Ontario College of Pharmacists
Putting patients first since 1871

Drug Preparation Premises (DPP) ASSESSMENT CRITERIA

The following chart outlines the DPP Criteria that is used by the DPP Advisors when conducting an assessment of the DPP. This document is divided into sections which have been taken from relevant legislation, policies, guidelines or standards of practice. The guidance section illustrates specific insights or activities required to ensure adherence to the standard and is provided to assist practitioners in understanding expectations and preparing for the assessment.

If you have received notice of an upcoming assessment, complete this document and have it ready to share with your DPP advisor when they visit. Ensure all staff members are aware of where the completed form is located should you not be present on the date of the visit. For each standard, check the guidance that your DPP has in place and work on achieving the remaining criteria prior to the visit. Educational/ Informational resources are also listed in the Guidance Column to assist you in preparing for your upcoming assessment or to ensure that your DPP is up to standard.

CATEGORIES

- **General**
- **Standards of Practice and Delegation**
- **Incident and Accident Management**
- **Medication Storage**
- **Standards of Operation**
- **Medication Security**
- **Narcotic & Controlled Substances**
- **Medication Safety**
- **Record Retention, Auditability and Traceability**
- **Technology used within the DPP**
- **Packaging & Labelling**
- **Transportation**
- **Hazardous Sterile Preparations**
- **Non-Hazardous Sterile Preparations**
- **Non-Sterile Preparations**

GENERAL	
STANDARD	**GUIDANCE**
The DPP does not share space with an accredited pharmacy.	☐ The DPP must have a designated space and must not share space or premises with an accredited pharmacy. Pharmacy Act, 1991. Ontario Regulation 202/94, Part IX, S53 (1)
The DPP does not provide direct patient care.	☐ Direct patient care cannot be provided by the DPP. Pharmacy Act, 1991. Ontario Regulation 202/94, Part IX, s 53 (1) b and 53 (1)
The DPP Administrator possesses competencies, knowledge, and skills to be responsible and accountable for a safe medication system.	☐ The DPP Administrator must possess competencies, knowledge and skills to be responsible and accountable for a safe medication system within the DPP. Model Standards of Practice for Canadian Pharmacists (2009) 1.46-1.54 Model Standards of Practice for Canadian Pharmacy Technicians (2011) 1.1-8, 1. 28-35, 2.3, 2.8, 3.1-3.7 OCP Policy- Designated Manager-Professional Supervision of Pharmacy Personnel (2014)
	☐ The DPP Administrator or designate must possess the knowledge and skills to be responsible and accountable for the planning and implementation of infection control practices at the DPP. Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings, 3rd Edition April 2018, Public Health Ontario, Provincial Infectious Diseases Advisory Committee (PIDAC) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd edition, May 2013, PIDAC OCP: Infection Control for Regulated Professionals (2013) Accreditation Canada, Infection Prevention and Control Standards, Version 14 (1, 4, 7,9,10) CSHP Compounding Guidelines for Pharmacies (2014) 17.1
	☐ Where compounding is undertaken for another DPP (i.e. as part of Emergency preparedness plan) the DPP should include in its general procedures manual information about policies and procedures for acquiring compounded sterile preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.2
The DPP does not engage in manufacturing activities.	☐ The DPP must have processes in place to ensure they do not engage in activities considered to be manufacturing by Health Canada. Health Canada, Policy -0051, Policy on Manufacturing and Compounding Drug Products in Canada
	☐ The DPP must not compound preparation(s) that are identical to a commercially available product. The only exception is during time of documented drug shortage. Health Canada, Policy -0051, Policy on Manufacturing and Compounding Drug Products in Canada
	☐ The DPP must have processes in place to ensure they do not fabricate drugs. Health Canada, Policy -0051, Policy on Manufacturing and Compounding Drug Products in Canada
	☐ The DPP must have processes in place to ensure they do not repackage drugs. Health Canada, Policy -0051, Policy on Manufacturing and Compounding Drug Products in Canada, 5.2 h)
	☐ The DPP Administrator must maintain a list of all compounded preparations including risk level, BUD and volumes. The initial list is submitted to the College with application and thereafter twice a year. For example, submit Jan-June in July and July-Dec submitted in January. The list is provided for information purposes, the College is not approving the list or its contents.

	☐ The DPP must have processes in place to ensure it is not in violation of the Food and Drug Regulations Division 1A Establishment Licensing requirements. Food& Drug Regulations, Part C, Division 1A, C.01A.001 (1)-0.19 (1)
STANDARDS OF PRACTICE & DELEGATION	
STANDARD	**GUIDANCE**
There is a delegation process in place authorizing an individual to perform a controlled act(s) in the DPP.	☐ The DPP Administrator or designate must ensure a delegation process is in place for all Controlled Acts undertaken by unregulated staff in the DPP, who are not authorized to perform these Acts. There is a delegation process for all controlled acts undertaken by regulated staff if not within their scope, if this is occurring. This includes documentation of the delegation. `Only a Part A Pharmacist can delegate a controlled act. The DPP Administrator must review the OCP policy on Medical Directives and the Delegation of Controlled Acts. NAPRA MSOP RPh (2009) (3.3 & 3.4) RHPA 1991 S.O. 1991 c. 18 s28 (1), (2) OCP Medical Directives and the Delegation of Controlled Acts (2014)
	☐ The DPP must have written policies and procedures outlining; duties, appropriate knowledge, skill and judgement required to competently perform the acts assigned to unregulated personnel. NAPRA MSOP RPh (2009) 3.7-9, OCP Medical Directives and the Delegation of Controlled Acts (2014)
The DPP Administrator or designate ensures that Pharmacists and Pharmacy Technicians work within their scope, knowledge, skills and abilities and are held accountable for their actions.	☐ The DPP Administrator or designate must be responsible for ensuring Pharmacists and Pharmacy Technicians working at the DPP maintain current licensure with the Ontario College of Pharmacists. NAPRA MSOP RPh 1.49, 1.53 NAPRA MSOP Pharmacy Technicians 1.5-1.6
	☐ The DPP Administrator must be responsible for ensuring that a Pharmacist who is supervising compounding or delegation is a Registrant in Part A of the College register. Part A & B Register (OCP website)
	☐ The DPP Administrator or designate must have a system to assess and update policies and procedures to ensure consistency with Federal and Provincial legislation, NAPRA Standards and OCP bylaws, standards, polices and guidelines. NAPRA MSOP RPh (2009) (1.52) Accreditation Canada, Medication Management v 14 (2.1)

STANDARDS OF PRACTICE & DELEGATION	
STANDARD	**GUIDANCE**
There is a delegation process in place authorizing an individual to perform a controlled act(s) in the DPP.	☐ The DPP Administrator or designate must ensure a delegation process is in place for all Controlled Acts undertaken by unregulated staff in the DPP, who are not authorized to perform these Acts. There is a delegation process for all controlled acts undertaken by regulated staff if not within their scope, if this is occurring. This includes documentation of the delegation. `Only a Part A Pharmacist can delegate a controlled act. The DPP Administrator must review the OCP policy on Medical Directives and the Delegation of Controlled Acts. NAPRA MSOP RPh (2009) (3.3 & 3.4) RHPA 1991 S.O. 1991 c. 18 s28 (1), (2) OCP Medical Directives and the Delegation of Controlled Acts (2014)
	☐ The DPP must have written policies and procedures outlining; duties, appropriate knowledge, skill and judgement required to competently perform the acts assigned to unregulated personnel. NAPRA MSOP RPh (2009) 3.7-9, OCP Medical Directives and the Delegation of Controlled Acts (2014)
The DPP Administrator or designate ensures that Pharmacists and Pharmacy Technicians work within their scope, knowledge, skills and abilities and are held accountable for their actions.	☐ The DPP Administrator or designate must be responsible for ensuring Pharmacists and Pharmacy Technicians working at the DPP maintain current licensure with the Ontario College of Pharmacists. NAPRA MSOP RPh 1.49, 1.53 NAPRA MSOP Pharmacy Technicians 1.5-1.6
	☐ The DPP Administrator must be responsible for ensuring that a Pharmacist who is supervising compounding or delegation is a Registrant in Part A of the College register. Part A & B Register (OCP website)
	☐ The DPP Administrator or designate must have a system to assess and update policies and procedures to ensure consistency with Federal and Provincial legislation, NAPRA Standards and OCP bylaws, standards, polices and guidelines. NAPRA MSOP RPh (2009) (1.52) Accreditation Canada, Medication Management v 14 (2.1)
INCIDENT AND ACCIDENT MANAGEMENT	
STANDARD	**GUIDANCE**
The DPP has policies and procedures in place to address incident and accident management with respect to compounding activities.	☐ All accidents and medication incidents must be reported and documented. They must be reviewed by the DPP Administrator or delegate in a timely manner. NAPRA MSOP RPh (2009) 3.10-3.16 NAPRA MSOP Pharmacy Technicians (2011) 3.0 NAPRA Non-Hazardous Sterile Preparation (2016) 6.11 OCP-AIMS (Assurance & Improvement in Medication Safety) OCP- Standards & Expectations, Supplemental Standards of Practice CSHP Medication Incidents Guidelines on Reporting and Prevention (2012) Accreditation Canada, Medication Management v 14 (27)

	☐	The DPP must have policies and procedures in place that minimize errors, incidents and unsafe practices, including supporting College registrants in their obligation to report incidents and near misses. NAPRA MSOP RPH (2009) (1.52, 3.10-3.16) Accreditation Canada, Medication Management. v 14, (27, 27.1)
	☐	The DPP Administrator or delegate must be responsible to ensure the reporting of medication incidents to a confidential external reporting system. Example: Institute for Safe Medication Practices Canada (ISMP) Medication Incident Reporting System or Canadian Medication Incident Reporting and Prevention System (CMIRPS). OCP-AIMS (Assurance & Improvement in Medication Safety) OCP- Standards & Expectations, Supplemental Standards of Practice ISMP Canada, Reporting and Prevention Systems Medication Incident and Near Miss Reporting Programs, www.ismp-canada.org CMIRPS, www.cmirps-scdpim.ca
	☐	A process must be in place for review of medication incidents and near misses including follow-up with individuals involved and an action plan for system improvements and/or risk mitigation strategies. NAPRA MSOP RPh (2009) (3.10-3.16) NAPRA MSOP Pharmacy Technicians (2011) 3.8-3.12 Accreditation Canada, Medication Management, v 14, (27, 27.2-27.5)
The DPP has a process in place to communicate and manage safe medication practices within the DPP.	☐	The DPP must document and exchange information regarding medication incidents with staff about trends, recommended actions & improvements. NAPRA MSOP RPH 3.14, 3.16 NAPRA MSOP Pharmacy Technicians (2011) 3.12 Accreditation Canada, Medication Management v.14 (27.5)
The DPP has written policies and/or procedures for the review and investigation of adverse drug reactions.	☐	The DPP Administrator or designate must ensure that staff understand their role in reporting adverse drug reactions. NAPRA MSOP RPh (2009) 1.52, 3.10-3.16 NAPRA MSOP Pharmacy Technicians (2011) 3.8-3.10 Accreditation Canada, Medication Management, v 14, (28.1) *Health Canada Medeffect - ADR reporting* Health Canada- Adverse Reaction Reporting Guide-Health Care Professionals Vanessa's Law Protecting Canadians from Unsafe Drug Act
MEDICATION STORAGE		
STANDARD	**GUIDANCE**	
The DPP has operational processes in place for the safe handling, storage and monitoring of medications.	☐	The DPP Administrator must ensure there is a process to report adverse drug reactions to Health Canada and or the manufacturer. NAPRA MSOP RPh (2009) (3.16) NAPRA MSOP Pharmacy Technicians (2011) 3.10, 3.12 *Health Canada- Adverse Reaction Reporting Guide-Health Care Professionals* Health Protection & Promotion Act, RSO, 1990, c.H.7 *Health Canada Medeffect - ADR reporting* Accreditation Canada, Medication Management, v.14, (28.2)

	☐	There must be a review process for each reported adverse drug events, including follow-up with individuals involved, a plan for system improvements to mitigate risk and to identify trends. NAPRA MSOP RPh (2009) (3.15, 3.16) NAPPRA MSOP Pharmacy Technicians (2011) 3.11, 3.12 Accreditation Canada, Medication Management v 14, (28.3)
	☐	The DPP must ensure there are processes in place to ensure medications are stored in a safe, secure and appropriate manner and location. NAPRA MSOP RPh. (2009) 1.42
	☐	The DPP must ensure there are proper conditions of sanitation, temperature, light, humidity, ventilation, segregation and security are provided for medication storage and preparation areas. The DPP provides evidence of supporting documentation (manual or electronic). Humidity requirements for control will vary with climatic region; in general humidity should be maintained below 60%, ideally between 35- 45%. NAPRA Model Standards for Pharmacists (2009), 1.42 NAPRA Hazardous Sterile Preparations (2016) 6.8.2 Accreditation Canada, Medication Management v 14, (13.2,13.4,13.5,) CSHP Compounding Guidelines for Pharmacies (2014) 9.3, 11.2.1
	☐	The DPP must not permit beverages or food in areas where medications and supplies are handled, prepared or stored in the DPP. OHSA O. Reg 67/93, S 32
	☐	There must be adequate storage space for medications, supplies and equipment to support safe medication practice. Medications and supplies must be kept off the floor. NAPRA MSOP RPh (2009) 1.42,1.45 NAPRA MSOP Pharmacy Technicians (2011) 1.29 d-g OCP Policy: Protecting the Cold Chain (2012) Accreditation Canada, Medication Management v 14, (2.5,13.1,13.2,13.4,13.7,13.11)
	☐	The DPP must ensure there is a process for storage of quarantined preparations. For example, awaiting results of sterility testing, validation testing, verification procedures or recalled preparations. Preparations may be released once the results of the sterility test are obtained, if favorable. NAPRA Non-Hazardous Sterile Preparation (2016).6.1.1
	☐	The DPP must ensure there is clear segregation and differentiation for look-alike, sound-alike, different concentrations of the same medication and high-alert medications. NAPRA MSOP RPh. (2009) 1.45, 3.16 Accreditation Canada, Medication Management v 14, (13, 13.7)
	☐	Products for irrigation must be clearly differentiated (labelling) and stored separately from parenteral solutions. Accreditation Canada, Medication Managementv.14 (13.7) ISMP Canada Bulletin, Volume 16, Issue 6, August 30, 2016
	☐	The DPP must ensure there are processes to remove expired medications in a timely manner and ensure a separate area or secure storage area dedicated for the storage of non-usable and expired medication(s) until final disposal. NAPRA MSOP Pharmacy Technician (2011), 1.29 f & g NAPRA MSOP Pharmacists (2009) 1.51 Recommended Guidance in the areas of Security, Inventory, Reconciliation and Record Keeping for Community Pharmacies, Health Canada, 2019 Accreditation Canada, Medication Management v.14 (13.8)

