College of Pharmacists of British Columbia

PRE-OPENING/CHANGE IN LAYOUT INSPECTION REPORT

Hospital

Form 10C

1. PHARMACY INFORMATION

Operating Name		Pharmacy Licence #(if available)		Proposed Licensure/Completion Date MMM | DD | YYYY
Pharmacy Address	**City**	**Province** BC	**Postal Code**	**Phone Number**
Email Address		**Website**		**Fax Number**

Type of Pharmacy Application for this Inspection Report:

☐ New Hospital Pharmacy Licence/Satellite Authorization ☐ Change in Location (Relocation) ☐ Change in Layout (Renovation)

2. PHARMACY SERVICES

TYPE	SUBTYPE	YES	NO	TYPE	YES	NO	If "YES", PROVIDE ADDITIONAL INFORMATION
OPIOID AGONIST TREATMENT	Methadone (Maintenance)	☐	☐	SATELLITE(S)	☐	☐	Provide name(s) of the satellites your pharmacy provides administrative support to:
	Oral Morphine	☐	☐				
	Buprenorphine & Naloxone (Suboxone)	☐	☐	RESIDENTIAL CARE SERVICES	☐	☐	Facility Name & Number of Beds:
	Injectable Opioid Agonist (iOAT)	☐	☐				
COMPOUNDING	Non-Sterile Preparation	☐	☐	CENTRALIZED PRESCRIPTION PROCESSING SERVICES PROVIDED TO	☐	☐	Provide the name(s) of the pharmacy(ies) that your pharmacy prepares/processes prescriptions/drug orders for:
	Sterile, Non-Hazardous	☐	☐				
	Sterile, Hazardous	☐	☐				
OTHER	Injection & Intranasal Drug Administration	☐	☐	OUTSOURCED PRESCRIPTION PROCESSING SERVICES RECEIVED FROM	☐	☐	Provide the name(s) of the pharmacy(ies) that prepare/process prescriptions/drug orders for your pharmacy:
	No Public Access	☐	☐				
	Schedule 1A drugs On-Site	☐	☐				
	Internet Pharmacy	☐	☐				
	Outpatient	☐	☐				

3. HOURS OF OPERATION

TYPE	SUN	MON	TUE	WED	THU	FRI	SAT	STAT
Pharmacy Hours								

4. PHARMACY ROSTER*

STAFF	REGISTRATION #	FIRST NAME/INFORMAL NAME	LAST NAME	REGISTRATION CLASS
Pharmacy Manager				☒ Pharmacist
Staff #1				☐ Pharmacist ☐ Pharmacy Technician
Staff #2				☐ Pharmacist ☐ Pharmacy Technician
Staff #3				☐ Pharmacist ☐ Pharmacy Technician
Staff #4				☐ Pharmacist ☐ Pharmacy Technician
Staff #5				☐ Pharmacist ☐ Pharmacy Technician

*Use a separate page if more space is needed

5. INFORMATION OF THE PERSON WHO COMPLETED THE NEXT SECTION

Last Name	**First Name**	**Completion Date** MMM | DD | YYYY

Relationship to the Pharmacy

☐ Pharmacy Manager ☐ Authorized Representative (Registrant) ☐ Authorized Representative (Non-Registrant) ☐ College Inspector

Email Address of the Person Named above	**Phone Number of the Person Named above**	**Fax Number of the Person Named above**

☐ I hereby declare that the information provided above including the accompanying digital evidence is true and correct to the best of my knowledge. If any of the above information is found to be false, untrue, misleading or misrepresenting, I am aware that I may be referred to the Inquiry Committee and the pharmacy licence may not be issued.

Signature	**Date** MMM | DD | YYYY

CPBC USE ONLY

Approved by: _____ **Approved date:** _____

6. PRE-OPENING INSPECTION

Confirm whether your pharmacy complies with each of the following requirements.

