Model Standards for Pharmacy Compounding of Non-Sterile Preparations

Published with the Guidance Document For Pharmacy Compounding of Non-Sterile Preparations

National Association of Pharmacy Regulatory Authorities

ACKNOWLEDGEMENTS

The National Association of Pharmacy Regulatory Authorities (NAPRA) would like to first thank one of its members, the Ordre des pharmaciens du Québec, for having made possible the adaptation of its document entitled “Préparation magistrales non stériles en pharmacie – Norme 2012.01” to create this national document, “Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the accompanying document “Guidance for the Model Standards for Pharmacy Compounding of Non-Sterile Preparations”

In addition, NAPRA would like to thank the members of the National Advisory Committee on Pharmacy Practice for their continued diligence in the establishment of these documents

Table of Contents

1. INTRODUCTION

The "Guidelines to Pharmacy Compounding" published by the National Association of Pharmacy Regulatory Authorities (NAPRA) in October 2006 have recently been reviewed, resulting in a new set of documents: the NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations[1]; the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations[2]; the Model Standards for Pharmacy Compounding of Non-Sterile Preparations and its accompanying document Guidance for the Model Standards for Pharmacy Compounding of Non-Sterile Preparations (Guidance Document).

The NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the accompanying Guidance Document have been adapted from standards originally developed by the Ordre des Pharmaciens du Quebec, which are in turn based on General Chapter <795> of the United States Pharmacopeia – National Formulary (USP–NF) in effect in the United States since 2004. Their preparation was led by the NAPRA National Advisory Committee on Pharmacy Practice (NACPP) and involved extensive consultation with experts and stakeholders. These Model Standards and Guidance Document are put in place to ensure patient safety and the safety of personnel involved in compounding non-sterile drugs.

Each standard has a corresponding section in the Guidance Document with details on how these standards can be achieved. Requirements of the applicable pharmacy regulatory authority should also be consulted.

2. OBJECTIVES

The aim of these Model Standards is to provide pharmacists and pharmacy technicians who compound non-sterile preparations with the standards necessary to evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel, with a view to guaranteeing the overall quality and safety of non-sterile preparations. The Model Standards apply to all non-sterile compounding by pharmacy personnel; however, not every standard will apply in all practice settings. These Model Standards will come into effect in each province/territory once they have been adopted by the respective provincial/territorial pharmacy regulatory authorities.

These Model Standards represent the **minimum** requirements to be applied in compounding non-sterile preparations; however, it is always possible to exceed these standards. The use of other technologies, techniques, materials and procedures may be acceptable, if they are proven to be equivalent or superior to those described in the accompanying Guidance Document.

[1] National Association of Pharmacy Regulatory Authorities (NAPRA), Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations, November 2015. Available from: http://napra.ca/Content_Files/Files/Mdl_Stnds_for_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Dec2015_FINAL.pdf

[2] National Association of Pharmacy Regulatory Authorities (NAPRA), Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, Draft 4, March 2015

These Model Standards support NAPRA's Model Standards of Practice for Canadian Pharmacists and Pharmacy Technicians[3, 4], as well as other policies and guidelines that may be in place in provincial/territorial jurisdictions.

As with all prescriptions, a pharmacist would be expected to review the prescription and use their expertise to determine if the compounded preparation is appropriate for the patient. In addition, the pharmacist and/or pharmacy technician, designated as the compounding supervisor, must determine if they have the appropriate knowledge and resources to develop the formulation and/or the appropriate equipment and competency to compound the preparation. See section G 2.1 in the Guidance Document for a guideline which may help make the determination on whether or not to compound a preparation. Once it has been determined that it is appropriate to compound the preparation, the model standards for pharmacy compounding of non-sterile preparations must be applied.

3. REGULATORY FRAMEWORK

While compounded non-sterile preparations are prepared by other health care professionals, including nurses, physicians and veterinarians, the majority of non-sterile compounding is performed by pharmacy personnel under the supervision or direction of pharmacists. Although these standards could serve as best practices for other health care practitioners, they pertain specifically to compounding by pharmacy personnel for human or animal use[5] in all pharmacy settings where compounded non-sterile preparations are prepared.