	☐ Purpose built (Commercial biomedical grade units) refrigerator(s) and freezer(s) must be clean and in good working condition. Refrigerator temperature(s) must be monitored continuously to maintain a temperature between 2 to 8 °C and freezer(s) to maintain a temperature between– 25 to – 10°C. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.3.2
	☐ The DPP must ensure they have processes for alternate storage to be provided when conditions are beyond acceptable temperature variations and when refrigerators and freezers are being cleaned. NAPRA Non-Hazardous Sterile Preparations (2016) 6.8
	☐ The DPP must ensure that refrigerators and freezers have an alarm system (recommended external monitoring for after-hours) to detect temperature variations. The DPP ensures there is a process to document any corrective action taken due to temperature deviations. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.3.2

STANDARDS OF OPERATIONS	
STANDARD	**GUIDANCE**
The DPP has adequate resources and work space for staff to provide safe medication practice.	☐ The DPP must ensure they have adequate work space for staff to provide safe medication practice. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.1 NAPRA Model Standards for Pharmacists (2009) 1.48 NAPRA MSOP Pharmacy Technicians (2011) 1.28, 1.31 CSHP Compounding for Pharmacies (2014) 8,9 OHSA RSO 1990 c. O.1.s 25 (1)
	☐ The DPP must ensure they have appropriate equipment to support safe DPP services. NAPRA MSOP RPh (2009) 1.50, 3.6 NAPRA MSOP Pharmacy Technician (2011) 1.28
	☐ The DPP must ensure they have appropriate equipment to support safe DPP services. NAPRA MSOP RPh (2009) 1.50, 3.6 NAPRA MSOP Pharmacy Technician (2011) 1.28
	☐ There must be an established work flow to ensure safe medication practice. NAPRA MSOP RPh (2009) 1.48 NAPRA MSOP Pharmacy Technicians (2011) 1.31 CSHP Compounding Guidelines for Pharmacies (2014) s10
	☐ Storage of poisons and flammable products and preparations must follow appropriate WHMIS, legislative guidelines/requirements and standards. WHMIS CSHP Compounding Guidelines for Pharmacies 2014 (9.3)
	☐ The DPP must have a process to remove expired/outdated medications and chemicals (i.e. API) from storage in a timely manner. NAPRA Non-Hazardous Sterile Preparations (2016) 6.1.2 NAPRA MSOP RPh (2009) 1.51 NAPRA MSOP Pharmacy Technicians (2011) 1.29 f, g Accreditation Canada, Medication Management, v. 14 (13.8)

MEDICATION SECURITY	
STANDARD	**GUIDANCE**
The DPP ensures processes are in place to maintain medication security.	☐ The DPP must ensure that all medication storage areas are secure and safeguarded from unauthorized access. (I.e. DPP alarm, locked doors or similar barriers within the DPP). Model Standards of Practice for Pharmacists (2009) 1.48, 1.52 Accreditation Canada, Medication Management v. 14 (13.0, 13.1)
	☐ The DPP must ensure medications are appropriately stored in alocked area with controlled, restricted access (swipe card, key, access code, locked door and access is restricted to authorized staff, Pharmacists or Pharmacy Technicians and documented). Health Canada: Recommended Guidance in the areas of Security, Inventory Reconciliation and Record Keeping for Community Pharmacies (2019), s (2) Accreditation Canada, Medication Management v.14 (13, 13.6)
	☐ The DPP must have a process to monitor personnel with access to secure areas including removing access when staff leave employment with the DPP and including extended leave. MSOP RPh (2009) 1.2, 1.52 Narcotic Control Regulation (NCR), s 27.5-27.8 and 43-49 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations
NARCOTIC & CONTROLLED SUBSTANCES	
STANDARD	**GUIDANCE**
The DPP Administrator or designate ensures that the requirements of the Narcotic and Controlled Drugs legislation as well as Benzodiazepines and other Targeted Substances are met.	☐ The DPP Administrator or designate must be responsible for ensuring that narcotics, controlled drugs, benzodiazepines and other targeted substances are secure. DPP has systems and procedures in place to ensure the security of narcotic, controlled drugs, benzodiazepines and other targeted substances. OCP Fact sheet: Narcotic Reconciliation and Security (Aug 2012) OCP Fact sheet: Narcotic Purchases (Aug 2012) OCP Fact sheet: Narcotic Purchase Records (Feb 2012) Health Canada, Recommended Guidance in the areas of security, inventory, reconciliation and record keeping for community pharmacists (2019-5-27) CSHP Controlled Drugs and Substances in Hospitals and Healthcare Facilities –Guidelines on Secure Management and Diversion Prevention (2019) Narcotic Control Regulation (NCR), s 27.5-27.8 and 43-49 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations Framework for Improving the Safety and Security of Controlled Substances in Hospital High Risk Areas (2019)
The DPP possesses a Health Canada issued Dealer's License.	☐ The DPP must possess a valid Dealer's License for narcotics, benzodiazepines, controlled drug(s) or other targeted substances. NCR s. 8.1 and 10.1 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations s. 12, 13-16 Application for a Dealer's Licence (Health Canada)

The DPP has policies and procedures to identify and resolve discrepancies of Narcotics, controlled drugs, benzodiazepines and other targeted substances.	☐	The DPP must ensure that they have policies and procedures to identify and resolve discrepancies of narcotics, controlled drugs, benzodiazepines and other targeted substances. NCR s. 27, 43 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations OCP Fact sheet: Narcotic Reconciliation and Security (Aug 2012) CSHP Controlled Drugs and Substances in Hospitals & Healthcare Facilities- Guidelines on Secure Management and diversion prevention (2019) Framework for Improving the Safety and Security of Controlled Substances in Hospital High Risk Areas (2019)
	☐	The DPP must ensure they have processes to ensure narcotic reconciliation(s) must be completed on a frequent and regular basis, in addition to when there is change in staffing and or after a theft or robbery. OCP Fact sheet: Narcotic Reconciliation and Security (Aug 2012) NCR s 28, 30-38, 43 Controlled Drug & Substances Act,Benzodiazepines & Other Targeted Substances Regulations CSHP Controlled Drugs and Substances in Hospitals & Healthcare Facilities- Guidelines on Secure Management and diversion prevention
	☐	The DPP Administrator must ensure that a staff member reviews the Narcotic Sales Report, purchase orders and compare to inventory to protect DPP against narcotic diversion. OCP Fact sheet: Narcotic Purchases (Aug 2012) OCP Fact sheet: Narcotic Purchase Records (Feb 2012) OCP Designated Manager-Medication Procurement & Inventory Management (2014) NCR s 43
	☐	Each incident of unexpected loss of Narcotics, Controlled drugs. Benzodiazepines and other targeted substances must be reported to Health Canada must be reported within 72 hours to Health Canada and within 24 hours to police of the discovery. NCR S 27- 27.4(Theft, losses and suspicious transactions) and S 42 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations, s.35 Health Canada Loss Theft Report Form
	☐	The DPP must ensure they have policy and procedure(s) to perform random audits and verifications of purchase orders, receipts, dispensing, and compounding as well as perpetual inventory control of all narcotics, controlled drugs, benzodiazepines and targeted substances. OCP Fact sheet –Narcotic Reconciliation and Security, Narcotic Purchase Records OCP Designated Manager-Medication Procurement & Inventory Management (2014) NCR s 43 Accreditation Canada, Medication Management v 14 (2.6)
	☐	The DPP must ensure that all parts of the transportation delivery system protect compounded preparations/medications from diversion. NCR S 26 and 43 Controlled Drug & Substances Act, Benzodiazepines & Other Targeted Substances Regulations, s. 34 Accreditation Canada, Medication Management v 14 (21.0)
A random narcotic count performed during the OCP assessment reveals no discrepancies	☐	A random narcotic count (includes controlled drugs, benzodiazepines and other targeted substances) performed during the OCP assessment revealed discrepancies. NCR s. 42, s. 43, s 27, s 28 Controlled Drug & Substances Act Benzodiazepines & Other Targeted Substances Regulations OCP Fact sheet: Narcotic Reconciliation and Security (Aug 2012)

MEDICATION SAFETY	
STANDARD	**GUIDANCE**
The DPP ensures that they compound preparations that promote patient safety	☐ The DPP must ensure they do not compound preparations that have been removed from the market due to safety concerns or preparations with significant safety risks. Health Canada-Advisories, Warnings and Recalls for Drugs & Health Products
	☐ The DPP must ensure they use commercially available products as a priority. If a sterile product is commercially available, compounding personnel must use the commercial product. The DPP must not use a non- sterile ingredient(s) to compound a sterile preparation in this situation. NAPRA Non-Hazardous Sterile Preparations (2016), 6.1.2
The DPP has operational processes in place to ensure that infection prevention and control practices are followed.	☐ The DPP must ensure there is a policy in place to address infection prevention and control (IPAC) procedures are in place at the DPP. Public Health Ontario-Best Practice for Environmental Cleaning for Prevention & Control in all Health Care Settings (3rd Ed) Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd edition, May 2013, PIDAC NAPRA Non- Hazardous Sterile Preparations (2016) 6.6 NAPRA Hazardous Sterile Preparations (2016) 6.6
	☐ The DPP Administrator must ensure that the DPP has policies and procedures for the cleaning requirements of the DPP. NAPRA Hazardous Sterile Preparations (2016)5.3.4 NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.4 NAPRA Non-sterile Compounding (2018) 9.3 CSHP Guidelines Compounding for Pharmacies 2014 (17)
The DPP has policies and procedures in place to ensure processes do not contribute to cross contamination.	☐ The DPP must ensure there are policies and procedure(s) to ensure appropriate cleaning and monitoring of multi-use and non-dedicated equipment. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.4.3 OHSA O.Reg 67/93 s. 32
	☐ The DPP must ensure there are policies and procedures for changeover of equipment (i.e. cleaning, decontamination and disinfecting procedures for equipment and utensils) and cross-contamination controls. NAPRA Non-hazardous Sterile Preparations (2016) 5.3.4.3, 5.3.4.5
	☐ The DPP must ensure they have processes to ensure that compounded preparations that have left the direct control of the DPP are not reissued. NAPRA Non-Hazardous Sterile Compounding (2016) 6.9
	☐ The DPP must ensure the medication supply is kept free of potential contamination. Medications must be stored and prepared in proper sanitary conditions. NAPRA Non-sterile Guidance Document (2016) (6.3.2) OCP Policy- Designated Manager Medication procurement and inventory management (2014) Accreditation Canada, Medication Management v14, (13.2,14)
	☐ The DPP must ensure there are procedures for handling of powdered medications to manage cross-contamination (especially if cytotoxic). NAPRA Non-Hazardous Sterile Compounding (2016) 6.6.3, 6.6.4, 6, 6.5 OHSA, Ontario, RSO, 1990 c.01

	☐	The DPP must ensure they have separate and or defined areas for operations. There must be separate areas for non-sterile preparations, non- hazardous sterile preparations, hazardous sterile preparations and separate area for activities involving highly sensitizing powders (i.e. penicillins). NAPRA Hazardous Sterile Preparations (2016) 5.3.2, 5.3.2.5, 5.3.2.6, NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2, 5.3.2.3, Accreditation Canada, Medication Management, v 14 (17, 17.3, 17.4)
	☐	The DPP must ensure they have established procedures/processes for the DPP Administrator or delegate to determine the appropriateness of medications to be utilized in each machine (i.e. hazardous or non-hazardous prepared within equipment). NAPRA Non-Hazardous Sterile Preparations (2016), 5.1,5.1.1.1, 5.1.1.2 NAPRA Hazardous Sterile Preparations (2016), 5.1, 5.1.1.1, 5.1.1.2
The DPP has an emergency preparedness plan	☐	The DPP must ensure they have an emergency preparedness plan. Emergency Management and Civil Protection Act, RSO 1990 Chapter E. 9, 7.0.2 (1), (4), (5) Public Health Ontario-Public Health Emergency Preparedness Framework &Indicators Accreditation Canada, Emergency & Disaster Preparedness, v. 4 (for surveys after July 1,2019), 6.0,7.1,7.2, OCP- Pandemic planning
The DPP has a business continuity plan in the event of downtime due to equipment failures or other situations.	☐	The DPP must ensure they have a business continuity plan for downtime to mitigate supply interruptions to their customers. The plan may include such items as: downtime plans for equipment failure (i.e. primary engineering control, autoclave or computers), use of back-up generator for power failure(s), agreement with another DPP for extended downtime including plans for validation if using another DPP. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.12
The DPP communicates changes in the processes that affect the final preparation.	☐	There must be a communication process to notify the customer of any change in procedures that may or will affect the final preparation. Examples include: change(s) of ingredients or processes that change the final BUD. NAPRA MSOP RPh. (2009), 2.13-16

RECORD RETENTION, AUDITABILITY AND TRACEABILITY	
STANDARD	**GUIDANCE**
The DPP records are retained for ten years.	☐ The DPP must ensure that they are working towards audit and traceability of all compounding records and retains all such records for 10 years. DPRA 264/16 (s) 156(2) PHIPA 13 (2) Records section OCP Guideline: Documentation (2015) OCP Guideline: Record Retention Disclosure and Disposal (2014) Regulated Health Professions Act (1991) NAPRA Non-sterile preparations (2018) 6,7 NAPRA Non-hazardous Sterile Preparations (2016) 6.3.1
	The DPP must ensure that quality assurance and quality improvement records and documentation including audits, medication incidents, adverse drug reaction (ADR), BUD validation, inspections and other relevant documents are retained for 10 years. DPRA & Regulation Section IV 21 PHIPA 13 (2) records section OCP- Guidelines: Documentation