- **If compliant, mark "Yes" under the "Compliant" column.**
- **If not applicable, enter "N/A" under the "Compliant" column and provide the reason in the comment field.**
- **For digital inspections you must submit digital evidence (e.g. photos/videos) using this Powerpoint template (Hospital) together with this Pre-opening/Change in Layout Inspection Report to the Licensure Department at licensure@bcpharmacists.org.**
- **For in-person inspections pharmacy managers may use this form as a self-audit tool.**

Dispensary

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
1a	**Placeholder for pharmacy licence**	***PODSA* s.4.1(2)** A direct owner and a manager must display a pharmacy licence in the pharmacy in a place conspicuous to the public.			
1b	**Dispensary area**	***PPP-59 Policy Statement #3*** All hospital pharmacies and hospital pharmacy satellites must be adequately equipped to provide safe and proper medication compounding, dispensing and/or preparation of medication orders, and for the provision of patient-oriented and administrative pharmacy services.			
1c	**Bulk or batch packaging area**	***PPP-59 Policy Statement #3*** All hospital pharmacies and hospital pharmacy satellites must be adequately equipped to provide safe and proper medication compounding, dispensing and/or preparation of medication orders, and for the provision of patient-oriented and administrative pharmacy services.			
1d	**Computer terminals for prescription processing**	***PODSA Bylaws s.34*** A pharmacy must connect to PharmaNet ***HPA Bylaws s.72*** A registrant must maintain confidentiality of personal information about a patient.			

Security

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
2a	**Narcotic storage equipment**	***Narcotic Control Regulations s.43*** A pharmacist shall take all reasonable steps that are necessary to protect narcotics on his premises or under his control against loss or theft.			
2b	**Security system**	***PODSA Bylaws s.30(2)*** When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry. ***HPA Bylaws s.77(1)*** A registrant must protect personal information about patients by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or disposal.		Describe system used:	
2c	**After hours services:** ☐ **Locked cabinet OR** ☐ **Other secure enclosure (describe)**	***PODSA Bylaws s.30(1)*** If continuous pharmacy services are not provided in a hospital, the hospital pharmacy's manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by a) providing a cabinet which must (i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access, (ii) be stocked with a minimum supply of drugs most commonly required for urgent use, (iii) not contain controlled drug substances unless they are provided by an automated dispensing system, (iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and (v) include a log in which drug withdrawals are documented, and			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		b) arranging for a full pharmacist to be available for consultation on an on-call basis.			

Equipment and References

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
3a	**Equipment (Cold Chain)** **1. Digital thermometer** **2. Temperature log**	***PPP-68* Policy Statement:** For a drug that requires cold chain management, the pharmacy manager must ensure the following: 1. the drug is maintained in accordance with the manufacturer's requirements and any other applicable requirements. 2. the pharmacy is equipped with cold storage equipment that a. must be purposed for drugs only, b. must maintain only one temperature range enclosed by a door with an air-tight seal (a standard "bar" fridge (combination fridge/freezer with one exterior door) is not acceptable as it does not maintain even temperatures), and c. is equipped with a digital thermometer or temperature monitoring system; 3. temperatures of the cold storage equipment are monitored and recorded a. manually at least twice each working day, preferably at opening and closing of the pharmacy, documenting the current temperature, and the minimum and maximum temperatures reached since the last temperature recording, or b. automatically with a temperature monitoring system that i. records temperatures at a frequency that can determine current temperatures, and minimum and maximum temperatures reached at least twice a day, and			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		ii. monitors and notifies pharmacy staff when a temperature excursion occurs;			
3b	**Equipment (Electronic Recordkeeping)** **1. Device for inputting/creating coloured electronic records (eg. scanner)** **2. Backed up records storage area** **OR N/A = Not storing prescriptions electronically**	***PODSA Bylaws s.23.1(5)*** Prescriptions stored electronically must accurately reflect the original prescription, including the original colour composition of that prescription. ***PODSA Bylaws s.23.3(3)*** A pharmacy manager must ensure that electronic records are preserved and backed up at least once daily and that such electronically preserved and backed up records are stored: (a) in a location resistant to environment perils including but not limited to fires and floods; (b) so that they are secure from unauthorized access, use, modification, destruction and disclosure; and, (c) in a manner that would enable the backed up records, once restored, to be compliant with section 23.1(1) requirements.			
3c	**References**	***PODSA Bylaws* s.18(2)(v)** The manager must ensure the pharmacy contains the reference material and equipment in accordance with the policies approved by the board; ***PPP-3 Policy Statement*** All hospital pharmacies and hospital pharmacy satellites must be equipped with, current references relevant to the service provided (examples including but not limited to: Pediatrics, Psychiatric, Geriatric, Oncology and Compounding)		List references available:	

