surfaces and furniture are constructed of smooth, impervious and non-porous materials, preferably stainless steel.
1 2 3 N/A ❑ ❑ ❑ ❑	Any breakage is repaired and sealed at the earliest opportunity.

1 2 3 N/A ❑ ❑ ❑ ❑	All furniture, as well as the floor and wall surfaces, have been designed and placed to facilitate cleaning and disinfecting.
1 2 3 N/A ❑ ❑ ❑ ❑	A cleaning schedule appropriate to the level and type of non-sterile compounding has been established.
1 2 3 N/A ❑ ❑ ❑ ❑	The worktop surface used for non-sterile compounding is cleaned before and after each compounding session.
1 2 3 N/A ❑ ❑ ❑ ❑	The equipment, instruments and accessories chosen are appropriate for the type of preparations to be compounded, and are reserved for compounding activities.
1 2 3 N/A ❑ ❑ ❑ ❑	Any surfaces of instruments and accessories that come into contact with preparations do not negatively affect the purity or quality of the preparation being compounded
1 2 3 N/A ❑ ❑ ❑ ❑	To ensure precision and reliability, all equipment, instruments and accessories are routinely inspected and checked to ensure proper performance and if applicable, calibrated at appropriate intervals as recommended by the manufacturer, or at least once a year if there are no manufacture recommendations
1 2 3 N/A ❑ ❑ ❑ ❑	All specialized equipment and instruments used for compounding are cleaned regularly, as recommended by the manufacturer.
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning work recommended by the manufacturer is noted in the maintenance log.
1 2 3 N/A ❑ ❑ ❑ ❑	Equipment, instruments and accessories used for several different preparations are completely and thoroughly cleaned after each compounding session to remove all traces of the previous product and any remaining water and solvent, thus preventing any cross-contamination between preparations
1 2 3 N/A ❑ ❑ ❑ ❑	A maintenance log is kept to record the dates of cleaning and/or calibration of specialized equipment and instruments; these entries include the name of the person carrying out the cleaning or calibration**.**

Level A Requirements

Level A refers to requirements to be met when compounding simple and moderate preparations, as defined in USP *General chapter <795>*, excluding mixing or reconstituting (in accordance with Health Canada's policy on compounding). Requirements for Level A include a separate compounding area and the general requirements for procedures and equipment.

1 2 3 N/A ❑ ❑ ❑ ❑	Pharmacists have undertaken a risk assessment (*see* section 4 of the NAPRA Guidance document for Pharmacy compounding of non-sterile preparations) and identified the appropriate level of requirements needed to guarantee a high-quality product and adequate protection for personnel.
1 2 3 N/A ❑ ❑ ❑ ❑	Level A preparations could include simple or moderate preparations containing hazardous drugs in NIOSH Group 2 or 3,
1 2 3 N/A ❑ ❑ ❑ ❑	A non-sterile compounding supervisor has been appointed.
1 2 3 N/A ❑ ❑ ❑ ❑	Compounding personnel have received orientation and training during education or on the job concerning the preparations to be compounded and underwent a skills assessment at the time of hiring; training has included learning and assimilating workplace operating procedures
1 2 3 N/A ❑ ❑ ❑ ❑	Compounding personnel participate in an annual skills assessment program.
1 2 3 N/A ❑ ❑ ❑ ❑	Level A preparations are compounded in a designated non-sterile compounding area

Phase 2:

Beyond Use Dating (BUD)

1 2 3 N/A ❑ ❑ ❑ ❑	Beyond Use Dating is determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge.
1 2 3 N/A ❑ ❑ ❑ ❑	Beyond Use Dating is assigned after consulting the manufacturer's documentation and literature on the stability, compatibility and degradation of ingredients.
1 2 3 N/A ❑ ❑ ❑ ❑	Compounded products are monitored for signs of instability and/or degradation.
1 2 3 N/A ❑ ❑ ❑ ❑	The manufacturer's expiry date for the drug is not used as the BUD for the final preparation.