TECHNOLOGY USED WITHIN THE DPP	
STANDARD	**GUIDANCE**
The DPP ensures the safe operation of all technology and equipment as per standards.	☐ The DPP must ensure there is documentation (in a log or in an electronic database) that tracks the compounding process from entry of medication into the system to final verification and includes the signatures of the individuals involved in each step of the process. Policies and procedures need to outline the checks embedded into the process in order to minimize the risk of error and detect unauthorized access. NAPRA Non-Hazardous Sterile Compounding (2016), 6.6.6.2, 6.6.6.3
	☐ The DPP must ensure technology used is safe to use and fit for its purpose, including as applicable, for the preparation, storage and compounding of preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.3.2
	☐ The DPP must ensure they have policies, procedures and operational guidelines for the use of technology, equipment and automated compounders to ensure the safe and optimal performance of the equipment. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.3.2, Appendix 1
	☐ The DPP must ensure there is a process to identify deficiencies within the technology used (scanning, barcoding, compounding automation etc.) to determine the root cause. These deficiencies must be reviewed by the DPP Administrator or delegate to track and trend improvements. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.3.2
	☐ The DPP must have established policies and procedures related to medication related equipment down time or machine failure. Prompt action should be taken to resolve, production should be halted until issue fixed. Contingency or down time procedures should be tested, documented and reviewed for system improvements. Emergency Management and Civil Protection Act RSO 1990 c. E.9, 7.0.2 (1), (4), (5) NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.12, 7.6`, Table 3

PACKAGING & LABELLING	
STANDARD	**GUIDANCE**
The DPP has policy and procedures that ensure the appropriate selection of packaging material(s) and labeling of final preparation(s).	☐ The DPP must ensure there are policies and procedures on the appropriate selection of packaging containers and materials to maintain the physical integrity, sterility and stability of the medication during handling, storage and transportation. Policy shall consider that the primary packaging for storage of preparation is selected to avoid interaction with the preparation and ensure maintenance of the physical and chemical integrity of the preparation until administered. NAPRA Non-Hazardous Sterile Preparations (2016) (6.7 Packaging, 6.7.1,6.8, 6.9) Chapter 797 19.2 Packaging of CSPs DPRA s 156 NAPRA MSOP RPh (1.40) CSHP Compounding for Pharmacies (2014) 19.6
	☐ The DPP must ensure they have policies and procedures which outline which medications can be prepared/packaged using specific packaging and equipment/machines. NAPRA Non-Hazardous Sterile Preparation (2016) 6.7.2
	☐ The DPP must ensure they utilize specially designed oral syringes, for packaging of oral/enteral liquid medications when final preparation is packaged in syringe format. NAPRA MSOP RPh. (2009) 1.40
The DPP has policy and procedures in place to ensure labels comply with standards.	☐ The DPP must ensure there is a policy in place to ensure that labels are consistent and comply with standards. NAPRA Non-Hazardous Sterile Preparation (2016) 6.67 CSHP Compounding guidelines 2014 page 141 #19 Good Label and Practice Guides for Prescription Drugs (ISMP/Health Canada) ISMP TALL Man Lettering

TRANSPORTATION	
STANDARD	**GUIDANCE**
The DPP has policies and procedures to ensure protection of the preparation(s), personnel and environment during transportation of compounded preparations to their customers.	☐ Policies and procedures must be developed and implemented for the transport of compounded preparations (i.e. sterile, non-sterile and hazardous preparations) to their customers. The DPP should consider packaging containers and materials that are expected to maintain physical integrity sterility and stability of CSPs during transit. Packaging must be selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation and protects personnel who transport packed CSPs from harm. NAPRA Non-Hazardous Sterile Preparation (2016) 6.9 OHSA RSO 1990 Chapter 0.1 s 25 (1) WHMIS Health Canada Guidelines -0069, Environmental Control of drugs during Storage & Transportation USP Chapter 797 (19.3 , Packaging and Transporting CSPs)

	☐	The DPP Administrator or delegate must ensure that delivery of narcotic (including controlled drugs and other targeted substances) preparations to their customers are secure, auditable and traceable. Narcotic Control Regulation Controlled Drug & Substances Act Benzodiazepines & Other Targeted Substances Regulations CSHP Controlled Drugs and Substances in Hospitals and Health Care Facilities-Guidelines on Secure Management and Diversion Prevention (2019)
The DPP ensures that cold chain procedures are followed to ensure the integrity of preparations.	☐	The DPP must ensure there is a policy and procedure(s) that addresses protecting the cold chain of preparation(s) during preparation and shipment to their customers. OCP “Protecting the cold chain” 2012 OCP “Delivery of prescriptions” March 2020 Health Canada Guidelines -0069, Environmental Control of drugs during Storage & Transportation Vaccine Storage & Handling Guidelines (Ontario)

Drug Preparation Premises (DPP) HAZARDOUS STERILE PREPARATIONS ASSESSMENT CRITERIA

HAZARDOUS STERILE PREPARATIONS	
STANDARD	**GUIDANCE**
CORE REQUIREMENTS - PERSONNEL	
The DPP Administrator is responsible for developing, organizing and supervising all activities related to DPP compounding of hazardous sterile preparations.	☐ The DPP Administrator must be responsible for developing, organizing and supervising all activities related to DPP compounding of hazardous sterile preparations. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.1 Pharmacy Act: O Reg 202/94: Part IX: s 58 OHSA R.S.O. 1990, C 0.1, s 25 (1,2) s 26(i)
	☐ The DPP Administrator must be familiar with the relevant NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.1
	☐ The DPP has a system in place to ensure all DPP personnel, trainees, preceptees and volunteers receive appropriate orientation, training and certification for assigned functions and responsibilities. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.1 NAPRA Hazardous Sterile Preparations (2016) 5.1.2 OHSA R.S.O. 1990, C 0.1, s 25 (1,2) s 26(i)
The hazardous sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of hazardous sterile preparations	☐ There must be a sterile compounding supervisor designated to supervise activities related to the compounding of hazardous sterile preparations. This person is a registrant of the College. This person works with the DPP Administrator and with the compounding personnel. NAPRA Hazardous Sterile Prep. (2016) 5.1.1.2
	☐ The sterile compounding supervisor must have successfully completed training (i.e., courses) in the compounding of hazardous sterile preparations, maintained up-to- date knowledge and demonstrated the required competencies. NAPRA Hazardous Sterile Preparations (2016) 5.1.2.3
	☐ The sterile compounding supervisor must be evaluated for knowledge and abilities, at the same frequency as compounding personnel, by a third party (an evaluator with expertise in the compounding of hazardous sterile preparations, at arm's length from the DPP and free of any real or perceived conflict of interest with the individual being evaluated). NAPRA Hazardous Sterile Preparations (2016) 5.1.2.3
	☐ The sterile compounding supervisor must ensure that all policies and procedures are in place and readily accessible to staff. Policies and procedures must be specific to the individual DPP. Policies and procedures must be reviewed at least every 3 years or when there is a change in standards. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.2 OHSA RSO 1990, c.0.1. s. 25, s 27, s (37) WHMIS
	☐ The sterile compounding supervisor must be responsible for the training of and competency assessment program for all employees involved in the compounding of hazardous sterile preparations. OHSA R.S.O. 1990, c. O.1, s 25, 27 s. 37, s 42 NAPRA Hazardous Sterile Preparations (2016), 5.1.2.3, 5.1.2.4

	☐	The sterile compounding upervisor must ensure the cleaning and disinfecting personnel understand and follow the training and work procedures created in collaboration with the DPP Administrator. Only trained and qualified cleaning and disinfecting personnel may be allowed to clean controlled areas. NAPRA Hazardous Sterile Preparations (2016) 5.1.2.2
	☐	The sterile compounding supervisor must ensure the competency of the certifier and the personnel chosen to conduct the sampling, and that the certification is performed in accordance with the most recent certification standards. NAPRA Hazardous Sterile Preparations (2016) 5.1.2.4
	☐	The sterile compounding supervisor must analyze the data obtained via air sampling, surface sampling or GFS and the trends observed with respect to the microbial load. If necessary, the sterile compounding supervisor should consult a microbiologist or infectious diseases specialist. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
The DPP Administrator or delegate must be responsible for ensuring that all standards of practice associated with compounding the preparation have been met before releasing a preparation(s).	☐	The DPP Administrator or delegate must be responsible for ensuring that there is a compounding procedure/worksheet that is completed and has calculations and measurements for each preparation produced. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.3
	☐	The DPP Administrator or delegate must be responsible for enforcing/ensuring compliance with required rules relating to asepsis, hygiene, cleanliness and safety. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.3
	☐	The DPP Administrator or delegate must be responsible for ensuring application and compliance with existing compounding procedures and to follow the compounding process defined in the compounding protocol. NAPRA Hazardous Sterile Preparations (2016)5.1.1.3 NAPRA Model Standards for Pharmacy Technicians (2018) 1.42-1.44 NAPRA Model Standards for Pharmacists (2009), 1.39
	☐	The DPP Administrator or delegate must be responsible for ensuring that verification is performed during the various stages of compounding. All required verification and quality control measures must ensure the quality, sterility and verification of the final preparation. NAPRA Hazardous Sterile Preparations (2016) 5.1.1.3
All cleaning and disinfecting personnel for hazardous sterile compounding have received initial training and completed a competency assessment program in the workplace.	☐	The initial training and assessment program for cleaning and disinfecting personnel must have the following components: theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding hazardous sterile preparations; practical training and assessment in the areas reserved for the compounding of hazardous sterile preparations. NAPRA Hazardous Sterile Compounding (2016) 5.1.2.2.
	☐	A competency assessment program for cleaning and disinfecting personnel must be implemented in the workplace. NAPRA Hazardous Sterile Compounding (2016) 5.1.2.3

PERSONNEL INVOLVED IN ASEPTIC COMPOUNDING	
STANDARD	**GUIDANCE**
There is a quality assurance program in place that addresses the personnel involved in hazardous aseptic compounding.	☐ The quality assurance program for the aseptic compounding process for personnel must include GFS and a media fill test, and must be performed under real compounding conditions and must represent the most complex preparations according to the microbiological risk. NAPRA Hazardous Sterile Compounding (2016) 7.4.1, 7.4.2
There is a quality assurance program in place for hazardous sterile compounding that addresses the content of the program itself, the results & actions taken, the product preparation process and documentation.	☐ The sterile compounding supervisor must establish a quality assurance program to ensure the clear definition, application and verification of all activities that will affect the quality of compounded sterile preparations and the protection of personnel. In addition, must also ensure that sterile preparations are compounded in compliance with established procedures. NAPRA Hazardous Sterile Compounding (2016) 7.0 and Appendix 12
	☐ The quality assurance program must have four components; 1. verification of equipment, including the C-PEC, 2. verification of controlled areas (clean room and anteroom), 3. verification of aseptic compounding processes, verification of final preparations.
	☐ For each of the specified components, the sterile compounding supervisor must establish a verification process, the results of which are assigned one of three levels; Compliance (no action required): mandatory specifications have been attained, Alert (tendency toward noncompliance): increased vigilance is required to prevent non-compliance, Action required (noncompliant): more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non- compliance. Each component of the quality assurance program and its activities must be documented. NAPRA Hazardous Sterile Preparations (2016) 7.1, 7.2
	☐ Written documentation related to the quality assurance program must be verified, analyzed and signed by the sterile compounding supervisor and retained for a period designated in federal/provincial/ regulations. NAPRA Hazardous Sterile Preparations Appendix 12
Conduct of personnel in controlled areas must meet NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The conduct of personnel in any controlled area must meet NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations including health, presentation, and behavior of the personnel. OHSA R.S.O. 1990, CHAPTER O.1 s28 NAPRA Hazardous Sterile Preparations (2016) 6.5
	☐ Compounding personnel must use meticulous aseptic technique when preparing hazardous compounded sterile preparations. Compounding must occur in the critical area of the PEC, such that critical sites are exposed to first air. NAPRA Hazardous Sterile Preparations (2016), 6.6.5.1

	☐	Hand and forearm hygiene is required for sterile compounding, regardless of the type of PEC that is used. Hand and forearm hygiene is required for anyone entering the clean room. The DPP must have a detailed policy and procedure that describes the garbing requirements, and hand/forearm hygiene. These policies and procedures must be updated as appropriate. NAPRA Hazardous Sterile Preparations (2016) 6.2.2
	☐	Compounding personnel must verify the final sterile product including: perform a visual inspection of each unit for evidence of particulate to verify the clarity, colour and volume of the solution, to check the container for possible leaks and to verify the integrity of the container; verify the information on the label; place final hazardous compounded sterile preparations that require storage at 2°C to 8°C in the refrigerator pending verification and delivery to customer. NAPRA Hazardous Sterile Preparations (2016) 6.6.6.1
	☐	Each preparation must be inspected by a person other than the individual who performed the aseptic compounding. NAPRA Hazardous Sterile Preparations (2016) 6.6.6.4

COMPOUNDED STERILE PREPARATION PROTOCOLS **COMPOUNDED STERILE LOG PREPARATION**		
Effective documentation and record keeping processes are in place according to standards of practice and NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐	Protocols for the compounding of sterile hazardous preparations must include all of the information required to prepare the compound. Protocols must be reviewed and approved by the Sterile Compounding Supervisor or delegate. NAPRA Hazardous Sterile Preparations (2016) 7.5
	☐	A compounded sterile hazardous preparation log must be completed during the compounding process. The DPP must keep such a log for sterile preparations made in batches or individual preparation(s). NAPRA Hazardous Sterile Preparations (2016) 7.5
The DPP must ensure that there are process controls in place to ensure intended sterile preparations are sterile.	☐	The DPP ensures that preparations compounded using aseptic technique and non-sterile ingredients must be sterilized before administration. The sterilization method chosen will ensure sterilization of the preparation without compromising quality, purity, strength and packaging. The sterilization processes must be validated to demonstrate they achieve sterilization. NAPRA Hazardous Sterile Preparations (2016) 6.1.3 USP Chapter 797, page 11
The DPP has access to the current required references as listed in the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐	The DPP must have access to NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. NAPRA Hazardous Sterile Preparations (2016) Appendix 2
	☐	The DPP must have access to the relevant current chapters of USP. NAPRA Hazardous Sterile Preparations (2016) Appendix 2
	☐	The DPP must have access to National Institute for Occupational Safety and Health (NIOSH) List of antineoplastic and other hazardous drugs in healthcare settings, current version. NAPRA Hazardous Sterile Preparations (2016) Appendix 2