Medication Administration Record

#	Item		Compliant	Comment	CPBC Use
4a	**Medication administration record**	***HPA bylaws Schedule F Part 2 s.14(2)*** A medication administration record of all prescribed drugs for each patient must be produced from the pharmacy maintained patient record. ***HPA Bylaws Schedule F Part 2 s.14(3)*** The medication administration record must include a) the patient's full name and identification number, b) the patient's location in the hospital, c) the presence or absence of known allergies, adverse drug reactions, and intolerances, d) the date or period for which the drug administration record is to be used, e) the name, dosage and form of all drugs currently ordered, f) complete directions for use for all drugs, g) stop or expiry dates for drug orders for which there is an automatic stop policy (if not reported by another means) h) predetermined, standard medication administration times for regularly scheduled drugs and, i) changes to drug orders			

Confidentiality

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
5a	☐ **Shredder** **OR** ☐ **Contract with a document destruction company**	***HPA Bylaws* s.75** A registrant must ensure that records referred to in section 74 are disposed of only by (a) transferring the record to another registrant, or (b) effectively destroying a physical record by utilizing a shredder or by complete burning, or by (c) erasing information recorded or stored by electronic methods on tapes, disks or cassettes in a manner that ensures that the information cannot be reconstructed. ***HPA Bylaws* s.78**			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which includes an undertaking by the recipient that confidentiality and physical security will be maintained.			
5b	**Offsite storage contract** **OR N/A**	***HPA Bylaws* s.74(b)** A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored off site.			

Inventory Management

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
6a	**Drug receiving area**	***PODSA Bylaws* s.20(4)** All drug shipments must be delivered unopened to (a) the pharmacy, or (b) an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure			
6b	**Storage area for non-usable and expired drugs**	***PODSA Bylaws* s.20(5)** Non-usable and expired drugs must be stored in the pharmacy in an area separate from other pharmacy stock or drug products until final disposal.			
6c	**Hazardous drugs storage area** **OR N/A**	***USP Chapter <797> (2013)*** Hazardous drugs are stored separately from other inventory to prevent contamination and personnel exposure.			
6d	**Storage area for sample drugs OR N/A**	***PODSA Bylaws s.29(2)*** If sample drugs are used within a hospital, the hospital pharmacy's manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.			

Dispensed Products

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
7a	**Drug packaging**	***HPA Bylaws Schedule F Part 2 s.3(2)*** A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing drugs.			
7b	**Drug container label**	***HPA Bylaws Schedule F Part 2 s.4(1)*** Drug container labels must include (a) the generic name of the drug, strength and dosage form, and (b) Hospital approved abbreviations and symbols.			
7c	**Inpatient prescription labels**	***HPA Bylaws Schedule F Part 2 s.4(3)*** Inpatient prescription labels must include: a) a unique patient name and identifier, b) the generic name of the drug, strength and dosage form, c) parenteral vehicle if applicable, and d) Hospital approved abbreviations and symbols. ***HPA Bylaws Schedule F Part 2 s.4(4)*** The following information must be included on the inpatient prescription label if not available on the medication administration record: a) the frequency of administration; b) the route of administration or dosage form; c) auxiliary or cautionary statements if applicable; d) The date dispensed.			

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7d	**Outpatient prescription labels** **1. Single-entity product** **2. Multiple-entity product** **OR N/A**	***HPA Bylaws Schedule F Part 2 s.4(5)*** All drugs dispensed to staff, outpatients or the general public from a hospital pharmacy or hospital pharmacy satellite must be labeled and dispensed according to the Community Pharmacy Standards of Practice. ***HPA Bylaws Schedule F Part 1 s.9(2)*** The label for all prescription drugs must include (a) the name, address and telephone number of the pharmacy, (b) the prescription number and dispensing date, (c) the full name of the patient, (d) the name of the practitioner, (e) the quantity and strength of the drug, (f) the practitioner's directions for use, and (g) any other information required by good pharmacy practice. ***HPA Bylaws Schedule F Part 1 s.9(3)*** For a single-entity product, the label must include (a) the generic name, and (b) at least one of (i) the brand name, (ii) the manufacturer's name, or (iii) the drug identification number (DIN). **HPA Bylaws Schedule F Part 1 s.9(4)** For a multiple-entity product, the label must include (a) the brand name, or (b) all active ingredients and at least one of (i) the manufacturer's name or (ii) the drug identification number (DIN).			