Master Formulation Record

1 2 3 N/A ❑ ❑ ❑ ❑	The master formulation record has been developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge.
1 2 3 N/A ❑ ❑ ❑ ❑	The master formulation record includes all necessary information to compound the non-sterile preparation

1 2 3 N/A ❑ ❑ ❑ ❑	The master formulation record contains supporting rationale and references
1 2 3 N/A ❑ ❑ ❑ ❑	The master formulation record is kept in a format that is readily accessible to compounding personnel.

Quality and Storage of Ingredients

1 2 3 N/A ❑ ❑ ❑ ❑	The ingredients used for compounding are pure and of good quality
1 2 3 N/A ❑ ❑ ❑ ❑	Purified water or water of equivalent or superior quality is used whenever the formula specifies water as an ingredient.
1 2 3 N/A ❑ ❑ ❑ ❑	Tap water is not used for compounding products.
1 2 3 N/A ❑ ❑ ❑ ❑	The ingredients used for compounding are obtained from recognized and reliable sources.
1 2 3 N/A ❑ ❑ ❑ ❑	The sources of ingredients used for compounding, as well as lot numbers, expiry dates and date of receipt in the pharmacy must be traceable.
1 2 3 N/A ❑ ❑ ❑ ❑	Ingredients for compounding that have been recalled or withdrawn from the market for safety reasons are not used.
1 2 3 N/A ❑ ❑ ❑ ❑	Current safety data sheets are readily accessible for all ingredients.
1 2 3 N/A ❑ ❑ ❑ ❑	Ingredients used for compounding are stored under conditions that will preserve their purity and quality.
1 2 3 N/A ❑ ❑ ❑ ❑	For ingredients without an expiry date assigned by the manufacturer, the container is labelled with the date of receipt and a conservative expiry date, that does not exceed 3 years after receipt, depending on the nature of the ingredient, the container and storage conditions.

Compounding Record

1 2 3 N/A ❑ ❑ ❑ ❑	The compounding record is kept for each individual prescription and for non-sterile preparations made in batches. (can be paper based or electronic form)
1 2 3 N/A ❑ ❑ ❑ ❑	In cases where the preparation was made by another pharmacy, the origin of the compounded non-sterile preparation dispensed to the patient is recorded in the patient's file.

Phase 3

Verification of final compounded non-sterile preparations

1 2 3 N/A ❑ ❑ ❑ ❑	Verification is performed at each stage of the compounding process.
1 2 3 N/A ❑ ❑ ❑ ❑	Final verification takes place before the preparation is dispensed.
1 2 3 N/A ❑ ❑ ❑ ❑	The master formulation record and compounding record are reviewed to ensure no errors have occurred in the compounding process and the preparation is suitable for use.
1 2 3 N/A ❑ ❑ ❑ ❑	All information on the final label is verified, including the BUD.

Labelling and packaging

1 2 3 N/A ❑ ❑ ❑ ❑	A policy for labelling and packaging has been established and is followed.
1 2 3 N/A ❑ ❑ ❑ ❑	The label and supplementary label provides all the information required for proper use of the compounded preparation by the patient or for safe administration by a third party.
1 2 3 N/A ❑ ❑ ❑ ❑	Special precautions related to drug storage (ie refrigerate) are included on the label or supplemental label.
1 2 3 N/A ❑ ❑ ❑ ❑	All active ingredients and the concentration of the active ingredients are identified on the label.
1 2 3 N/A ❑ ❑ ❑ ❑	The label includes the BUD, storage and handling information.
1 2 3 N/A ❑ ❑ ❑ ❑	Packaging used is appropriate to maintain the integrity of the compounded preparation.

Storage

1 2 3 N/A ❑ ❑ ❑ ❑	A storage procedure has been established and is followed.
1 2 3 N/A ❑ ❑ ❑ ❑	Active and inactive ingredients are stored according to manufacturer's recommendations, in a manner that prevents cross-contamination.
1 2 3 N/A ❑ ❑ ❑ ❑	Each finished product is stored according to requirements outlined in the master formulation record.
1 2 3 N/A ❑ ❑ ❑ ❑	Products that have been stored are inspected before use to detect any signs of deterioration.