CORE REQUIREMENTS – FACILITIES AND EQUIPMENT	
STANDARD	**GUIDANCE**
The clean room is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Facilities for the compounding of hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, with provincial and local regulations and for health system facilities, with other applicable standards regulating the construction of buildings. NAPRA Hazardous Sterile Preparations (2016) 5.3
	☐ The DPP ensures that facilities that compound both hazardous and non- hazardous sterile preparations must have two clean rooms: one for the compounding of hazardous sterile preparations and the other for the compounding of non- hazardous sterile preparations, as well two anterooms (i.e. one for hazardous and the other for non-hazardous compounding). NAPRA Hazardous Sterile Preparations (2016) 5.3.2.6
	☐ The DPP ensures that facilities that compound both hazardous and non- hazardous sterile preparations do not share an anteroom. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.6
	☐ Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the C-PEC is located and an anteroom, located next to the clean room. NAPRA Hazardous Sterile Preparations (2016), 5.3.2.5
	☐ The clean room must be physically separated from contiguous areas by walls, doors and pass-throughs NAPRA Hazardous Sterile Preparations (2016), 5.3.2.5
	☐ The clean room must only be used for the compounding of hazardous sterile preparations. NAPRA Hazardous Sterile Preparations (2016) ,5.3.2.5
	☐ ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions. NAPRA Hazardous Sterile Preparations (2016), 5.3.2.3
	☐ The air supplied to areas used for compounding hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter. HEPA filters are regularly maintained and tested. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.3
	☐ The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and C-PECs. The particle count may also be measured by a qualified certifier. NAPRA Hazardous Sterile Preparations (2016) ,5.3.2.3
	☐ Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward. Ensure that air vents are not obstructed. NAPRA Hazardous Sterile Preparations (2016), 5.3.2.3

	☐ 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, nonporous 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 Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ All joints must be sealed. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ Flooring must be flat, smooth, impervious, non-friable, non-porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed immediately. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ In the clean room, the floor must be covered up the side wall, at least 10–15 cm. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ There must be no carpets, rugs, “sticky mats” or anti-fatigue mats. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ Controlled rooms must be identified with appropriate and informative signs (e.g., pictograms indicating cytotoxicity, the need for special care, hazards, restricted access, dress code. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.11
	☐ DPP staff should review the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. (i.e. Bacillus Calmette–Guérin [BCG])
	☐ The clean room must be kept under negative pressure relative to the adjacent areas. The clean room must be kept under negative pressure relative to the anteroom. The pressure of the clean room must be –2.5 Pa (equivalent to 0.01-inch water column) relative to surrounding areas. The pressure differential between the anteroom and the clean room must be at least 2.5 Pa to maintain unidirectional airflow from the anteroom to the clean room. The pressure in the anteroom must be positive. The pressure differential must be at least 5.0 Pa relative to the area adjacent to the anteroom. NAPRA Hazardous Sterile Preparations (2016) Table 2
An anteroom is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Facilities for the compounding of hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, with provincial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings. NAPRA Hazardous Sterile Preparations (2016) 5.3

	☐ The anteroom must be separated into two spaces by a visible demarcation line: the first space or area, referred to as “dirty”, is located at the entrance to the anteroom, in the section adjacent to the non-controlled area; the second space or area, referred to as “clean”, is adjacent to the dirty area on one side and the clean room on the other. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
	☐ Controlled rooms are identified must be identified with appropriate and informative signs (e.g., pictograms indicating cytotoxicity, the need for special care, hazards, restricted access, dress code). NAPRA Hazardous Sterile Preparations (2016) 5.3.2.11
	☐ Activity in the anteroom, with higher generation of particulates, must be kept to a minimum and must be limited to those activities that are essential to or that directly support the work undertaken in the clean room. (Ex. Garbing, hand hygiene, labelling, staging). NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
	☐ Access of supplies, equipment and personnel into the clean room must be through the anteroom. No supplies, equipment or personnel shall enter into the clean room from a non-controlled area. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
	☐ LEFT OFF ISO Class 7 air quality must be maintained in the clean room and the anteroom under dynamic operating conditions. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
	☐ The air supplied to areas used for compounding hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.3
	☐ Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.3
	☐ The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and C-PECs. The particle count may also be measured by a qualified certifier. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.3
	☐ The surfaces of ceilings (with all joints sealed), walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, nonporous 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 Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ Joints between the ceiling and walls should be free of sharp corners where foreign substances could accumulate. In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in ceilings must be repaired and sealed at the earliest opportunity. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8

	☐	Flooring must be flat, smooth, impervious, non-friable, non-porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed immediately. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	In the anteroom, the floor must be coved up the side wall, at least 10–15 cm. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	There must be no carpets, rugs, “sticky mats” or anti-fatigue mats. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.8
The storage of hazardous drugs is in compliance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐	Hazardous products must be stored separately from non-hazardous products in a dedicated room and include a separate unpacking area. NAPRA Hazardous Sterile Preparations (2016) 6.8.2.1, 5.3.2.5 and Table 3
	☐	The hazardous storage area must be clearly segregated physically by location, by shelf, by drawers or another means. Storage areas should prevent spillage or breakage if the container falls. Labelling of these separate areas is clearly visible to alert all personnel. NAPRA Hazardous Sterile Preparations (2016),6.8.2.1,6.8.2.2,6.8.2.3 CSHP compounding guidelines 2014 (10.2.3,11.3.5)
	☐	Hazardous drugs must be stored within a negative-pressure room with all air exhausted to the exterior. The storage area must have at least 12 air changes per hour (ACPH). NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
	☐	Hazardous sterile preparations and the refrigerator in which they are stored may be placed in the clean room for compounding hazardous sterile preparations. The DPP must ensure that air exhausts are placed so that they will remove particles generated within the storage area and the refrigerator and must also ensure sufficient ACPH to maintain an ISO Class 7 clean room. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5
The DPP has operational processes in place to ensure the safe handling, storage and monitoring of hazardous medications to ensure staff and patient safety.	☐	Refrigerated hazardous drugs must be stored in a dedicated commercial biomedical grade refrigerator(s) in a negative pressure area. NAPRA Hazardous Sterile Preparations (2016) 5.3.2.5, Table 2 & 3
	☐	The DPP must have an inventory list of hazardous medications in the DPP and personnel are educated on specific handling and storage requirements.
	☐	Hazardous waste must be sealed and packaged in the appropriate container(s), kept segregated and clearly labelled. NAPRA Hazardous Sterile Preparations (2016) 6.12
Personal Protective Equipment (PPE) for the compounding of hazardous sterile preparations must meet the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐	Compounding personnel must wear clean room scrubs, not street clothes. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3
	☐	Gloves used in the clean room, in the clean area of the anteroom and during aseptic processes in all C-PECs (including isolators) must be: non-powdered; compliant with standard D-6978-05 of ASTM International; sterile (outer glove only). Compounding personnel wear two pairs of gloves meeting the ASTM International standard when performing specified activities. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3
	☐	Two pairs of disposable shoe covers are required at all times in the clean area of the anteroom and in the clean room, even if dedicated shoes are worn. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3

	☐	A disposable hair cover must be worn during the compounding of hazardous sterile preparations. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3
	☐	If the compounder has facial hair, a disposable beard cover must be worn while compounding hazardous sterile preparations. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3
	☐	A gown must be worn and have been tested by the manufacturer for resistance to permeability by hazardous drugs. It must close in the back, and it must have long sleeves with fitted cuffs at the wrists. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3
	☐	NAPRA outlines the uses for and limitations of different types of masks and when a N95, N100 mask or chemical cartridge respirator (NIOSH- approved) mask should be used. Any mask must first be fit-tested. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.3, Table 5
Equipment for the compounding of hazardous sterile preparations is designed, built, and maintained in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐	For hazardous compounding, C-PECs must be Class II or III BSCs or CACIs that meets the requirement. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1
	☐	The Containment Primary Engineering Control (C-PEC) must ensure an ISO Class 5 air quality environment for the exposure of critical sites when sterile preparations are being compounded. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1
	☐	Each C-PEC must be certified at least every 6 months, when relocated, after major repairs or when viable air sampling indicates that the C- PEC may not be in compliance with specifications. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1
	☐	The Biological Safety Cabinet (BSC) must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom. The BSC must not be placed near doors or other sources of drafts that might adversely affect unidirectional airflow. If multiple BSCs are used, they must be positioned to prevent interference with one another. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1
	☐	The compounding aseptic containment isolator (CACI) must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom. Compounding personnel working in a CACI must comply with the garbing procedure for compounding of hazardous sterile preparations, both to maintain air quality and to protect themselves from spills. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1
	☐	Sterile Isopropyl alcohol (IPA) 70% must be available for use in the appropriate areas. NAPRA Hazardous Sterile Preparations (2016) 6.6.3
	☐	Refrigerator and freezer when used to store hazardous medications must be commercial, biomedical-grade units. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.2, 6.8.2.1
	☐	Refrigerator and freezer designated for hazardous drugs must be used only for this purpose. They must not be used to store food or other medications/solutions, etc. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.2
	☐	Preventive maintenance for C-PECs and other equipment must be performed when no compounding is in progress, before cleaning and disinfection operations. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1

	☐	The automated compounding device (ACD) must be positioned in the C-PEC such that compounding occurs while critical sites are exposed to first air. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.2
	☐	Carts used to bring supplies into the anteroom from outside the controlled area must not cross the demarcation line. Likewise, carts taken into the anteroom from the clean room shall not be moved beyond the clean side of the demarcation line. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.2
	☐	An incubator is used to maintain a constant temperature for the culture of microorganisms. The incubation temperature must be controlled (20°C to 25°C or 30°C to 35°C, depending on the culture medium and incubation period). NAPRA Hazardous Sterile Preparations (2016) 5.3.3.2
	☐	Equipment used for cleaning and disinfection and its storage must be specifically designated for cleaning areas used for the compounding of hazardous sterile preparations. NAPRA Hazardous Sterile Preparations (2016) 5.3.4.4
	☐	The DPP ensures that dedicated equipment must be segregated and properly labelled for hazardous drug use. Equipment must be deactivated, decontaminated and cleaned after each use, or if disposable equipment is used, disposed of appropriately. NAPRA Hazardous Sterile Preparations (2016) 5.3.4.2, 5.3.4.4
There is a cleaning, disinfecting, deactivating and surface decontaminating procedure in place that addresses all hazardous compounding areas.	☐	Personnel must comply with the requirements for cleaning and disinfecting as outlined in NAPRA. NAPRA Hazardous Sterile Preparations (2016) 6.6.4.3, 5.3.4.2, Table 8
	☐	Cleaning and disinfecting personnel must comply with the DPP's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties. NAPRA Hazardous Sterile Preparations (2016) 5.3.4.2
	☐	The DPP must have a policy in place to ensure the use of sterile 70% isopropyl alcohol (IPA) for the disinfection of gloved hands surfaces/equipment/supplies used in the compounding of hazardous sterile products. NAPRA Hazardous Sterile Preparations (2016) 6.6.2.2., 6.6.3
	☐	For daily activities such as disinfecting the inside of a C-PEC, a surface decontamination step using an appropriate agent must precede the usual disinfection step with sterile 70% isopropyl alcohol. NAPRA Hazardous Sterile Preparations (2016) 6.6.4.3
	☐	Surface decontamination, deactivation and disinfection of the C-PEC must be completed according to the frequencies set out in NAPRA. NAPRA Hazardous Sterile Preparations (2016) 6.6.4, Table 8

VERIFICATION OF EQUIPMENT AND FACILITIES

STANDARD	GUIDANCE
The DPP must have an environmental verification program that meets that meets the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The environmental verification program must include verification for chemical contamination by hazardous materials on surfaces used for receipt, storage, preparation and verification of products and preparations, in addition to verification of microbiological contamination of controlled areas twice per year. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ The differential pressure between controlled areas must be kept constant. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ Pressure must be measured continuously, and an alarm system must be in place to immediately advise personnel of noncompliance with specifications and to direct that action be taken. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ The indicators for proper operation of any device (BSC, CACI, ACD, etc.) must be verified every day, and data must be recorded in the general maintenance log. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ The temperature of controlled sterile compounding areas must be verified and documented at least once a day. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ Sampling of viable, non-viable and surface particles in controlled areas and the C-PEC. Minimally from air within the controlled areas and in the C-PEC every six months. Whenever there is new equipment installed or a new controlled area, during maintenance or repair of equipment or controlled area and during investigation of a contamination problem or problem involving non- compliance of personnel with aseptic processes. Samples must always be obtained under dynamic operating conditions. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ An Investigation must be undertaken when a contamination or a problem involving non-compliance in the aseptic compounding process is discovered. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.1
	☐ A written sampling plan for controlled areas and the C-PEC must be established and include sampling of viable, nonviable and surface particles. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism must be identified. Corrective and preventive actions (e.g., cleaning, disinfecting) must be completed and documented. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ An environmental program must be established to ensure that facilities that engage in hazardous compounding uphold the quality and safety standards set by the industry. NAPRA Hazardous Sterile Preparations (2016) 7.3.2.3

The DPP ensures there is a quality assurance program in place that addresses the verification of equipment and facilities for hazardous sterile compounding.	☐ Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, must be certified with respect to its installation and operation and must be calibrated before being put into service and thereafter as recommended by the manufacturer. NAPRA Hazardous Sterile Preparations (2016) 7.3.1.1
	☐ The DPP must ensure there are policies and procedures related to routine calibration and maintenance of equipment and technology. NAPRA Hazardous Sterile Preparations (2016) 5.3.3.1-2
	☐ At least once a day, compounding personnel must check the temperature log of equipment with an integrated recording device (e.g., refrigerator, freezer, incubator), to review temperatures over the previous 24 hours, and must take corrective actions if needed. For integrated recording devices the temperatures over the previous 24 hours must be reviewed. For manual thermometers, there must be twice daily readings, including minimum and maximum readings. NAPRA Hazardous Sterile Preparations (2016) 7.3.1.2
	☐ The general maintenance logs must be complete, accurate and maintained as per standards of practice and NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. NAPRA Hazardous Sterile Preparations (2016) 5.4

BEYOND USE DATE (BUD) AND DATING METHODS

STANDARD	GUIDANCE
The DPP's operating procedures describe the risk assessment process used to establish the Beyond Use Date (BUD) and the storage conditions according to NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The Sterile Compounding Supervisor must be responsible for assigning the BUDs, when there is no specific sterility testing for a preparation or a batch. The BUD must not exceed the earliest of the dates established by the following two criteria; 1. expiration date based on chemical and physical stability as per acceptable stability references (i.e. reference text or peer reviewed journal) 2. storage time related to risk of microbial contamination. NAPRA Hazardous Sterile Compounding (2016) 6.1.1
	☐ Levels of risk for microbial contamination must apply to preparations compounded in a compliant, certified C-PEC that maintains ISO Class 5 air quality or better and that is located in an ISO Class 7 clean room or a compliant certified CACI that meets the criteria specified when placed in environments with particle counts exceeding ISO Class 7. NAPRA Hazardous Sterile Compounding (2016) 6.1.3
	☐ Low Risk preparations are prepared and must meet beyond-use dates; • final product compounded using up to 3 "sterile units", • no more than 2 septum punctures at the injection site for each sterile unit, simple aseptic transfer technique; drug prepared for one patient (patient specific dose).
	☐ Risk of contamination Low; • At controlled room temperature BUD must be no more than 48 hours, • With storage in refrigerator BUD must be no more than 14 days, • With storage in freezer BUD must be no more than 45 days. NAPRA Hazardous Sterile Compounding (2016) 6.1.3, TABLE 6 & TABLE 7