In January 2009, Health Canada developed its "Policy on Manufacturing and Compounding Drug Products in Canada"[6]. It is expected that Health Canada policy will be followed along with these Model Standards. Compounding must always be carried out within a patient–healthcare professional relationship, or in the case of a compounded veterinary product, within a veterinarian/client/patient relationship. In the absence of a patient-specific prescription, and with a prescriber's order for office use, compounders may prepare a compounded product in such a scale, time or frequency to ensure it is being used within a patient-health care professional relationship. Compounders may also prepare batches of compounded product in limited quantities in anticipation of prescriptions. Requests to compound preparations outside the patient-healthcare professional relationship in bulk quantities for distribution or sale, generally fall into the realm of manufacturing, and outside the jurisdiction of pharmacies. Section G 3.1 in the Guidance Document provides general guidelines on differentiating between compounding and manufacturing activities.

NAPRA's professional competencies for Canadian pharmacists and pharmacy technicians at entry to practice provide guidance for developing an ethical, legal and professional practice. One of these competencies specifies that a pharmacist or pharmacy technician must seek

---

[3] National Association of Pharmacy Regulatory Authorities (NAPRA). *Model standards of practice for Canadian pharmacists.* Ottawa, ON: NAPRA; 2009. Available from: http://napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.pdf

[4] National Association of Pharmacy Regulatory Authorities (NAPRA). *Model standards of practice for Canadian pharmacy technicians.* Ottawa, ON: NAPRA; 2011. Available from: http://napra.ca/pages/PharmacyTechnicians/pharmacytechniciansstandards.aspx

[5] The Canadian Veterinary Medical Association's *Guidelines for the Legitimate Use of Compounded Drugs in Veterinary Practice,* states that the veterinarian is responsible for the safety and efficacy of the prescribed drug and for establishing adequate withdrawal times to avoid residues when it is used in food producing animals.

[6] Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.* POL-0051. Ottawa, ON: Health Canada; 2009. Available from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php

guidance when uncertain about his or her own knowledge, skills, abilities or scope of practice. Given that pharmacists and pharmacy technicians are expected to maintain competency in basic compounding skills, pharmacists and pharmacy technicians are expected to provide compounded preparations within their level of expertise and within the limitations of available and appropriate facilities and equipment. When individuals do not have the knowledge, training, expertise, facilities or equipment required for compounding complicated non-sterile preparations or hazardous non-sterile preparations, they must refer patients to a colleague who does have the competencies and facilities required to do so, or, where permitted by provincial/territorial legislation, ask another pharmacy to compound the preparation. The risk assessment (section G 4) and previously mentioned questions (section G 2.1) in the Guidance Document provide information for pharmacists and pharmacy technicians to consider when making the decision whether or not to compound the preparation.

The Model Standards for Pharmacy Compounding of Non-Sterile Preparations excludes mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on the label of a drug approved by Health Canada within the normal practice of pharmacy, as these minor modifications are not classified as "compounding" by Health Canada.[7] However, the minimum conditions for good pharmacy practice should be maintained when performing these activities, and pharmacies are encouraged to follow basic requirements for non-sterile compounding found in this document.

Pharmacists and pharmacy technicians must also comply with any federal regulations regarding the compounding of a product that is not a drug such as cosmetics or food, and it is recommended that, in the absence of specific legislation, these model standards be considered best practice for those compounded products.

4. ASSESSING RISK FOR COMPOUNDING NON-STERILE PREPARATIONS

A risk assessment must be undertaken to identify the appropriate level of requirements to minimize contamination of each compounded product and to provide adequate protection for personnel. In addition to assessing the compounding of single products for risk, the compounding supervisor must also consider the cumulative risk of all preparations compounded in the pharmacy.