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7e	**Inpatient pass and emergency department take-home drug labels**	***HPA Bylaws Schedule F Part 2 s.7(4)*** Labels for inpatient pass and emergency department take-home drugs must include a) the hospital's name, b) the patient's name, c) the practitioner's name, d) the drug name, strength and directions for use, e) identification of the person preparing the drug, and f) The date the drug is issued.			
7f	**Filling supplies (e.g. vials and bottles including caps)**	***HPA Bylaws Schedule F Part 2 s.7(5)*** Drugs must be dispensed in a container that is certified as child resistant			

Hazardous & Non-Hazardous Sterile Compounding⌘

⌘The College has set out a four-year implementation plan for pharmacies that compound sterile preparations to fully adopt NARPA's new model standards by May 2021 when the new bylaws come into effect. The new standards include Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations and Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. For more information, visit the College's website at http://www.bcpharmacists.org/compounding.

☐ Check this box and skip this section if your pharmacy does not compound sterile preparations.

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
8a	**Sterile compounding area (hazardous and non-hazardous)**	***HPA bylaws Schedule F Part 2 s.3(3)*** Sterile products must be prepared and distributed in an environment that is in accordance with (a) the Canadian Society of Hospital Pharmacists' Guidelines for Preparation of Sterile Products in Pharmacies, (b) the USP Pharmaceutical Compounding – Sterile Products Guidelines, and (c) such other published standards approved by the board from time to time. ***NAPRA Model Guidelines for Pharmacy Compounding Non-Hazardous & Hazardous Sterile preparations (2016) s.5.3.2.8*** The surfaces of ceilings, walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, non-porous and resistant to damage from cleaning and disinfecting products…. Dust-collecting overhangs, such as door sills, utility pipes, windowsills, window curtains and window blinds, must be avoided. ***NAPRA Model Guidelines for Pharmacy Compounding Non-Hazardous & Hazardous Sterile preparations (2016) s.5.3.2.11*** Each room must be identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, hazards, restricted access, dress code).			
8b	**Buffer area/Clean room** **1. No water sources** **2. ISO Class 7**	***HPA Bylaws Schedule F Part 2 s.3*** Sterile products must be prepared and distributed in an environment that is in accordance with			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
	3. Positive room pressure relative to the ante room/ adjacent area **4. Smooth, impervious, non-porous work surfaces**	(a) the Canadian Society of Hospital Pharmacists' Guidelines for Preparation of Sterile Products in Pharmacies, (b) the USP Pharmaceutical Compounding – Sterile Products Guidelines, and (c) Such other published standards approved by the board from time to time. ***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous Sterile preparations (2016)*** ***s.5.3.2.9*** Water sources, sinks and drains must not be located in a clean room but are permitted in the anteroom ***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous Sterile preparations (2016) s.5.3.2.5*** The clean room must be physically separated from the rest of the pharmacy and from other non-controlled areas, to reduce the risk of introducing viable and non-viable contaminants. It must be physically separated from contiguous areas by walls, doors and pass-throughs. The following functional parameters must be met: • The clean room must be kept under positive pressure relative to the anteroom and adjacent areas. • The pressure differential must be at least 5.0 Pa (ideally between 5.0 Pa and 12.5 Pa, equivalent to 0.02 to 0.05 inch water column), relative to the anteroom. Smaller pressure differentials may be more difficult to measure and maintain. • ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions. • There must be at least 30 or more air changes per hour (ACPH). Depending on the size of the room and the number of people working in it, a greater number of ACPH may be required. • The temperature of the clean room must be less than or equal to 20°C, taking into account employees' comfort once all clean room garb			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		(including PPE) has been donned. Medication storage temperatures must not exceed 25°C. ***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous Sterile preparations* 5.3.2.10** Work surfaces and furniture must be constructed of smooth, impervious, non-friable and non-porous materials, preferably stainless steel. A horizontal surface such as a shelf or a cart should be available in the clean room to aid in donning gloves. Gloves shall not be donned within the ISO Class 5 PEC.			
8c	**Pass-through AND/OR Clean room cart**	***NAPRA Model of Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.2.10*** A pass-through should be installed for transferring products into and out of the clean room. The pass-through should be sealed and made of stainless steel or a smooth, non-porous, antistatic material resistant to damage from cleaning and disinfecting products. It is recommended that the pass-through be equipped with an interlocking system that prevents both doors from being open at the same time. If an interlocking system is not available, a door-opening procedure must be implemented whereby only one door is open at a time. If there is no pass-through, the clean room cart may be used to transport materials from the "clean" area of the anteroom into the clean room. ***NAPRA Model of Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.3.2*** If carts are used, one cart must be reserved for the "dirty" area of the anteroom and must remain there. A second cart, dedicated to the "clean" area of the anteroom, may enter the clean room. Supplies are disinfected while they are being transferred onto the clean room cart….			