	☐ Medium Risk preparations are prepared and must meet beyond-use dates; • final product compounded using four or more “sterile units”, • complex manipulations; prolonged preparation time, batch preparations (preparing more than one unit of the same composition during one compounding session).
	☐ Risk of contamination Medium; • At controlled room temperature BUD must be no more than 30 hours, • With storage in refrigerator BUD must be no more than 9 days, • With storage in freezer BUD must be no more than 45 days NAPRA Hazardous Sterile Compounding (2016) 6.1.3, TABLE 6 & TABLE 7

RECALL OF STERILE PRODUCTS OR FINAL COMPOUNDED STERILE PREPARATIONS

There is a process in place when a sterile hazardous product or preparation does not meet requirements due to issues of internal control and/or a complaint or a product recall.	☐ The DPP must ensure that if 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 DPP Administrator or delegate must be able to: notify customers that there is a problem with the preparation. NAPRA Hazardous Sterile Preparations (2016) 6.10
	☐ The DPP will ensure that the customer will identify patients who have received the CSP and perform the necessary follow-up if the preparation has been administered. The process must include documentation of actions. NAPRA Hazardous Sterile Preparations (2016) 6.10

RECEIPT OF PRODUCTS

STANDARD	GUIDANCE
The DPP must ensure they have policies and procedures in place to ensure safe receipt, transport and delivery of compounded hazardous sterile preparations.	☐ Personnel involved in receipt, transport and delivery of drugs or preparations (Pharmacist, Pharmacy Technician, pharmacy assistant and driver) receive training including the procedure for dealing with accidental exposure or spills when applicable. NAPRA Hazardous Sterile Preparations (2016) 6.9
	☐ The garbing of personnel for unpacking intact hazardous products that have been received from the supplier sealed in impervious plastic must meet the NAPRA requirements. NAPRA Hazardous Sterile Preparations (2016) 6.8.1.2
	☐ If a shipping container for hazardous drugs appears damaged upon receipt, appropriate procedures must be followed. NAPRA Hazardous Sterile Preparations (2016)6.8.1
	☐ Products used for preparations must be unpacked outside of controlled areas (clean room and anteroom), to limit the introduction of dust and particles into the controlled areas. NAPRA Hazardous Sterile Preparations (2016) 6.8.1
	☐ Before any product is introduced into the anteroom, it must be removed from its cardboard shipping box. The product must then be wiped with a sporicidal agent. NAPRA Hazardous Sterile Preparations (2016).6.3

	☐	During packaging, compounding personnel must: put each final hazardous compounded sterile preparation in a clear plastic bag (or an amber bag, if the preparation must be protected from light) then in a rigid container; indicate storage requirements on the final package; indicate additional precautions on the final packaging; indicate transport precautions and instructions on the outside packaging of each item.) NAPRA Hazardous Sterile Preparations (2016) 6.7.1
	☐	Policies and procedures must be developed and implemented for the transport of hazardous compounded sterile preparations and their delivery to customers. NAPRA Hazardous Sterile Preparations (2016) 6.7.1 Cancer Care Ontario Safe Handling of Cytotoxics (2018) pg. 13-14 WHMIS OHSA RSO 1990, c.O.1, O Reg 67/93, S (104)
	☐	A spill kit must be available in locations where hazardous products are handled and must be present on carts used for transporting hazardous products.) NAPRA Hazardous Sterile Preparations (2016) 6.9, 6.11.2
INCIDENT AND ACCIDENT MANAGEMENT		
The DPP has policies and procedures in place to address incident and accident management with respect to hazardous sterile compounding.	☐	Policies and procedures must be in place and followed in case of accidental exposure of personnel to hazardous products. NAPRA Hazardous Sterile Preparations (2016) 6.11.1 NAPRA MSOP RPh. (3.10 - 3.16 inclusive)
	☐	Policies, procedures and training for managing spills must be in place for employees who clean up spills. NAPRA Hazardous Sterile Preparations (2016) 6.11.2, 6.11.3 OHSA R.S.O. 1990 c. 0.1, O Reg 67/93, s (97.1 & 97.2)
	☐	When an incident or accident involving a hazardous compounded sterile preparation occurs, an event report and explanation form must be completed. NAPRA Hazardous Sterile Preparations (2016) 6.11.2, 6.11.3 OHSA R.S.O. 1990 c. 0.1, O Reg 67/93, s (97.1 & 97.2)
HAZARDOUS WASTE MANAGEMENT		
The DPP has a hazardous waste management process in place.	☐	The DPP Administrator or delegate must ensure that medications and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws in force in the jurisdiction. NAPRA Hazardous Sterile Preparations (2016) 6.12
	☐	The DPP Administrator or delegate must ensure that medications to be destroyed are safely stored in a location separate from other medications in inventory. NAPRA Hazardous Sterile Preparations (2016) 6.12
	☐	The DPP ensures that there are policies and procedures for the management of hazardous waste must be developed and followed. These policies and procedures must comply with local, provincial and federal requirements. NAPRA Hazardous Sterile Preparations (2016) 6.12

Drug Preparation Premises (DPP) NON-HAZARDOUS STERILE PREPARATION ASSESSMENT CRITERIA

NON-HAZARDOUS STERILE PREPARATIONS	
STANDARD	**GUIDANCE**
CORE REQUIREMENTS - PERSONNEL	
The DPP Administrator is responsible for developing, organizing, and supervising all activities related to DPP compounding of Non-hazardous sterile preparations.	☐ The DPP Administrator must be responsible for developing, organizing and supervising all activities related to DPP compounding of Non-hazardous sterile preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.1 Pharmacy Act, Part IX, 53(1), S 58 and Part III (6.1), Part IV (10.1) NAPRA MSOP RPh 2009 (2.12-2.14), DPRA section 149(1)
	☐ The DPP Administrator must be familiar with the relevant NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.1
	☐ The DPP has a system in place to ensure all DPP personnel, trainees, preceptees and volunteers receive appropriate orientation, training and certification for assigned functions and responsibilities. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2, 5.1.2.2 OHSA R.S.O. 1990, C 0.1, s 25 (1,2) s 26(i)
The sterile compounding supervisor (SCS) develops, organizes and oversees all activities relate to the compounding of Non-hazardous sterile preparations.	☐ There must be a sterile compounding supervisor designated to supervise activities related to the compounding of Non-hazardous sterile preparations. This person is a registrant of the College. This person works with the DPP Administrator and with the compounding personnel. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.1, 5.1.1.2
	☐ The sterile compounding supervisor must have successfully completed training (i.e., courses) in the compounding of Non- hazardous sterile preparations, maintained up-to-date knowledge and demonstrated the required competencies. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.2, 5.1.2.3 OHSA RSO 1990, Chapter 01, Part 3, s 25 & 27 WHMIS
	☐ The sterile compounding supervisor must be evaluated for knowledge and abilities, at the same frequency as compounding personnel, by a third party (an evaluator with expertise in the compounding of Non-hazardous sterile preparations, at arm's length from the facility and free of any real or perceived conflict of interest with the individual being evaluated). NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.3
	☐ The sterile compounding supervisor must ensure that all policies and procedures are in place and readily accessible to staff. Policies must be specific to the individual DPP. Policies and procedures must be reviewed at least every 3 years or when there is a change in standards. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2, 5.1.1.2, 5.2 NAPRA MSOP RPH 2009 (1.52) OHSA RSO 1990, Chapter 0.1 s 25 (1)

	☐	The sterile compounding supervisor must be responsible for the training of and competency assessment program for all employees involved in the compounding of Non-hazardous sterile preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.2, 5.1.2 OHSA RSO 1990, Chapter O.1, s 25, s 26
	☐	The sterile compounding supervisor must ensure the cleaning and disinfecting personnel understand and follow the training and work procedures created in collaboration with the DPP Administrator. Only trained and qualified cleaning and disinfecting personnel may be allowed to clean controlled areas. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.2, 5.1.2.2 OHSA RSO 1990, Chapter O.1, s 25, s 26
	☐	The sterile compounding supervisor must ensure the competency of the certifier and the personnel chosen to conduct the sampling, and that the certification is performed in accordance with the most recent certification standards. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.3, 5.1.2.4
	☐	The sterile compounding supervisor must analyze the data obtained via air sampling, surface sampling or GFS and the trends observed with respect to the microbial load. If necessary, the sterile compounding supervisor should consult a microbiologist or infectious diseases specialist. NAPRA Non-Hazardous Sterile Preparations (2016) 7.5, 7.3.2.3, 7.4
The DPP Administer or delegate must be responsible for ensuring that all standards of practice associated with compounding the preparation have been met before releasing a preparation(s).	☐	The DPP Administrator or delegate must be responsible for ensuring that there is a compounding procedure /worksheet is completed and has calculations and measurements for each preparation produced. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.3,6.2, 6.3.1,6.3.2, OHSA RSO 1990, Chapter 1, s 26(1) WHMIS
	☐	The DPP Administrator or delegate must be responsible for enforcing/ensuring compliance with required rules relating to asepsis, hygiene, cleanliness and safety. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.3, WHMIS
	☐	The DPP Administrator or delegate must be responsible for ensuring application and compliance with existing compounding procedures and to follow the compounding process defined in the compounding protocol. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.3
	☐	The DPP Administrator or delegate must be responsible for ensuring verification is performed during the various stages of compounding. All required verification and quality control measures must ensure the quality, sterility and verification of the final preparation. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.1.3
All compounding personnel have received specific training and completed a competency assessment program in the workplace.	☐	The initial training and assessment program for compounding personnel must have the following components: reading and understanding the policies and procedures related to compounded sterile preparations; theoretical training, with assessment covering various topics; individualized practical training and assessment in the workplace clean room; assessment of aseptic techniques, based on gloved fingertip sampling (GFS) and a media fill test, for the various types of sterile preparations to be compounded. The training and assessment records will be readily available and up-to-date. Non-Hazardous Sterile Preparations (2016) 5.1.2.2 OHSA RSO 1990, C. O.1,s 25 , s 26 , s 27

	☐	A competency assessment program for all compounding personnel must be implemented in the workplace. This program must include the following: a theoretical test measuring required knowledge of policies and procedures, the aseptic compounding process, and accidental exposure and spills; a practical test in the workplace clean room (including GFS and a media fill test, with simulations involving a sterile product) to evaluate compliance with operating procedures and knowledge of aseptic compounding processes. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.3 OHSA RSO 1990, C 0.1, s 25, s 26
	☐	Personnel must pass GFS and a media fill test before working in the compounding area for sterile products. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.2, 7.4
	☐	Any other person who enters the sterile compounding area or who is involved in sterile compounding processes must be adequately trained and comply with specific policies and procedures. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.2, 5.1.2.3 OHSA RSO 1990, C. 0.1, s 25 , s 26, s27
	☐	All personnel assigned to the compounding of sterile preparations must undergo assessment at the following frequencies: 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 high risk level. NAPRA Non-Hazardous Sterile Preparations (2016) (5.1.2.2, 5.1.2.3,7.4)
	☐	A Pharmacist, whose activities are limited to supervising a Pharmacy Technician or pharmacy assistant during the compounding of sterile preparations, must possess a good understanding of the policies and procedures related to sterile compounding and demonstrate the ability to determine whether the compounding personnel are compliant with aseptic process. They must pass the practical section of the training program regarding assessment of the aseptic compounding process, the media fill test and GFS, if there is a possibility that this pharmacist will compound sterile preparations on an occasional basis NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.3, 7.4
All cleaning and disinfecting personnel have received initial training and completed a competency assessment program in the workplace.	☐	The initial training and assessment program for cleaning and disinfecting personnel must have the following components: theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding sterile preparations; practical training and assessment in the areas reserved for the compounding of sterile preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.1.2.2, Appendix 3, Training of Compounding Personnel and Cleaning and Disinfecting Personnel
	☐	A competency assessment program for cleaning and disinfecting personnel must be implemented in the workplace. NAPRA Non-Hazardous Sterile Preparation (2016) (5.1.2.3, 5.3.4.4, 5.3.4.5)

PERSONNEL INVOLVED IN ASEPTIC COMPOUNDING	
STANDARD	**GUIDANCE**
There is a quality assurance program in place that addresses the personnel involved in aseptic compounding.	☐ The quality assurance program for the aseptic compounding process for personnel must include GFS and a media fill test, must be performed under real compounding conditions and must represent the most complex preparation according to the microbiological risk. NAPRA Non-Hazardous Sterile Preparation (2016) 7.4.1 and 7.4.2
There is a quality assurance program in place that addresses the content of the program itself, the results & actions taken, the product preparation process and documentation.	☐ The sterile compounding supervisor must establish a quality assurance program to ensure the clear definition, application and verification of all activities that will affect the quality of compounded sterile preparations and the protection of personnel. In addition, must also ensure that sterile preparations are compounded in compliance with established procedures. NAPRA Non-Hazardous Sterile Preparation (2016) 7.1,7.2,7.3 and Appendix 12 (Components of a Quality Assurance Program), NAPRA MSOP RPh. (3.10 - 3.16 inclusive)
	☐ The quality assurance program must have four components; 1) verification of equipment, including the PEC 2) verification of controlled areas (clean room and anteroom) 3) verification of aseptic compounding processes 4) verification of final preparations For each of the specified components, the sterile compounding supervisor must establish 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. Each component of the quality assurance program and its activities must be documented. NAPRA Non-Hazardous Sterile Preparations (2016) 7.1, 7.2, 7.3,7.4, 7.5, 7.6
	☐ Written documentation related to the quality assurance program must be verified, analyzed and signed by the sterile compounding supervisor and retained for a period designated in federal/provincial/ regulations. NAPRA Non-Hazardous Sterile Preparations (2016) 7.6
CORE REQUIREMENTS – FACILITIES AND EQUIPMENT	
The clean room is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐ Facilities for the compounding of Non-hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, with provincial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3
	☐ Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the PEC is located, and an anteroom, located next to the clean room. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.5