Transport and delivery

1 2 3 N/A ❑ ❑ ❑ ❑	Policies for transport and delivery have been established.

1 2 3 N/A ❑ ❑ ❑ ❑	Policies for transport and delivery address special precautions for non-sterile compounded products.
1 2 3 N/A ❑ ❑ ❑ ❑	Preparations for delivery are packed and labelled in a manner that ensures the safety of patients and delivery persons.
1 2 3 N/A ❑ ❑ ❑ ❑	Transport conditions related to temperature, fragility and safety are indicated on the outside of the packaging.

Product recalls

1 2 3 N/A ❑ ❑ ❑ ❑	Procedures for recall of products include documentation that ensure traceability of all ingredients included in the non-sterile products.

Incident reporting

1 2 3 N/A ❑ ❑ ❑ ❑	An incident report is completed for any incident or accident involving a compounded non-sterile product.
1 2 3 N/A ❑ ❑ ❑ ❑	Complaints, accidents, incidents and reported side effects are evaluated to determine the cause, and necessary steps are taken to prevent a recurrence.

Quality Assurance

1 2 3 N/A ❑ ❑ ❑ ❑	A quality assurance program has been developed and implemented to ensure the clear definition, application and verification of all activities affecting the quality of the final product and the protection of personnel.
1 2 3 N/A ❑ ❑ ❑ ❑	Equipment used for compounding is certified at regular intervals and at installation.
1 2 3 N/A ❑ ❑ ❑ ❑	Temperature readings are taken at regular intervals to ensure the integrity of products stored in refrigerators, in freezers, or at room temperature.
1 2 3 N/A ❑ ❑ ❑ ❑	Compounding personnel are trained, certified and reassessed at regular intervals to ensure maintenance of competency.
1 2 3 N/A ❑ ❑ ❑ ❑	Non-compliance with the quality assurance program and corrective actions are documented.

Level B Requirements

Level B refers to requirements to be met when compounding complex preparations, as defined in USP General Chapter <795>, or when compounding small quantities of products that require ventilation. These compounded preparations require more specialized equipment, instruments and training. Level B requirements include a dedicated room that is separate from the rest of the pharmacy, to provide for a larger work space, storage of materials and equipment, uninterrupted workflow and greater protection from cross-contamination.

1 2 3 N/A ❑ ❑ ❑ ❑	Level B compounds are compounded in a separate, well-ventilated room.

1 2 3 N/A ❑ ❑ ❑ ❑	Level B compounds are compounded in an environment conducive to few or no interruptions.
1 2 3 N/A ❑ ❑ ❑ ❑	The facility has appropriate equipment and workspace to compound Level B compounds.
1 2 3 N/A ❑ ❑ ❑ ❑	Level B compounds are compounded in a ventilated containment device when certain powders, aromatic products or hazardous products are compounded.

Phase 4

Hazardous Preparations

1 2 3 N/A ❑ ❑ ❑ ❑	The risk assessment for hazardous materials is reviewed at least every 12 months.
1 2 3 N/A ❑ ❑ ❑ ❑	Facilities for handling hazardous products have been constructed to minimize the risk of exposure to compounding personnel and other pharmacy staff.
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding room is ventilated through high-efficiency particulate air (HEPA) filtration, has appropriate air exchange and has negative pressure relative to surrounding rooms
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding room contains an eyewash station and any other emergency or safety equipment required
1 2 3 N/A ❑ ❑ ❑ ❑	The compounding room has been constructed with smooth impermeable surfaces to promote adequate cleaning and decontamination
1 2 3 N/A ❑ ❑ ❑ ❑	The heating, ventilation and air conditioning system in the compounding room has been constructed to prevent contamination of the areas surrounding the compounding room and to ensure the comfort of personnel wearing PPE.
1 2 3 N/A ❑ ❑ ❑ ❑	Windows and other openings in the compounding room do not lead directly outside or to a non-controlled area
1 2 3 N/A ❑ ❑ ❑ ❑	There is an appropriate area for unpacking hazardous products, and a C-PEC is available for unpacking hazardous products that appear to be damaged
1 2 3 N/A ❑ ❑ ❑ ❑	Hazardous products are stored in a room with appropriate ventilation
1 2 3 N/A ❑ ❑ ❑ ❑	Areas for storing and preparing hazardous products are identified with appropriate signage
1 2 3 N/A ❑ ❑ ❑ ❑	A C-PEC that provides appropriate personal and environmental protection has been installed and maintained
1 2 3 N/A ❑ ❑ ❑ ❑	All reusable equipment and devices are adequately deactivated, decontaminated and cleaned
1 2 3 N/A ❑ ❑ ❑ ❑	PPE approved for the compounding of hazardous non-sterile preparations Are worn during compounding activities: - chemotherapy gloves - disposable, impermeable gown - head, hair, shoe and sleeve covers