8d	**Primary Engineering Control (PEC) (LAFW/BSC/CAI/CACI) – ISO Class 5 environment**	***NAPRA Model of Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.3.1*** The PEC ensures an ISO Class 5 air quality environment for the exposure of critical sites when sterile			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		preparations are being compounded. PEC options for non-hazardous sterile preparations include LAFWs and CAIs. The PEC is positioned in the clean room. ***NAPRA Model of Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.3.1*** Each PEC must be certified: • every 6 months; • when relocated; • after major repairs; • when viable air sampling indicates that the PEC may not be in compliance with specifications ***NAPRA Model of Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.3.1*** The LAFW must be positioned in an ISO Class 7 clean room that is adjacent to an ISO Class 8 anteroom and must not be placed near doors or other sources of drafts that might adversely affect unidirectional airflow. If multiple LAFWs are used, they must be positioned to prevent interference with one another.			
8e	☐ **Ante room (ISO Class 8 or 7)** **OR N/A (Low risk level CSP with <12 hr BUD)**	***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous Sterile preparations s.5.3.2.5*** The anteroom is separated into two spaces by a visible demarcation line: • A space or area referred to as "dirty," located at the entrance to the anteroom, in the section adjacent to the non-controlled areas; • A space or area referred to as "clean," adjacent to the dirty area on one side and the clean room on the other. HEPA-filtered air in unidirectional flow is introduced at the ceiling. The following functional parameters must be met: • The anteroom must be kept under positive pressure relative to both the clean room for compounding of hazardous drugs and non-controlled areas adjacent to the anteroom.			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		• The pressure differential must be at least 5.0 Pa37 (equivalent to 0.02 inch water column) relative to the adjacent areas. • A notification system must be installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications. • ISO Class 7 air quality must be maintained in the anteroom under dynamic operating conditions. • There must be at least 30 air changes per hour (ACPH). Depending on the size of the room and the number of people working in it, a greater number of ACPH may be required. • The temperature of the anteroom must be less than or equal to 20°C, taking into account employees' comfort once all clean room garb (including PPE) has been donned. Medication storage temperatures must not exceed 25°C. The air diffusers must be positioned so that the particle stream is directed toward the "dirty" area of the anteroom. All air flowing within the shared anteroom must be exhausted to the exterior of the building. The air flowing into the anteroom must not be recycled.			
8f	**Ante room equipment**	***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous/Hazardous Sterile preparations s.5.3.2.5*** The anteroom must contain the following items: • PPE and storage space for PPE, placed in the correct order to allow users to follow the correct garbing sequence (see section 5.3.3.3 for a description of PPE and section 6.6.2.2 for garbing sequence); • hands-free sink, ideally made of stainless steel or other material not harmed by cleaning products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing; • soap dispenser (cartridge or disposable, non-refillable unit);			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		• nail picks; • alcohol-based hand rub (ABHR) with persistent activity and its dispenser; • hand-drying system: - lint-free towels (preferred) with a dispenser - air hand dryer designed specifically for use in a controlled area (i.e., the anteroom) • mirror or other means to verify garbing; • clock; • cytotoxic waste container; (if hazardous compounding area) • eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby); ***NAPRA Model Standards for Pharmacy Compounding Non-Hazardous/Hazardous Sterile preparations s.5.3.3.3*** PPE to be worn for the compounding of non-hazardous sterile preparations and when accessing facilities for the compounding of non-hazardous sterile preparations includes the following: • pair of shoe covers or dedicated shoes • hair cover • beard cover (if applicable) • surgical mask • non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) • pair of non-powdered sterile gloves, which must cover the cuffs of the non-shedding gown			
8g	**Hazardous Drug Compounding Area (Clean Room) – ISO Class 7** **1. Separate area from non-hazardous sterile preparation** **2. Negative pressure room** **3. Return air externally vented**	***HPA Bylaws Schedule F Part 2 s.3 (4)*** Hazardous drugs must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time. ***NAPRA Model Standards for Pharmacy Compounding Hazardous Sterile preparations (2016) s.5.3.2.9***			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		Water sources, sinks and drains must not be located in a clean room but are permitted in the anteroom. ***NAPRA Model Standards for Pharmacy Compounding Hazardous Sterile Preparation s.5.3.2.5*** Many hazardous drugs can volatilize at room temperature. Therefore, they must be stored within a negative-pressure room. The storage area should have at least 12 air changes per hour (ACPH), with the air being completely exhausted to the exterior. • The clean room must be kept under negative pressure relative to the anteroom. • ISO Class 7 air quality must be maintained in the clean room and the anteroom under dynamic operating conditions. • The return air from the clean room must be externally vented.			
8h	**Hazardous Drug Spill Kits**	***NAPRA Model Standards for Pharmacy Compounding Hazardous Sterile Preparations s.6.11.2*** Spill kits must be available in locations where hazardous products are handled and must be present on carts used for transporting hazardous products.			