	☐ The DPP must not compound Non-hazardous sterile preparations in a segregated area. The PEC must be positioned in an ISO Class 7 clean room that is adjacent to an ISO Class 8 anteroom. NAPRA Non-Hazardous Sterile Preparations (2016) 6.1.5
	☐ The clean room must be physically separated from the contiguous areas by walls, doors and pass-throughs. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.5
	☐ The clean room must be used only for the compounding of Non- hazardous sterile preparations. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.6
	☐ 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. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.5, Table 2,Table 3
	☐ ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.5, Table 2
	☐ The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and PECs. The particle count may also be measured by a qualified certifier. NAPRA Non-Hazardous Sterile Preparations (2016) 7.3.2.3
	☐ Facilities that compound both hazardous and Non-hazardous sterile preparations must have two clean rooms: one for the compounding of hazardous sterile preparations and the other for the compounding of Non- hazardous sterile preparations, as well as an anteroom for each type of compounding. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.5, 5.3.2.6
	☐ The air supplied to areas used for compounding Non-hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter. HEPA filters are regularly maintained and tested. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.3
	☐ Return air intakes should be installed at the bottom of walls, forcing the particles to flow downward. Ensure that air vents are not obstructed. NAPRA Non-Hazardous Sterile Compounding 2016 5.3.2.3
	☐ 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 Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ All joints must be sealed. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐ Flooring must be flat, smooth, impervious, non-friable, non- porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed immediately. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8

	☐	In the clean room, the floor must be covered up the side wall, at least 10-15 cm. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	There must be no carpets, rugs, “sticky mats” or anti-fatigue mats. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
An anteroom is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐	Facilities for the compounding of Non-hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, with provincial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3
	☐	The Non-hazardous anteroom must be separated into two spaces by a visible demarcation line: the first space or area, referred to as “dirty”, is located at the entrance to the anteroom, in the section adjacent to the non-controlled area; the second space or area, referred to as “clean”, is adjacent to the dirty area on one side and the clean room on the other. NAPRA Non-Hazardous Sterile Preparations 2016 (5.3.2.5)
	☐	Activity in the anteroom, with higher generation of particulates, must be kept to a minimum and must be limited to those activities that are essential to or that directly support the work undertaken in the clean room. (e.g. Garbing, hand hygiene, labelling, staging). NAPRA Non-Hazardous Sterile Preparations 2016 (5.3.2.5)
	☐	Access of supplies, equipment and personnel into the clean room must be through the anteroom. No supplies, equipment or personnel must enter into the clean room from a non-controlled area. NAPRA Non-Hazardous Sterile Preparations 2016 (5.3.2.5)
	☐	ISO Class 8 air quality must be maintained in the anteroom under dynamic operating conditions. NAPRA Sterile Preparations (2016) 5.3.2.5, Table 3
	☐	The air supplied to areas used for compounding Non-hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.2.3
	☐	Return air intakes should be installed at the bottom of walls, forcing the particles to flow downward. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.2.3
	☐	The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and PECs. The particle count may also be measured by a qualified certifier. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.2.3
	☐	The surfaces of ceilings (with all joints sealed), 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 Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	Joints between the ceiling and walls should be free of sharp corners where foreign substances could accumulate. In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in ceilings must be repaired and sealed at the earliest opportunity. NAPRA Non-Hazardous Sterile Compounding (2016) 5.3.2.8

	☐	If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	Flooring must be flat, smooth, impervious, non-friable, non-porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed immediately. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	In the anteroom, the floor must be coved up the side wall, at least 10–15 cm. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
	☐	There must be no carpets, rugs, “sticky mats” or anti-fatigue mats. NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.2.8
Personal Protective Equipment (PPE) for the compounding of Non-hazardous sterile preparations must meet the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐	Compounding personnel must wear dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs). NAPRA Non-Hazardous Sterile Preparations (2016) 5.3.3.3, 6.6.2 OHSA 25 (2) (h), Ont. Reg. 67/93 S. 9(4), 10.1 (PPE) OHS R.S.O. 1990 Chapter 0.1, s 28
	☐	One pair of shoe covers or dedicated shoes are required at all times in the clean area of the anteroom and in the clean room. NAPRA Non-Hazardous Sterile Preparations (2016)5.3.3.3, 6.6.2.2 OHSA R.S.O. 1990, CHAPTER O.1 s.25, s.27, 28 (1)
	☐	A disposable hair cover must be worn during the compounding of sterile preparations. OHSA R.S.O. 1990, CHAPTER O.1 s.25, s.27, 28 (1) NAPRA Non-Hazardous Sterile Prep (2016) 5.3.3.3, 6.6.2.2
	☐	A face mask must be worn during the compounding of sterile preparations OHSA R.S.O. 1990, CHAPTER O.1 s.25, s.27, s 28 (1) NAPRA Non-Hazardous Sterile Preparations (2016) 6.6.2.2 (FIT testing): OHSA 25 (2) (h), Ont.reg. 67/93 S. 9(4), PPE 10.(1),(2)
	☐	If the compounder has facial hair, a disposable beard cover must be worn while compounding sterile preparations. OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) NAPRA Non-Hazardous Sterile Preparations (2016) 6.6.2.2, 5.3.3.3
	☐	Non-powdered sterile gloves which cover the cuffs of the non-shedding gown must be used in the clean room, in the clean area of the anteroom and during aseptic processes. OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) NAPRA Non-Hazardous Sterile Preparations 2016 (6.6.2.2, 5.3.3.3 and Table 5)
	☐	A non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) must be worn. OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) NAPRA Non-Hazardous Sterile Preparations (2016) (6.6.2.2, 5.3.3.3)

Equipment for the compounding of Non- hazardous sterile preparations is designed, built, and maintained in accordance with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐ For Non-hazardous compounding, the DPP must use either LAFWs and/or CAIs as PEC. NAPRA Non-hazardous Sterile Preparations 2016 (5.3.3.1)
	☐ The Primary Engineering Control (PEC) must ensure an ISO Class 5 air quality environment for the exposure of critical sites when sterile preparations are being compounded. NAPRA Non-hazardous Sterile Preparations 2016 (5.3.3.1)
	☐ Each PEC must be certified at least every 6 months, when relocated, after major repairs or when viable air sampling indicates that the PEC may not be in compliance with specifications. NAPRA Non-hazardous Sterile Preparations (2016) (5.3.3.1)
	☐ The compounding aseptic isolator (CAI) must be positioned in an ISO Class 7 clean room adjacent to an ISO Class 8 anteroom. NAPRA Non-hazardous Sterile Preparations (2016) (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. NAPRA Non-hazardous Sterile Preparations (2016)(5.3.3.1)
	☐ Sterile Isopropyl Alcohol (Sterile IPA) 70% must be available for use in the appropriate areas. NAPRA Non-Hazardous Sterile Preparations (2016) (6.6.3, 5.3.3.2, 6.6.4, 6.6.5, Table 9)
	☐ Refrigerator and freezer used to store Non-hazardous drugs must be commercial, biomedical-grade units. They must not be used to store food or other medications/solutions, etc. NAPRA Non-hazardous Sterile Preparations (2016) (5.3.3.2) Occupational Health and Safety Act O.Reg.67/93, s. 32
	☐ Preventive maintenance for PECs and othr equipment must be performed when no compounding is in progress, before cleaning and disinfection operations. NAPRA Non-hazardous Sterile Preparations (2016) (5.3.3.1)
	☐ The automated compounding device (ACD) must be positioned in the PEC such that compounding occurs while critical sites are exposed to first air. NAPRA Non-hazardous Sterile Preparations (2016) 5.3.3.2
	☐ Carts used to bring supplies into the anteroom from outside the controlled area must not cross the demarcation line. Likewise, carts taken into the anteroom from the clean room shall not be moved beyond the clean side of the demarcation line. NAPRA Non-hazardous Sterile Preparations (2016), 5.3.3.2
	☐ An incubator is used to maintain a constant temperature for the culture of microorganisms. The incubation temperature must be controlled (20°C to 25°C or 30°C to 35°C, depending on the culture medium and incubation period). NAPRA Non-hazardous Sterile Preparations (2016), 5.3.3.2
	☐ Equipment used for cleaning and disinfection and its storage must be specifically designated for cleaning areas used for the compounding of Non-hazardous sterile preparations. NAPRA Non-hazardous Sterile Preparations (2016) ,5.3.4.3

There is a cleaning and disinfecting procedure in place that addresses all sterile compounding areas.	☐	Personnel working in sterile compounding must comply with the requirements for cleaning and disinfecting as outlined in NAPRA. Daily cleaning and disinfecting are required for the following surfaces and areas: PEC, counters, carts, floors, surfaces that are touched frequently (e.g., doorknobs, switches, chairs. Waste and garbage removed daily. Monthly cleaning and disinfecting are required for the following surfaces and areas: walls, ceiling, shelves, and outer surfaces of the PEC. Disinfect the work surface of the PEC according to established procedures, ensuring the minimum, frequency of disinfection as outlined in Table 9. If a different frequency of disinfection is to be followed, it should be established and justified by the results of air and surface sampling for viable particles. NAPRA Non-Hazardous Sterile Compounding Preparations (2016). 5.3.4., 5.3.4.2, 5.3.4.5, 6.6.4, Table 9
	☐	A sporicidal agent must be used weekly to augment the use of a germicidal disinfectant detergent (that is required to disinfect all surfaces in a clean room and anteroom). NAPRA Non- Hazardous Sterile Preparations (2016)5.3.4.2
	☐	Cleaning and disinfecting personnel must comply with the DPP's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties. NAPRA Non-Hazardous Sterile Preparation (2016),5.3.4.4
	☐	The DPP must have a policy in place to ensure the use of sterile 70% isopropyl alcohol (IPA) for the disinfection of gloved hands surfaces/equipment/supplies used in the compounding of sterile products. NAPRA Non-Hazardous Sterile Preparations (2016), (5.3.3.2,6.6.2.2, 6.6.3, 6.6.4, 6.6.5, Table 9) CSHP Compounding for Pharmacies (2014) s 17.3
VERIFICATION OF EQUIPMENT AND FACILITIES		
There is an environmental verification program in place that meets the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐	An environmental program must be established to ensure that facilities that engage in Non-hazardous compounding uphold the quality and safety standards set by the industry. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	The differential pressure between controlled areas must be kept constant. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	Pressure must be measured continuously, and an alarm system must be in place to immediately advise personnel of noncompliance with specifications and to direct that action be taken. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	The indicators for proper operation of any device (LAFW, CAI, ACD, etc.) must be verified every day, and data must be recorded in the general maintenance log. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	The temperature of controlled sterile compounding areas must be verified and documented at least once a day. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3

	☐	Sampling of viable, non-viable and surface particles in controlled areas and the PEC must be completed. Minimally from air within the controlled areas and PEC every six months. Whenever there is new equipment installed or a new controlled area, during maintenance or repair of equipment or controlled area and during investigation of a contamination problem or problem involving non-compliance of personnel with aseptic processes. Samples should be taken more frequently during the first six months to establish baseline. Samples must always be obtained under dynamic operating conditions. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	An investigation must be undertaken when a contamination or a problem involving non-compliance in the aseptic compounding process is discovered. NAPRA Non-Hazardous Sterile Preparations (2016), 7.6
	☐	A written sampling plan for controlled areas and the PEC must be established. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3
	☐	If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism must be identified. Corrective and preventive actions (e.g., cleaning, disinfecting) must be completed and documented. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.2.3, 7.6
There is a quality assurance program in place that addresses the verification of equipment and facilities.	☐	Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, must be certified with respect to its installation and operation and must be calibrated before being put into service and thereafter as recommended by the manufacturer. NAPRA Non-Hazardous Sterile Preparations (2016), 7.3.1.1
	☐	The DPP must have policies and procedures related to routine calibration and maintenance of equipment and technology. NAPRA Non-Hazardous Sterile Preparations (2016), 5.3.3.1,5.3.3.2,5.4,7.3
	☐	At least once a day, compounding personnel must check the temperature log of equipment (e.g., refrigerator, freezer, incubator), to review temperatures over the previous 24 hours, and must take corrective actions if needed. For integrated recording devices the temperatures over the previous 24 hours must be reviewed. For manual thermometers, there must be twice daily readings including minimum and maximum readings. NAPRA Non-Hazardous Sterile Preparations (2016) 7.3, 7.3.1.2
	☐	The general maintenance logs must be complete, accurate and maintained as per standards of practice and NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. NAPRA Non-Hazardous Sterile Preparations (2016), 5.4

BEYOND USE DATE (BUD) AND DATING METHODS

STANDARD	GUIDANCE
The DPP's operating procedures describe the risk assessment process used to establish the Beyond Use Date (BUD) and the storage conditions according to the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.	☐ The Sterile Compounding Supervisor must be responsible for assigning the BUDs when there is no specific sterility testing for a preparation or a batch. The BUD must not exceed the earliest of the dates established by the following two criteria: 1. expiration date based on chemical and physical stability as per acceptable stability references (i.e. reference text or peer-reviewed journal). 2. storage time related to risk of microbial contamination. NAPRA Non-Hazardous Sterile Preparation (2016) 6.1.1, CSHP Compounding Guidelines 2014 s. 19.7, Appendix C
	☐ Levels of risk for microbial contamination apply to preparations compounded in a compliant, certified PEC that maintains ISO Class 5 air quality or better and that is located in an ISO Class 7 clean room or a compliant certified CAI that meets the criteria specified when placed in environments with particle counts exceeding ISO Class 7. NAPRA Non-Hazardous Sterile Preparations (2016)6.1.3
	☐ Low Risk preparations are prepared and must meet the beyond use dates; • final product compounded using up to 3 "sterile units", • no more than 2 septum punctures at the injection site for each sterile unit, • simple aseptic transfer technique drug prepared for one patient (patient- specific dose) Risk of contamination Low; • At controlled room temperature BUD must be no more than 48 hours, • With storage in refrigerator BUD must be no more than 14 days, • With storage in freezer BUD must be no more than 45 days. NAPRA Non-Hazardous Sterile Preparations (2016), 6.1.3, Table 6 and 7
	☐ Medium Risk preparations are prepared and must meet beyond- use dates; • final product compounded using 4 or more "sterile units", • complex manipulations; prolonged preparation time, • batch preparations (preparing more than one unit of the same composition during one compounding session). • Risk of contamination Medium; • At controlled room temperature BUD must be no more than 30 hours, • With storage in refrigerator BUD must be no more than 9 days, • With storage in freezer BUD must be no more than 45 days. NAPRA Non-Hazardous Sterile Preparations (2016), 6.1.3, Table 6 and 7

	☐	High Risk preparations are prepared and must meet beyond- use dates; • non-sterile ingredients or equipment used before terminal sterilization, • non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization, • improper garbing or gloving by compounding personnel. Risk of contamination High; • At controlled room temperature BUD must be no more than 24 hours, • With storage in refrigerator BUD must be no more than 3 days, • With storage in freezer BUD must be no more than 45 days. NAPRA Non-Hazardous Sterile Preparations (2016), 6.1.3, Table 6 and 7
	☐	The DPP must have evidence to support an extended BUD. The DPP ensures that they have performed sterility tests to establish a longer BUD. The sterility test must be completed using a validated sterility test (i.e. USP) and there must be acceptable stability data. Preparations must be quarantined while awaiting results of the sterility test. Preparations may be released once the results of the sterility test are obtained. NAPRA Non-Hazardous Sterile Preparation (2016).6.1.1 OCP Guideline: "Extending the Beyond Use Date for Sterile Preparations"
	☐	The DPP must have a policy in place to specify the beyond use dating of single-dose vials. No storage of an open ampoule is permitted; as such, no BUD applies. NAPRA Non-Hazardous Sterile Preparation (2016) 6.1.2.1,6.1.2.2
	☐	The DPP must have a policy in place to specify the beyond use dating of multi-dose vials. NAPRA Non-Hazardous Sterile Preparation (2016) 6.1.2.3
	☐	The DPP must have processes to ensure that high risk preparations are sterilized. The DPP has documentation to demonstrate that sterility test(s) via membrane filtration and a bacterial endotoxin test(s) for high-risk sterile preparations (see Table 6) have been performed in the following situations: when sterile preparations are compounded in batches of over 25 identical units, when there has been more than 12 hours of exposure time at a temperature between 2°C and 8°C before sterilization, when there has been more than 6 hours of exposure time at a temperature above 8°C before sterilization. NAPRA Non-Hazardous Sterile Preparation (2016) 6.1.3
RECALL OF STERILE PRODUCTS OR FINAL COMPOUNDED STERILE PREPARATIONS		
There is a process in place when a product or preparation does not meet requirements due to issues of internal control and/or a complaint or a product recall.	☐	If 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 DPP Administrator or delegate must be able to notify customers that there is a problem with the preparation. NAPRA Non-Hazardous Sterile Preparation (2016) 6.10
	☐	The DPP must ensure that the customer will identify patients who have received the CSP and perform the necessary follow-up if the preparation has been administered. The process must include documentation of actions. NAPRA Non-Hazardous Sterile Preparation (2016) 6.10

RECEIPT OF PRODUCTS	
The DPP has policies and procedures in place to ensure safe receipt of products used for sterile compounding.	☐ Space must be provided for unpacking supplies. NAPRA Non-Hazardous Sterile Preparation (2016) 6.8, 5.3.2.5 OCP Protecting the Cold Chain Policy
	☐ Products used for preparations must be unpacked outside of controlled areas (clean room and anteroom), to limit the introduction of dust and particles into the controlled areas. NAPRA Non-Hazardous Sterile Preparation (2016) 5.3.2.5, 6.8
	☐ Before any product is introduced into the anteroom, it must be removed from its cardboard shipping box. The product must then be wiped with a sporicidal agent. NAPRA Non-Hazardous Sterile Preparation (2016) 5.3.2.5, 6.6.3
LABELLING	
Labelling of the final compounded sterile preparation meets NAPRA Model Standards for Pharmacy Compounding of Non- Hazardous Sterile Preparations and provincial requirements.	☐ Each container for a compounded sterile preparation must be labelled. NAPRA Non-Hazardous Sterile Preparation (2016) 6.6.7, 6.6.7.1
The DPP has a policy in place to ensure that labels are consistent and comply with standards.	☐ The label must contain the following information, at a minimum: DPP identification (name, address and telephone number); drug identification (active ingredients, source, concentration, form, route of administration, volume, solute, amount prepared); overfill volume, when overfilling has occurred; special precautions, storage conditions; date when the sterile preparation was compounded; BUD and preparation batch number. An accompanying package insert must contain the following information: details concerning the mode of administration, special precautions related to drug storage, special precautions regarding disposal and emergency contact information for the DPP. NAPRA Non-Hazardous Sterile Preparation (2016), 6.6.61, 6.6.7.2
WASTE MANAGEMENT	
The DPP has a Non-hazardous waste management process in place.	☐ The DPP must have a sufficient number of easy-to-clean waste containers of suitable size and made of materials resistant to damage from cleaning and disinfecting products must be available. NAPRA Non-Hazardous Sterile Preparation (2016) 6.12
	☐ The DPP Administrator or delegate must ensure that medication and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws in force in the jurisdiction. NAPRA Non-Hazardous Sterile Preparation (2016) 6.12
	☐ The DPP Administrator or delegate must ensure that hazardous medications to be destroyed are safely stored in a location separate from other medications in inventory. NAPRA Non-Hazardous Sterile Preparation (2016)6.12
	☐ There must be a procedure developed and implemented for the destruction of pharmaceutical waste. NAPRA Non-Hazardous Sterile Preparation (2016) 6.12

Drug Preparation Premise (DPP) Non-Sterile Preparations Assessment Criteria

The following chart outlines key NAPRA Model Standards for DPP Compounding of Non-Sterile Preparations, divided by sections, with each statement in the first column representing a specific standard to be met. The guidance column references the corresponding sections of the accompanying NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations ("Guidance Document" or GD) and illustrates specific insights or activities required to ensure adherence to the standard.
This document is provided to assist registrants in understanding expectations, conducting a gap analysis to current processes, and preparing for full implementation of the Standards. For each standard, check the guidance that your DPP has in place and continue to work on achieving the remaining criteria prior to the implementation date. Implementation priorities and timelines for completion of each phase are:

- Phase 1: January 1, 2020 – Assessing Risks and Gaps
- Phase 2: July 1, 2021 – Personnel Training and Quality Assurance
- Phase 3: January 1, 2022 – Facilities and Equipment

Section 2: Objectives and Section 3: Regulatory Framework	
STANDARD	**GUIDANCE**
The DPP Administrator ensures that compounding personnel use professional judgment to determine if non-sterile compounding is appropriate.	☐ Compounding personnel must consider the general guidance in Section 2.1 of the Guidance Document when determining whether to compound a non-sterile preparation. GD – Section 2.1
	☐ Compounding personnel should review the questionnaire in Section 3.1 of the Guidance Document, which provides general guidelines to differentiate between non-sterile compounding and manufacturing activities. GD – Section 3.1
	☐ DPP staff should review the *Policy on Manufacturing and Compounding Drug Products in Canada* (POL-0051) on the Health Canada website.
Section 4: Assessing Risk for Compounding Non-Sterile Products	
STANDARD	**GUIDANCE**
The DPP Administrator ensures that a risk assessment has been performed to identify the appropriate level of requirements to minimize contamination of each non-sterile compounded preparation and to provide adequate protection for personnel.	☐ A risk assessment must be undertaken, covering risk to preparation and risk to person. Factors to consider include: Complexity of compounding the preparation, need for verification, frequency of compounding, risk of cross- contamination, physical characteristics and quantities of ingredients, facilities and equipment, type of hazardous drug, exposure to compounding personnel, and risk of microbial contamination. GD – Section 4 / 4.1
	☐ The risk assessment(s) must be reviewed at least every 12 months to ensure that it is still valid or more frequently if there is a change in practice or standards. GD – Section 4 / 4.1
	☐ The risk assessment(s) undertaken must utilize the Decision Algorithm for Risk Assessment in Section 4.2 of the Guidance Document to determine risk level and requirements for non-sterile compounds. GD – Section 4.2

	☐ The requirements for safe non-sterile compounding of all materials must be researched and documented.
	☐ Safety data sheets and other applicable references must be consulted, and appropriate procedures for safe compounding must be documented on the Master Formulation Record. GD –Section 4 / 4.2
	☐ DPP Administrator and Compounding personnel must review Section 4.3 in the NAPRA Guidance Document for references for assessing risk. GD – Section 4.3

Section 5: Requirements for All Levels of Non-Sterile Compounding Activities

STANDARD	GUIDANCE
The DPP Administrator ensures responsibility for all activities related to non-sterile compounding.	☐ The DPP Administrator must ensure the development, organization and supervision of all activities related to compounding of non sterile preparations in the pharmacy. These responsibilities may be assigned to a pharmacist or pharmacy technician who will be designated the non-sterile compounding supervisor. GD – Section 5.1
The non sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of non sterile preparations in the DPP	☐ There must be a non-sterile compounding supervisor designated to develop, organize and oversee all activities related to the compounding of non-sterile preparations in the DPP. GD – Section 5.1.2
	☐ The non-sterile compounding supervisor must be a pharmacist or pharmacy technician, as assigned by the DPP Administrator. GD – Section 5.1.2)
	☐ The non-sterile compounding supervisor must ensure the requirements outlined in Section 5.1.2 Guidance Document are met. GD – Section 5.1.2)
	☐ The non-sterile compounding supervisor must successfully complete the Non-Sterile Compounding Supervisor Training Course located on the OCP website.
	☐ DPP staff involved in compounding may complete the Non-Sterile Compounding Supervisor Training Course located on the OCP website.
Policies and procedures are in place for all activities related to non-sterile compounding	☐ The policies and procedures for all activities related to non- sterile compounding must be established and be readily retrievable to staff. Policies and procedures must provide detailed descriptions of all activities, including cleaning. GD -Section 5.3
	☐ The policies and procedures must be reviewed at least every 3 years or more frequently if there is a change in practice or standards. GD - Section 5.3
	☐ The DPP must have a process in place to verify (using an independent check where possible) each critical step (calculations, selection and measurement of ingredients, and mixing technique (if applicable), as well as a final check of the finished product, regardless of the individuals preparing the product) including sign off at appropriate intervals. GD - section 5.2.1.1

	☐	The DPP Administrator and staff must review Sections 5.3.1 and 5.3.2 in the Guidance Document for examples of, and template for, policies and procedures. GD - section 5.3.1 / 5.3.2
	☐	DPP staff must review the ISMP Canada Safety Bulletin - Death Due to Pharmacy Compounding Error Reinforces Need for Safety Focus (May 25, 2017) located on the ISMP Canada website.
All personnel involved in non-sterile compounding have the required expertise.	☐	All Non-sterile compounding personnel must know and comply with established policies and procedures. GD – Section 5.1
	☐	A training and skills assessment program must be established, administered and documented for all personnel involved in non-sterile compounding. GD –Section 5.2
	☐	The DPP Administrator and or delegate must review Table 1 in Section 5.2.1 in the Guidance Document for elements to cover in the training of non-sterile compounding personnel. GD – Section 5.2.1
	☐	The DPP Administrator and or delegate must review Checklist 1 in Section 5.2.1.1 in the Guidance Document for an example of a skills assessment for the steps in the non-sterile compounding process. GD – Section 5.2.1.1
	☐	All cleaning personnel must be trained and aware of roles and responsibilities as outlined in Table 2 in Section 5.2.2 of the Guidance Document. GD– Section 5.2.2
	☐	For hazardous non-sterile compounding, only trained and qualified cleaning and disinfecting personnel must be allowed to clean controlled rooms. GD – Section 9.3
	☐	For hazardous non-sterile compounding, Cleaning personnel must comply with the DPP's hand hygiene and garbing procedure before they enter areas reserved for compounding hazardous products to perform housekeeping duties. GD – Section 9.3.1
Non-sterile compounding is performed in a separate, specifically designated space that is appropriate for compounding and maintained to ensure the quality and integrity of the final preparation.	☐	All non-sterile compounding must be performed in a separate space specifically designated for compounding , which should be located away from parts of the DPP where there is a considerable amount of traffic and large enough for the orderly placement of equipment and products, to avoid cross-contamination, and for compounding personnel to work comfortably and safely. GD – Section 5.4.1
	☐	The areas used for non-sterile compounding must be maintained in clean, orderly and sanitary conditions with appropriate and sanitary waste disposal, and shall be maintained in a good state of repair. GD – Section 5.4.1
	☐	All components, equipment, and containers must be stored off the floor. To limit the accumulation of dust and particles, packaging and cardboard boxes from products used must not be allowed in the non-sterile compounding area. GD – Section 5.4.1 #84

	☐	The heating, ventilation and air conditioning system must be 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 non-sterile compounding personnel. Air vents should not be located directly over work areas, to avoid contamination of the products. Temperature and humidity monitoring must be performed. GD – Section 5.4.1.3
	☐	Work surfaces and furniture, as well as floor and wall surfaces, must be designed and placed to facilitate cleaning (e.g. constructed of smooth, impervious, and non-porous materials that are able to withstand repeated cleaning and disinfecting). GD – Section 5.4.1.5
A clean water supply, with hot and cold running water, is available in or close to the non-sterile compounding area.	☐	A clean water supply, with hot and cold running water, must be available in or close to the non-sterile compounding area or, for Level B and Level C requirements, in the non-sterile compounding room. GD– Section 5.4.1.4
Equipment, instruments and accessories are appropriate for the type of preparations to be compounded, and are maintained and cleaned.	☐	Equipment, instruments and accessories must be appropriate for the type of non-sterile preparations to be compounded, be cleaned after each use, and must not negatively affect the purity or quality of the preparation being compounded. GD – Section 5.4.2
	☐	Equipment, instruments and accessories should be routinely inspected 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 manufacturer recommendations. Records of calibration dates for equipment and instruments must be maintained and be readily retrievable. GD – Section 5.4.2

Section 6: Product and Preparation Requirements

STANDARD	GUIDANCE	
Beyond-use dates are appropriately assigned based on appropriate evidence and literature.	☐	The DPP must ensure that Beyond-use dates (BUDs) must be assigned conservatively. GD – Section 6.1
	☐	When assigning beyond-use dates, literature and documentation available on stability in general and on the specific stability of the active pharmaceutical ingredient (API) must be consulted. GD – Section 6.1
	☐	When a manufactured drug is used as the API, information provided by the manufacturer may be used as a reference for assigning beyond-use dates, but the manufacturer's expiry date for the drug must not be used as the beyond-use date for the final preparation. GD – Section 6.1
	☐	When determining beyond-use dates, other considerations in addition to stability must be considered such as the nature of the ingredient to be used, the compounding method, degradation mechanisms, compatibility, dosage form, potential for microbial proliferation in the preparation, the container in which the preparation is packaged, the expected storage conditions, and the intended use and duration of therapy. Documentation of these factors to be kept. GD – Section 6.1

	☐	In order to establish a longer BUD, stability tests must be performed on the specific drug or preparation, -using validated stability test(s) GD 6.1.1.
Master formulation records are established for each non-sterile compound and are readily retrievable.	☐	Master formulation records must be developed (or obtained) for each non-sterile compound. It must include all necessary information to compound the non-sterile preparation references and the developer of the formula. Review Section 6.2.1 of the Guidance Document for a template of a master formulation record. GD – Section 6.2.1
	☐	Master formulation records must be kept in a format that is readily accessible to non-sterile compounding personnel. GD – Section 6.2
Ingredients used for non-sterile compounding are obtained from recognized, reliable sources and are stored under conditions that will preserve quality and purity.	☐	The ingredients must be obtained from recognized and reliable sources. Reasonable measures should be taken to determine the purity and safety of the ingredients used for non-sterile compounding. GD – Section 6.3 , 6.3.2
	☐	The supporting documents must be obtained for the high- quality ingredients, including certificates of analysis for the ingredients. The sources of all ingredients and associated information, including lot numbers, expiry dates, and date of receipt in the DPP, must be traceable. GD – Section 6.3
	☐	All ingredients (powder, liquids, etc.) that require special precautions when used or stored must be identified. GD – Section 6.3
	☐	Ingredients and raw materials must be stored and kept safely under conditions that will preserve their quality and purity as directed by the manufacturer or according to pharmacopeia monographs. GD – Section 6.3
	☐	Safety data sheets must be kept up-to-date and be made available to all personnel involved in non-sterile compounding. GD – Section 6.3
The DPP keeps complete compounding records for non-sterile preparations.	☐	The DPP must keep a compounding record for each preparation(s), including: the name, source, lot number and expiry date of each active ingredient; the quantity required and weighed; the date of preparation; the assigned BUD; the name of the compounder, the DPP Administrator or assigned individual responsible for quality control, and the person who approved the preparation; and reference to the master formulation record for the preparation. Quality control procedures or issues must be documented as appropriate. GD – Section 6.4
Personnel behave in a professional manner, following all pertinent policies and procedures.	☐	All personnel must take reasonable measures to ensure hygiene, safety, and to avoid possible contamination during nonsterile compounding. This includes using appropriate personal protective equipment, avoiding sources that might contaminate the preparation (e.g. jewelry, food and drink), and following all pertinent policies. GD – Section 6.5

	☐ The DPP ensures that Personal Protective Equipment (PPE) approved for the compounding of non-sterile preparations must be worn and replaced/discarded at the appropriate intervals during compounding activities. GD-6.5
Steps are taken to verify each stage of the process, as well as the final compounded non-sterile preparation. compounding	☐ Each stage of the non-sterile compounding process, in addition to the final preparation, must be verified. This includes the formula, calculations, ingredients and their amounts, compounding technique, the compounding record and the master formulation record, the final label, and the final preparation in its final packaging. GD – Section 6.6
The DPP has processes in place to ensure compounded preparations are labelled and packaged appropriately.	☐ The preparation label (and if necessary, a supplementary label) must identify all active ingredients and the concentration of each active ingredient. GD – Section 6.7
	☐ The preparation label (and if necessary, a supplementary label) must include the beyond use date, as well as special storage and handling information if applicable. GD – Section 6.7
	☐ The packaging, container, storage and transportation are suitable for the stability of the preparation and proper patient use. GD – Section 6.7.3
The DPP has a recall procedure for compounded non-sterile preparations.	☐ If as a result of internal control, a complaint or a product recall shows that the grade or quality of a preparation does not meet requirements, the DPP must have a recall procedure to notify customers that have received the compounded non-sterile preparation. The DPP Administrator or delegate will ensure that their customers notify patient(s) of the recall and perform the necessary follow-up if the preparation has been administered. The process must be documented. GD – Section 6.10
Section 7: Quality Assurance	
STANDARD	**GUIDANCE**
A quality assurance program is in place to verify that all non-sterile compounding activities are being carried out according to the standards.	☐ A quality assurance program must be in place to verify and document that all non-sterile compounding activities are being carried out according to the Standards. GD – Section 7
	☐ The quality assurance program must address the verification of equipment and facilities and includes Verification of compounding area(s) for Level A, B, or C requirements. The areas must be verified at least every 6 months (more frequently at the start of the quality assurance program), when the controlled room is installed, when new equipment is installed, when the controlled room or equipment is repaired or maintained (e.g., when high efficiency particulate air filter is changed), when a contamination problem is identified. GD-Section 7, Table 6
	☐ The verification of daily temperature and humidity readings must be documented in controlled areas. Temperature readings from refrigerators and freezers must be verified daily. GD Table 6, 7.2.2

	☐ There must be evidence of certification of C-PEC (for Level B and C compounding). Documentation must include: before first use, every 6 months, when a new C- PEC is installed, when the C-PEC is repaired or maintained, when a contamination problem is identified, when investigation of a contamination problem or non- compliance in the preparation process requires exclusion of malfunctioning equipment. GD Table 6, 7.2.1
	☐ The manufacturers' factory issued certificates for the C- PEC must be retained for the service life of the equipment. 9.6.3, Table 6
	☐ The operational indicator logs of C-PEC and other instruments (e.g., those for automated compounding) must be reviewed regularly. GD Table 6
	☐ There must be evidence of a personnel training program that includes a skills assessment, theoretical and practical aspects. The training must be completed initially and then periodically to ensure compliance. It is repeated after an extended leave, when assessing incidents and when there is a contamination issue. GD Table 6, 7.3
	☐ There must be evidence of the QA program monitoring that preparations are compounded in compliance with established procedures. GD 7.4
	☐ There must be evidence of verification of final compounded non-sterile preparations. GD Table 6
	☐ There must be documentation that supports safe non- sterile compounding, examples include: policies and procedures that are updated every 3 years or earlier if standards change, current safety data sheets readily available, and all compounding records and logs are up-to-date. GD-Table 6
	☐ DPP Administrator and staff must review Table 6 in Section 7.6 of the Guidance Document for examples of components of a quality assurance program. GD – Section 7.6
Section 8: Levels of Requirements	
STANDARD	**GUIDANCE**
The DPP meets the requirements for non- sterile compounding (Level A, B, or C) based on the complexity and risks associated with compounding the preparation. There is not shared or combined space for the different levels.	☐ Level A: the DPP must have a separate space designated for non-sterile compounding. GD – Section 8.1
	☐ Level B: the DPP must have a separate, well-ventilated room, with a larger workspace, greater protection from cross- contamination, and appropriate equipment. The DPP may require a ventilated containment device (C-PEC; Containment Primary Engineering Control) when certain powders, aromatic products or hazardous products are compounded. GD – Section 8.2
	☐ Level C: the DPP must have a separate, well-ventilated room with appropriate air exchange and negative pressure. An appropriate C-PEC must be available for materials being compounded. GD – Section 8.3

	☐ DPP Administrator and staff, review Table 7 in Section 8.4 of the Guidance Document for a summary of requirements for compounding non- sterile preparations. GD – Section 8.4

Section 9: Requirements for Hazardous Preparations

STANDARD	GUIDANCE
The DPP ensures that facilities for the compounding of hazardous non-sterile preparations are designed and built in accordance with the Standards, and provincial and local regulations.	☐ A sink with hot and cold running water must d be available for handwashing, along with an eyewash station and/or other emergency or safety features that meet applicable laws and regulations. Water sources and drains should be located at least 1 meter away from the C-PEC. GD – Section 9.1.1
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should have external venting through high-efficiency particulate air (HEPA) filtration. GD – Section 9.1.1
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should have physical separation from other preparation rooms. GD – Section 9.1.1
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should have appropriate air exchange (at least 12 air changes per hour [ACPH]). GD – Section 9.1.1
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should have negative pressure (–2.5 Pa relative to surrounding areas). GD – Section 9.1.1
	☐ The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the hazardous non-sterile compounding area should be smooth, impermeable, free from cracks and crevices, and made of non-shedding material. GD – Section 9.1.1
	☐ Controlled rooms must not have windows or doors opening directly to the exterior of the building. Any doors or windows leading to the outside or to a non-controlled area (other than the doors designated for accessing the room) should also be sealed. GD – Section 9.1.3
	☐ A procedure must be established for receiving, unpacking and storing hazardous products that includes processes for undamaged, sealed/unsealed products and damaged packaging. Refer to Diagram 2 in the Guidance Document in Section 9.1.4. GD – Section 9.1.4
	☐ Hazardous products must be stored in a room with appropriate ventilation and identified with appropriate signage to indicate the presence of hazardous products. See Table 8 in Section 9.1.5 of the Guidance Document for required conditions for a hazardous products storage area. GD – Section 9.1.5

Appropriate equipment is in place for the handling of hazardous drugs or preparations.	☐	The C-PEC is installed in the non-sterile compounding room and should either be externally vented (preferred) or have redundant HEPA filters in a series. GD – Section 9.2.1
	☐	Hazardous non-sterile preparations, such as volatile, liquid or powder forms of cytotoxic products, should be compounded inside a C-PEC that provides protection for personnel and the environment (e.g. Class I or II biological safety cabinet, a containment ventilated enclosure (CVE), etc.). GD – Section 9.2.1
	☐	The C-PEC must be certified at installation, every six months and must be maintained according to manufacturer's recommendations, and records of maintenance should be maintained. GD – Section 9.2.1, NAPRA Non -sterile 2016 6.3.4,8.2.3.1 and NIOSH pg. 7 and table 7
	☐	All reusable instruments, devices and accessories used to handle hazardous non-sterile products must be deactivated, decontaminated and cleaned. GD – Section 9.2.2
The DPP has the PPE approved for the compounding of hazardous preparations and ensures staff compliance with use.	☐	Personal Protective Equipment (PPE) approved for the compounding of hazardous non-sterile preparations must be worn and replaced/discarded at the appropriate intervals during compounding activities, as described in Section 9.2.3 of the Guidance Document. GD – Section 9.2.3
The DPP has procedures in place to ensure that the areas used for compounding of hazardous non-sterile preparations are kept clean.	☐	The room used for compounding of hazardous non-sterile preparations must be kept clean at all times, which entails periodic washing of the walls, ceiling and storage areas. The floors must be washed at least once a day when the room is in use. GD – Section 9.3
	☐	The compounding area must be meticulously cleaned immediately after compounding of preparations containing hazardous products; it is strongly recommended that equipment used for compounding these classes of ingredients are set aside specifically for these products, or disposable equipment be used if possible, to reduce bioburden or cross-contamination. GD – Section 9.3
	☐	Safety data sheets for products used in the facility for deactivation, decontamination and cleaning must be available on site and readily accessible. GD – Section 9.3.2
The DPP has procedures in place to ensure that the equipment used for compounding of hazardous non-sterile preparations are kept clean.	☐	Equipment and accessories must be meticulously cleaned immediately after compounding of preparations containing hazardous products or allergenic ingredients; it is strongly recommended that equipment used for compounding these classes of ingredients are set aside specifically for these products, or disposable equipment be used if possible to reduce bioburden or cross-contamination.
	☐	Tablet and capsule forms of hazardous drugs must not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area. NIOSH List of Antineoplastic and other Hazardous Drugs in Healthcare settings (2016), page 2
	☐	Hazardous drug manipulation (such as crushing/splitting tablets or opening capsules) must be performed in a BSC/CACI with a plastic-backed preparation mat on the work surface, using appropriate PPE and clean equipment. NAPRA guidance document-non sterile (S 9 CSHP Compounding guidelines 2014 (17.3.3)

The DPP has procedures in place for deactivating, decontaminating and cleaning in areas reserved for the compounding of hazardous non-sterile preparations.	☐	The work surface of the C-PEC must be deactivated, decontaminated and cleaned at least daily when in use, after spills, after interruptions, if ventilation is moved, and before starting the compounding of different preparations. GD – Section 9.3.3
	☐	There must be procedures for deactivating, decontamination and cleaning in the controlled room(s) used for compounding of hazardous non-sterile preparations. For example, Minimally, the floor must be cleaned at least once a day, when the room is in use. GD-9.3
The DPP has policies and equipment are in place to handle incidents and spills involving hazardous products.	☐	The policies and procedures must be followed in case of accidental exposure of personnel to hazardous products must be established. GD – Section 9.4.1
	☐	The policies, procedures, and training programs must be established to prevent spills and to direct the cleanup of hazardous product spills. Adequate training must be provided to employees who clean up spills, including the use of spill kits, and appropriate PPE. GD – Section 9.4.2
	☐	Spill kits must be available in locations where hazardous products are handled and must be present when transporting hazardous products. The contents of spill kits must be verified regularly and their expiration dates checked. GD – Section 9.4.2
Procedures for the destruction and/or disposal of pharmaceutical waste are implemented.	☐	The procedures must be in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation. GD – Section 9.5 #100
	☐	All personnel involved in the management of hazardous product waste must receive appropriate training on destruction procedures to ensure their own protection and to prevent contamination of the premises or the environment. GD –Section 9.5
	☐	All equipment, products and vials used in the compounding of hazardous non-sterile preparations must be discarded in a hazardous waste container. GD – Section 9.5
	☐	Waste used in the compounding of hazardous non-sterile preparations must be 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. GD – Section 9.5
	☐	All PPE must be discarded into the hazardous waste container. GD – Section 9.5
	☐	Bins used for hazardous product waste must comply with local, provincial and federal requirements. GD – Section 9.5
Controlled areas are certified and verified according to standards.	☐	The controlled room (C-SEC) must be certified at installation and then at least every 6 months thereafter or after repairs/renovations. GD – Section 9.6.1
	☐	Manufacturers' factory-issued certificates for all HEPA filters must be retained for the service life of the equipment. GD – Section 9.6.3

	☐	An environmental verification program established must include verification for chemical contamination by hazardous products on surfaces used for receipt, storage, preparation and verification of product and preparations. GD – Section 9.6.3
	☐	The level of hazardous product contamination must be measured (e.g. wipe sampling) at least once every 6 months, more frequently if there has been a major change in placement of furniture, compounding processes or cleaning practices. GD – Section 9.6.3
	☐	The temperature of controlled rooms must be verified and documented at least once a day. GD – Section 9.6.3
	☐	Pressure(s) must be measured continuously in the controlled room, and an alarm system should be in place to immediately advise personnel of non-compliance with specifications. GD – Section 9.6.3
	☐	All completed documentation concerning aspects of testing controlled rooms, the C-PEC and supporting equipment for hazardous product contamination must be filed and retained. GD – Section 9.6.4