[7] Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.* POL-051. Ottawa, ON: Health Canada; 2009. Available from: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php

Steps for Conducting a Risk Assessment

<table>
<tr><td rowspan="2">Conduct a risk assessment for compounding non-sterile preparations including: risk to preparation and risk to person(s). See G4.1 for references and G 4.2 for factors to consider</td><td>Risk to Preparation

The preparation must be compounded in an area free from interruption from other activities in the surrounding space

The area must be large enough for compounding equipment and ingredients

The compounder must ensure that they or anything in the surrounding area do not contaminate the preparation being compounded</td></tr>
<tr><td>Risk to Person(s)

The compounder must be protected from materials which may be hazardous or harmful

The compounding area must be contained so it does not create a hazardous environment for others</td></tr>
<tr><td>Document your risk assessment clearly explaining how you have mitigated the risk to preparation and risk to person(s)

See Decision Algorithm G 4.2.1</td><td>Document rationale on the Master Formulation Record

Document procedures for mitigating risk on the Master Formulation Record

Rationale and procedure must be referenced

Rationale and procedure must be clear to all

Rationale and procedure must be reviewed at least every 12 months</td></tr>
<tr><td rowspan="3">Implement the level of requirements which are commensurate with the risk.

See Section 8 in this document and the Guidance Document</td><td>Level A

Simple and moderate compounds as defined in USP 795[8]</td></tr>
<tr><td>Level B

Complex compounds defined in USP 795

Small quantities of ingredients / preparations which require ventilation</td></tr>
<tr><td>Level C</td></tr>
</table>

[8] Excludes reconstituting and mixing as per Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.*

	Hazardous drugs which are classified by NIOSH[9] as Group 1 Hazardous materials classified by WHMIS[10] as a health hazard, such as those very irritating to the respiratory tract, the skin and the mucous membrane NIOSH group 2 and 3 drugs where large quantities of APIs are used routinely

5 REQUIREMENTS FOR ALL LEVELS[11] OF NON-STERILE COMPOUNDING ACTIVITIES

5.1 Compounding Personnel

All personnel are responsible to know and perform their roles and responsibilities in accordance with these standards and the applicable pharmacy regulatory authority.

Pharmacy Manager Pharmacy Department Head	Responsible for the development, organization and supervision of all activities related to compounding of non-sterile preparations in the pharmacy (see G 5.1.1)
Compounding supervisor Pharmacist Pharmacy Technician	Develops, organizes and oversees all activities related to compounding of non-sterile preparations in the pharmacy (see G 5.1.2)
	Ensures personnel are fully trained and know policies and procedures
	Ensures a risk assessment is performed for each preparation
	Ensures appropriate facilities, equipment and references are available for use
	Ensures Master Formulas and BUDs are developed using scientific references and that these are reviewed appropriately
	Ensures a quality assurance program is in place
	Ensures all records of decisions, activities or specifications are complete and appropriately documented
Regulated pharmacy personnel	Compounds non-sterile preparations in accordance with

[9] National Institute for Occupational Safety and Health (NIOSH), NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. Available from : http://www.cdc.gov/niosh/docs/2014-138/

[10] WHMIS at http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php

[11] Additional information on the compounding of hazardous preparations can be found in section 9.

Pharmacist / Pharmacy Technician	approved formula (see G 5.1.3)
	Complies with established policies and procedures
	Clearly documents decisions, completed activities and verifications prior to dispensing (pharmacist) or releasing (pharmacy technician)
	Ensures all compounding standards and standards of practice have been met
Non-regulated pharmacy personnel	Compounds non-sterile preparations under appropriate supervision in compliance with the requirements of the provincial/territorial regulatory authority. (see G 5.1.4)

5.2 Training and Skills Assessment

All compounding personnel must possess an expertise commensurate with their responsibilities	A training program must be in place for all compounding personnel and a record of all training must be kept (see G 5.2.1 for a template elements to cover in training)
	A skills assessment must be established, administered and documented for all personnel involved in non-sterile compounding (see G 5.2.1.1 for an example of a skills assessment)
	A record of the results of skills assessments and any corrective action taken must be maintained
Cleaning Personnel	Those involved in the cleaning of compounding areas must be properly trained and assessed such that they are aware of the importance of cleaning activities required to prevent cross-contamination. (see section G 5.2.2 for template of elements to cover in training)

5.3 Policies and procedures[12, 13]

Policies and Procedures for all activities related to compounding (see G 5.3.1 for a	Must be clear and provide detailed descriptions of all activities, including cleaning
	Must be reviewed at least every 3 years, or more frequently if

[12] United States Pharmacopeial Convention (USP). General chapter <795>: pharmaceutical compounding — non-sterile preparations. USP 39. Rockville, MD: USP; 2016. pp.31,37.

[13] Pharmacy Compounding Accreditation Board (PCAB). Standard 1.40: Standard operating procedures compliance indicators. In: *PCAB accreditation manual.* Washington, DC: PCAB; 2011. p. 7.

table with examples of policies and procedures and 5.3.2 for a template)	there is a change in practice or standards
	Must be promptly updated when there is a change affecting practice
	Additional procedures must be developed if handling hazardous products

5.4 Facilities and equipment

This section applies to all levels of non-sterile compounding. Additional requirements are expected for Level B and Level C as described in section 9.

5.4.1. Facilities for Non-sterile Compounding

All compounding must be performed in a separate space specifically designated for compounding	Compounding areas must be large enough for compounding personnel to be able to work comfortably and safely. There must be room to store equipment and products in an orderly fashion, in clean and secure surroundings (G.5.4.1.1)
	All components, equipment and containers must be stored off the floor in a manner that prevents contamination and allows for appropriate cleaning
	The compounding area must be conducive to necessary cleaning, maintained in sanitary condition, and in good repair. There must be adequate systems in place to ensure safe and appropriate waste disposal
	Lighting fixtures must be located such that they provide sufficient light for all compounding activities (G 5.4.1.2)
	The heating, ventilation and air conditioning systems must be controlled to avoid decomposition and contamination of chemicals, maintain the quality of products and ensure the safety and comfort of compounding personnel. (G 5.4.1.3)
	A clean water supply with hot and cold running water must be available in, or close to, the compounding area. (G 5.4.1.4)
	Work surfaces and furniture, as well as floor and wall surfaces must be designed to facilitate repeated cleaning. (G 5.4.1.5)
	Compounding areas must be maintained with the cleanliness and hygiene needed to ensure the quality and integrity of the final preparations (G 5.4.1.6)

5.4.2. Equipment for Non-sterile Compounding

Equipment, instruments and accessories	Must be appropriate for the type of preparations to be compounded
	Must not negatively impact the purity or quality of the preparation being compounded
	Must be well cleaned after each use
All equipment, instruments and accessories must be maintained to ensure proper performance (G 5.4.2.1)	Must be routinely inspected and calibrated, if applicable, at appropriate intervals as recommended by the manufacturer, and at least once a year if there are no such recommendations
	Equipment (i.e., fridges, balances, etc.) must meet any requirements established by the pharmacy regulatory authority
	Records of calibration dates for equipment and instruments must be maintained
All specialized equipment must be clean	Must be cleaned regularly, as recommended by the manufacturer (G 5.4.2.2)
	A log must be kept to record the cleaning (G 5.4.2.3)

6 PRODUCT AND PREPARATION REQUIREMENTS

Beyond-use date (BUD) and dating methods (see G6.1.1 for guidelines on assigning BUD)	Must be determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge
	Must be assigned after consulting the manufacturer and literature on the stability, compatibility and degradation of ingredients
	Compounded preparations must be monitored for signs of instability and/or degradation
Master Formulation Record (see G 6.2 for requirements and template)	Must be developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge
	Must include all necessary information to prepare a non-sterile compound

	Must contain supporting rationale and references
	Must be kept in a format that is easily accessible to compounding personnel
Ingredients used for compounding (G 6.3)	Must be pure and of good quality(G 6.3.1)
	Purified Water or water of equivalent or superior quality must be used whenever the formula requires water as an ingredient (G 6.3.1)
	Must be sourced from recognized and reliable sources (G 6.3.2)
	The source of ingredients (including lot numbers, expiry dates, and date of receipt in the pharmacy) must be traceable. (G 6.3.3)
	Ingredients for compounding that have been recalled or withdrawn from the market for safety reasons must not be used (G 6.3.3)
	Current Safety Data Sheets must be readily accessible for all ingredients. (G6.3.4)
	Must be stored in conditions that preserve their purity and quality. (G 6.3.5)
Compounding Record (G 6.4)	Must be kept (paper-based or electronically) for each individual prescription, as well as for non-sterile preparations made in batches.
Conduct of Personnel (G 6.5)	Compounding personnel must behave in a professional manner, following all pertinent procedures on the Master Formulation Record
	Must perform good hand hygiene
	Must wear a clean lab coat, reserved for compounding
	Must wear powder free gloves
	Must use any other PPE or equipment indicated on the Master Formulation Record
	Must not store or consume food or drink, or use tobacco in the compounding area.
	Must take any other reasonable measures to prevent cross

	contamination and to protect themselves from chemical exposure
Verification (G 6.6)	Must be performed at each stage of the compounding process
	Final verification must take place prior to dispensing the preparation
Labelling and Packaging (G 6.7)	A policy for labelling and packaging must be established which is consistent with the applicable provincial/territorial regulatory requirements (6.7.1)
	The label and supplementary label must provide all information required for proper use of the compounded preparation by the patient or for safe administration by a third party (G 6.7.2)
	Packaging appropriate to maintain integrity of the compounded preparation must be used (G 6.7.3)
Storage (G 6.8)	A storage procedure must be established which is consistent with any requirements of the pharmacy regulatory authority, as applicable
	Active and inactive ingredients must be stored according to manufacturer's recommendations, and in a manner which prevents cross contamination (See G 6.8.1 for chart on recommended temperatures)
	Finished product must be stored according to the requirements outlined in the Master Formulation Record
Transportation and delivery	Policies for transportation and delivery must meet regulatory requirements and address any special precautions for non-sterile compounded products (G 6.9)
Recalls	Procedures for recall of products must include documentation to ensure traceability of all ingredients included in non-sterile compounded products (G 6.10)
Incidents and accidents	An event report must be completed for any incident or accident involving a compounded non-sterile compound (See G 6.11.1 for an example of an incident/accident reporting and follow up form)

7 QUALITY ASSURANCE

Quality Assurance Program (see G 7.6 for example components of a QA program)	Must be implemented to ensure the clear definition, application and verification of all activities affecting the quality of the final product, and the protection of personnel (G 7.1)
Equipment and Compounding areas (G 7.2)	Equipment must be certified at installation and regular intervals as recommended by the manufacturer (G 7.2.1)
	Temperature readings must be taken at regular intervals to ensure integrity of products stored in refrigerators, freezers or at room temperature (G 7.2.2)
Compounding personnel (G 7.3)	Must be trained, certified, and reassessed at regular intervals to maintain competency
Compounding procedures (G 7.4)	Compliance with compounding procedures must be monitored
Documentation (G 7.5)	Must be verified, signed and retained as per regulatory requirements
	Non-compliance with the QA program and corrective actions must be documented

8 LEVELS OF REQUIREMENTS

The requirements for non-sterile compounding are based on the complexity and risks associated with preparing the compound and handling the substances used to make the compound. The requirements have been categorized into three levels. A summary of requirements chart can be found in G 8.4. See sections 5, 6 and 7 above and G5, G6 and G7 for more detail

8.1 Level A

What is included	Requirements
Simple and moderate compounds as defined in USP 795[14]	Separate space designated for compounding

[14] Excludes reconstituting and mixing as per Health Canada, Health Products and Food Branch Inspectorate. *Policy on manufacturing and compounding drug products in Canada.*

8.2 Level B

What is included	Requirements
Complex compounds defined in USP 795	
	Separate well-ventilated room
	Larger workspace and appropriate equipment
	Environment conducive to little or no interruptions
	Greater protection from cross contamination
Complex and small quantities of ingredients / preparations which require ventilation	May require a ventilated containment device when certain powders, aromatic products or hazardous products are compounded

8.3 Level C

What is included	Requirements
Hazardous drugs which are classified by NIOSH[15] as Group 1	Separate room
Hazardous materials classified by WHMIS[16] as a health hazard, such as those very irritating to the respiratory tract, the skin and the mucous membrane	Well-ventilated with appropriate air exchange, negative pressure
NIOSH group 2 and 3 drugs where large quantities of APIs are used routinely	Appropriate containment device (C-PEC) for materials being compounded

9 REQUIREMENTS FOR HAZARDOUS PREPARATIONS

Risk Assessment for Hazardous materials (as per Section G 5)	Must be reviewed at least every 12 months

[15] National Institute for Occupational Safety and Health (NIOSH), NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. Available from : http://www.cdc.gov/niosh/docs/2014-138/

[16] WHMIS at http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/index-eng.php

9.1 Facilities for handling hazardous products (Level C)

Facilities	Must be constructed to minimize the risk of exposure to compounding personnel and other pharmacy staff
Compounding Room (G 9.1.1)	Must be ventilated through HEPA filtration, have appropriate air exchange, and have a negative pressure relative to surrounding rooms
	Must contain an eyewash station and any other emergency or safety equipment required
	Must be constructed with smooth impermeable surfaces to promote adequate cleaning and decontamination.
	The heating, ventilation and air conditioning system must be constructed to prevent contamination of the areas surrounding the compounding room, and ensure comfort of personnel wearing PPE. (G 9.1.2)
	Windows and openings must not lead directly outside or to a non-controlled area (G 9.1.3)
	There must be an appropriate area for unpacking hazardous products. A Containment Primary Engineering Control (C-PEC) must be available for unpacking hazardous products which appear to be damaged (G 9.1.4)
Hazardous Product Storage	Hazardous products must be stored in a room with appropriate ventilation. (G 9.1.5)
	Areas for storing and preparing hazardous products must be identified with appropriate signage (G 9.1.6)

9.2 Equipment for handling hazardous products

Equipment (9.2)	A Containment Primary Engineering Control (C-PEC) that provides appropriate personnel and environmental protection must be installed and maintained (G 9.2.1)
	All reusable equipment and devices must be adequately deactivated, decontaminated and cleaned (G 9.2.2)

	Personal Protective Equipment (PPE) approved for compounding of hazardous preparations must be worn during compounding activities (G 9.2.3) - chemotherapy gloves - disposable, impermeable gown - head, hair shoe and sleeve covers - respiratory protection - eye and face protection

9.3 Deactivating, Decontaminating and Cleaning in areas reserved for the compounding of hazardous non-sterile preparations

Cleaning of the premises and equipment	Compounding area, equipment and accessories must be meticulously cleaned (9.3).
	Cleaning must also eliminate chemical contamination by deactivating, decontaminating and cleaning the areas and equipment (G 9.3.1)
	Cleaning personnel must comply with hand hygiene and garbing procedure for handling hazardous products (G 9.3.2)
	The work surface of the Containment Primary Engineering Control (C-PEC) must be deactivated, decontaminated and cleaned before starting the compounding of a different compound (G 9.3.3)

9.4 Incident and accident management

Incidents and accidents	Policies and procedures must be developed and followed for cases of accidental exposure of personnel to hazardous products. (G 9.4.1)
	Personnel must be trained to prevent spills, and on appropriate procedures to clean up spills, including the use of a spill kit. (G 9.4.2)

	Must be documented and followed up to prevent recurrence. (G 9.4.3)

9.5 Hazardous waste management

Hazardous Waste (G 9.5)	Procedures must be in place for destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation.
	All personnel involved in the management of hazardous product waste must receive appropriate training and have access to all necessary PPE and cleaning supplies

9.6 Verification of controlled rooms and the containment primary engineering control (CPEC)

Environmental Verification (G 9.6)	The compounding room must be examined and certified every 6 months and the Containment Primary Engineering Control (C-PEC) according to manufacturer's recommendations (and more often in case of new equipment installation, repairs or a contamination problem). (G 9.6.1)
	Manufacturer's certificates issued in the factory for all High Efficiency Particulate Air (HEPA) filters and Containment Primary Engineering Controls (C-PECs) shall be retained for the service life of the equipment. (G 9.6.2)
	An environmental verification program must be established to ensure safety standards (G 9.6.3)
	All completed documentation concerning components of hazardous product contamination testing of controlled rooms, and equipment must be filed and retained with other compounding records, as per provincial/territorial pharmacy authorities. (G 9.6.4)

Abbreviations and Glossary of Terms as well as the Bibliography can be found in the Guidance Document