Pharmacy Manager's Responsibilities

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
9a	**Staff Identification (e.g. name tag/badge)**	***PODSA Bylaws* s.18(2)(n)** A manager must ensure that each individual working in the pharmacy presents themselves to the public in a manner that clearly identifies their registration class;			
9b	**Policy & procedure manual**	***PODSA Bylaws* s.18(2)(c)** A manager must establish policies and procedures (i) to specify the duties to be performed by registrants and support persons. (ii) for inventory management, product selection, and proper destruction of non-usable drugs and devices. (iii) for pharmacy security. (iv) For emergency preparedness, and (v) For drug recall of pharmacy inventory; ***PODSA Bylaws* s.18(2)(d)** A manager must ensure all policies and procedures are in writing and regularly maintained. ***PODSA Bylaws s.23.2(1)*** A pharmacy manager must ensure that a policy is in place that: (a) describes the pharmacy's records filing system, the records format and the method and system for storing records, (b) is compliant with the sections 23.1, 23.2 and 23.3 requirements; and (c) is readily accessible to and understood by pharmacy staff. ***PODSA Bylaws s.23.2(2)*** With respect to electronic records, the policy must include a description of the process for the preservation, storage and backing up of records that is compliant with section 23.3 requirements. ***PODSA Bylaws* s.29(1)** A hospital pharmacy's manager must establish and maintain written quality management policies and procedures that a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and			

#	Item	Reference and Requirements	Compliant	Comment	CPBC Use
		policies applicable to the operation of a hospital pharmacy, b) include a process to monitor compliance with the quality management policies and procedures, c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies, d) document periodic audits of the drug distribution process, e) include a process to review patient-oriented recommendations, f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records, g) include a process to evaluate drug use, and h) regularly update policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees. ***HPA Bylaws* s.79** A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered. ***PPP-68 Policy Statement*** 4. establish written policies and procedures that include processes a. to ensure proper cold chain management b. to record temperatures of the cold storage equipment in accordance with section 3(of the policy), c. to determine and document actions taken when a temperature excursion occurs, and d. for regular maintenance that ensures functionality of cold chain equipment and documenting those processes;			