	- respiratory protection - eye and face protection
1 2 3 N/A ❑ ❑ ❑ ❑	Compounding area, equipment and accessories are meticulously Cleaned.
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning is done to eliminate chemical contamination, specifically by deactivating, decontaminating and cleaning the premises and equipment
1 2 3 N/A ❑ ❑ ❑ ❑	Cleaning personnel comply with the pharmacy's hand hygiene and garbing procedure for handling hazardous products
1 2 3 N/A ❑ ❑ ❑ ❑	The work surface of the C-PEC is deactivated, decontaminated and cleaned before starting the compounding of a different preparation
1 2 3 N/A ❑ ❑ ❑ ❑	Policies and procedures have been developed and followed for cases of accidental exposure of personnel to hazardous products
1 2 3 N/A ❑ ❑ ❑ ❑	Personnel receive training to prevent spills, as well as training on appropriate procedures to clean up spills, including use of a spill kit
1 2 3 N/A ❑ ❑ ❑ ❑	Incidents and accidents are documented and followed up to prevent recurrence.
1 2 3 N/A ❑ ❑ ❑ ❑	Procedures are in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation
1 2 3 N/A ❑ ❑ ❑ ❑	All personnel involved in the management of hazardous product waste receive appropriate training and have access to all necessary PPE and cleaning supplies
1 2 3 N/A ❑ ❑ ❑ ❑	The controlled room and C-PEC are examined and certified every 6 months according to manufacturer's recommendations, as appropriate (and more often in the case of new equipment installation, repairs or a contamination problem)
1 2 3 N/A ❑ ❑ ❑ ❑	Manufacturers' factory-issued certificates for all HEPA filters and C-PECs are retained for the service life of the equipment.
1 2 3 N/A ❑ ❑ ❑ ❑	An environmental verification program has been established to ensure safety Standards.
1 2 3 N/A ❑ ❑ ❑ ❑	All completed documentation concerning components of testing of controlled rooms and equipment for hazardous product contamination are filed and retained with other compounding records.

<u>Level C requirements</u>

Level C refers to requirements to be met when compounding hazardous drugs that are classified by NIOSH as Group 1 or hazardous materials that are classified by WHMIS as a health hazard, such as those very irritating to the respiratory tract, skin, or mucous membranes. This level of requirements may also apply to NIOSH Group 2 and 3 drugs involving routine use of large quantities of APIs, according to the risk assessment. Level C requirements include a room under negative pressure and appropriate air exchange, a ventilated containment device and PPE appropriate for handling hazardous products.

1 2 3 N/A ❑ ❑ ❑ ❑	Level C compounds are compounded in a separate, negative pressure room.
1 2 3 N/A ❑ ❑ ❑ ❑	Level C compounds are compounded in an appropriate containment device.
1 2 3 N/A ❑ ❑ ❑ ❑	Hazardous drugs classified as Group 1 by NIOSH are considered Level C.
1 2 3 N/A ❑ ❑ ❑ ❑	Hazardous materials classified by WHMIS as representing a health hazard, such as those that are very irritating to the respiratory tract, the skin or the mucous membranes are considered Level C.
1 2 3 N/A ❑ ❑ ❑ ❑	NIOSH Group 2 and 3 drugs for which large quantities of APIs are used routinely are considered Level C.

Notes for discussion or comment: