Inspection Form

DPP Information					
Name of DPP Owner		Name of DPP (if different from owner's name)			
DPP Designated Member					
Designated Member Email		Designated Member Phone number			
Street		City		Postal Code	
Phone Number		Fax Number			
Pharmacy Hours (Weekday)					
Pharmacy Hours (Weekends and Holidays)					

Inspection Information			
Last Inspection Date			
Current Inspection Date		First Inspection	☐
Type of Inspection		Re-Inspection	☐

Staff Information		
Name of Pharmacy Staff	Role	OCP Number

Service Information			
Type of Compounding		Other Services	
Non-Sterile Preparations	☐	Pre-packing/Repackaging	☐
Hazourdous Sterile Preparations	☐	Direct delivery to patient	☐
Non-Hazourdous Sterile Preparations	☐	Delivery to other organizations	☐

Extemporaneous	☐
Batch/Bulk (Non-prescription)	☐

List of organizations that regularly receive products prepared by this DPP

Additional Information

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
A. SYSTEMS TO PROVIDE SAFE, EFFECTIVE AND APPROPRIATE SERVICES FOR THE DPP **A.1 DPP PERSONNEL GENERAL**								
	☐	☐	☐	☐	**1**	The DPP does not provide direct patient care in relation to their work in the DPP.		
	☐	☐	☐	☐	**2**	DPP position descriptions contain detailed information on the knowledge, skills, experience and abilities that pharmacists, pharmacy technicians, and other DPP support personnel should possess.		CSHP Practice Management Guidelines 2007 (3.4.2.1)
	☐	☐	☐	☐	**3**	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.		OHSA R.S.O. 1990, c. O.1, s.25 (2) s.26 (l)
DPP ADMINISTRATOR / DESIGNATE								
	☐	☐	☐	☐	**4**	The DPP administrator/ designate possesses competencies, knowledge and skills to be responsible and accountable for a safe medication system.		CSHP Practice Management Guidelines 2007 (3.2.1.1)
	☐	☐	☐	☐	**5**	The DPP administrator/ designate ensures that regulated DPP personnel are active and in good standing with the Ontario College of Pharmacists.		
	☐	☐	☐	☐	**6**	The DPP administrator/ designate has the ability to evaluate appropriate staffing to support safe DPP services.		NAPRA MSOP R.Ph 2009 (2.12-2.14)
	☐	☐	☐	☐	**7**	The DPP administrator/ designate ensures that the requirements of the Narcotic and Controlled Drugs legislation as well as Benzodiazepines and other targeted substances are met.		Narcotic and Controlled Drugs; Physical Security of Controlled Drugs 1985, ONMS, Guideline for Secure Distribution of Narcotic and Controlled Drugs in Hospital 1990. Patch 4 Patch.
REGULATED DPP PERSONNEL								
	☐	☐	☐	☐	**8**	Pharmacists and pharmacy technicians know and work within their scope of practice, duties and competencies.		NAPRA MSOP R.Ph 2009 (1.4-1.5) NAPRA MSOP R.Ph T 2011 (1.5-1.7)
	☐	☐	☐	☐	**9**	Pharmacists are able to meet the required standards of practice.		NAPRA MSOP R.Ph 2009 (1.48-1.49)
	☐	☐	☐	☐	**10**	Pharmacy Technicians are able to meet the required standards of practice.		NAPRA MSOP R.Ph T 2011 (2.3)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
UNREGULATED DPP PERSONNEL								
	☐	☐	☐	☐	**11**	**Policies and procedures on delegation must be in place and adhered to if unregulated personnel or volunteers are allowed to perform the controlled acts of compounding and dispensing.**		RHPA, 1991, S.O. 1991, c. 18 s28 (1),(2) Federation of Health Regulatory Colleges of Ontario Guide to Medical Directives and Delegation http://www.regulatedhealthprofessions.on.ca/for-practitioners.html OCP Medical Directives and the Delegation of Controlled Acts Policy
A. 2 ADMINISTRATION								
	☐	☐	☐	☐	**12**	The DPP has a system to assess and update policies and procedures to ensure consistency with legislation, OCP bylaws, OCP standards, practice policies and guidelines.		NAPRA MSOP R.Ph. 2009 (1.52) AC Med Mgmt 2017 (2.1)
	☐	☐	☐	☐	**13**	The DPP provides staff with access to approved medication information resources.		
	☐	☐	☐	☐	**14**	All medication incident reports and/or documentation are reviewed and acted upon in a timely manner.		
	☐	☐	☐	☐	**15**	There is a process for review of individual medication incidents, including follow-up with individuals involved. The process includes creating an action plan for system improvements and/or risk mitigation strategies.		
	☐	☐	☐	☐	**16**	There is a process to review medication incident trends and/or summary reports. Tracking and trending is used to identify areas for improvements/changes to the medication management processes. Changes are implemented to reduce the potential for similar future incidents.		
	☐	☐	☐	☐	**17**	The DPP has documentation related to medication incident tracking and trending including resolution strategies implemented.		
	☐	☐	☐	☐	**18**	Education on patterns and trends of medication incidents is delivered to staff and documented.		
	☐	☐	☐	☐	**19**	Changes made subsequent to review of medication incidents are implemented and monitored for evidence of safer systems/processes subsequent to changes/system improvements.		
	☐	☐	☐	☐	**20**	The DPP personnel receive appropriate orientation and training to premises-specific procedures and equipment, relevant to the services provided.		OHSA R.S.O. 1990, c. O.1, s.25 (2) s.26 (l) CSHP Practice Management Guidelines 2007 (3.4.8)
	☐	☐	☐	☐	**21**	The DPP has an emergency preparedness plan.		Emergency Management and Civil Protection Act, R.S.O. 1990, c. E.9 7.0.2 (4) 4, and 5 CSHP Practice Management Guidelines 2007 (3.5.4) CSHP Guidelines for Drug-Use Control 2008 (4.4.10.4)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	22	Staff members are fit tested with N95 and/or P100 masks and/or Powdered Air Purifying Respirator (PAPR).		OHSA 25 (2) (h), Ont.reg. 67/93 S. 9(4) PPE 10. (1),(2)

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A.3 SECURITY								
	☐	☐	☐	☐	**23**	All medication storage areas are secured and protected by locked doors or similar secure barriers within DPP.		DPRA R.S.O. 1990, c. H.4 Part IV 21 (1) AC Med Mgmt 2017 (12.0)
	☐	☐	☐	☐	**24**	There is appropriate security and storage of all medications throughout the DPP. i.e. protected by locked doors or similar secure barriers.		DPRA R.S.O. 1990, c. H.4 Part IV 21 (1) AC Med Mgmt 2017 (12.0)
	☐	☐	☐	☐	**25**	The DPP keeps narcotics, controlled drugs, benzodiazepines and other targeted substances double locked and has a policy on the restriction of the access to designated staff.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals (Bureau of Dangerous Drugs, CNA,CHA,CSHP) 1990 s 5.3.2 (p.11) s. 7.2.1 (p.16)
	☐	☐	☐	☐	**26**	When the DPP is closed, the premises must be equipped with a monitored security system that will detect unauthorized entry.		
	☐	☐	☐	☐	**27**	The alarm code or keys to the DPP are restricted to staff with authority to access.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals (Bureau of Dangerous Drugs, CNA,CHA,CSHP) 1990 s 5.3.2 (p.11)
	☐	☐	☐	☐	**28**	A separate area or a secure storage area has been dedicated for non-usable and expired drugs storage until final disposal.		NAPRA Resources for Operators 2009 CSHP Guidelines for Drug-Use Control 2008 (4.3.6.1)
A.4 FACILITIES AND EQUIPMENT FOR DPP								
	☐	☐	☐	☐	**29**	The DPP has adequate work space for staff and storage space to provide safe medication practice.		DPRA R.S.O. 1990, c. H.4 Part IV s.21 CSHP Guidelines for Drug-Use Control 2008 (2.1) OCP Protecting the Cold Chain Policy
	☐	☐	☐	☐	**30**	The DPP has appropriate equipment to support safe DPP services. The following equipment must be available: a) Telephone b) Fax machine, or alternative mechanism to transmit and receive information c) Purpose-built refrigerator of sufficient size for the exclusive storage of refrigerated medications and vaccines. d) Sink with running hot and cold water e) Printers that allow computer generated labels f) A dedicated counter space for non-sterile compounding if appropriate.		OHSA, R.S.O. 1990, c. O.1 s.25 (1) CSHP Guidelines for Drug-Use Control 2008 (2.1)
	☐	☐	☐	☐	**31**	Medications are stored and prepared in proper conditions.		DPRA R.S.O. 1990, c. H.4 Part IV s.24 AC Med Mgmt 2017 (12.3, 12.4, 16.2) CSHP Guidelines for Drug-Use Control 2008 (4.3.5.2)
	☐	☐	☐	☐	**32**	DPP complies with provincial and local by-laws and requirements for water, waste disposal and air ventilation.		DPRA R.S.O. 1990, c. H.4 Part IV s.24 AC Med Mgmt 2017 (12.3, 12.4, 16.2) CSHP Guidelines for Drug-Use Control 2008 (4.3.5.2)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	33	A written workplace safe handling program is in place and reviewed annually, based on the workplace evaluation.		WHMIS AC Med Mgmt 2017 (13.2)
	☐	☐	☐	☐	34	The temperature within medication storage areas is between 15° C to 25° C to maintain potency of medications that require storage at room temperature.		
	☐	☐	☐	☐	35	The purpose built refrigerator(s) used exclusively for medication storage.		DPRA R.S.O. 1990, c. H.4 Part IV s.21 € NAPRA Non Hazardous Sterile Preparations 2015 (p.31)
	☐	☐	☐	☐	36	The purpose built freezer(s) used exclusively for medication storage.		AC Med Mgmt 2017 (12.10) NAPRA Non Hazardous Sterile Preparations 2015 (p.31)
	☐	☐	☐	☐	37	The DPP has a policy and procedure to address temperature excursions where medications and vaccines are stored.		NAPRA Non Hazardous Sterile Preparations 2015 (p.31)
	☐	☐	☐	☐	38	DPP meets DPRA and OHSA requirements related to no beverages or food permitted.		Occupational Health and Safety Act O.Reg.67/93, s. 32
	☐	☐	☐	☐	39	DPP has a policy and procedure to ensure safe operation of all DPP equipment.		Occupational Health and Safety Act O.Reg.67/93, s. 32 DPRA R.S.O. 1990, c. H.4 Part IV s.21 (3) j s. 57
	☐	☐	☐	☐	40	The DPP has established policies and procedures for DPP and medication related equipment down time or machine failure.		DPRA R.S.O. 1990, c. H.4 Part IX, s.50 (2) NAPRA Non Hazardous Sterile Preparations 2015 (p.31)
	☐	☐	☐	☐	41	The DPP administrator/designate reviews relevant reports, of DPP and medication related equipment, to ensure safety.		CSHP Guidelines for Drug-Use Control 2008 (2.7.2, 4.3.2.2 f) and g)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
A.5 TECHNOLOGY WITHIN THE DPP								
	☐	☐	☐	☐	**42**	The DPP has a policy to establish appropriate levels of access for designated staff for each DPP and medication related equipment/ technology.		DPRA R.S.O. 1990, c. H.4 Part IV s.21 (4) AC Med Mgmt 2017 (12.0)
	☐	☐	☐	☐	**43**	The DPP has established procedures for a pharmacist to determine the appropriateness of medications to be utilized in each machine.		CSHP Guidelines for Drug-Use Control 2008 (2.4.1 e) (2.4.2 f,g,h) (2.4.4)
	☐	☐	☐	☐	**44**	The DPP has policies and procedures on how to operate each piece of equipment/technology.		CSHP Guidelines for Drug-Use Control 2008 (2.4.2)
	☐	☐	☐	☐	**45**	The DPP has a policy and procedure for assignment of beyond use dates (BUD) for repackaged and compounded medications by DPP personnel.		CSHP Compounding Guidelines 2014 s. 19.7, Appendix C ISMP bulletin on syringes
	☐	☐	☐	☐	**46**	The DPP has a policy and procedure for staff to review machine-generated inventory reports to ensure that the inventory is within the “use-by” date.		CSHP Guidelines for Drug-Use Control 2008 (2.4.4)
A.6 INVENTORY MANAGEMENT								
	☐	☐	☐	☐	**47**	The DPP is not in violation of the Food and Drug Regulations Division 1A Establishment Licensing requirements.		
	☐	☐	☐	☐	**48**	There is supervision for the purchase, receipt, control and distribution of medications. There is a system to to ensure complete auditability and traceability from purchase order initiation to drug administration.		CSHP Practice Management Guidelines 2007 (3.2.1) CSHP Guidelines for Drug -Use Control 2008 (4.3.2) DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice: Requirement #36) NAPRA Sterile Preparations 2015 (5.1.1.2, 6.4) OCP Record Retention, Disclosure, and Disposal Guideline OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**49**	There is an inventory management system.		NAPRA MSOP RPh. 2009 (1.51, 1.52, 1.61) CSHP Guidelines for Drug-Use Control 2008 (4.3.2.4.3.3)
	☐	☐	☐	☐	**50**	The DPP has policies and procedures to manage medications recalls, shortages, backorders.		AC Med Mgmt 2017 (2.14, 9.6) CSHP Guidelines for Drug-Use Control 2008 (4.3.3, 4.3.7, 4.3.7.1)
	☐	☐	☐	☐	**51**	The DPP has a policy and procedure for pharmaceutical manufacturer’s representative activities within the DPP.		CSHP Guidelines for Drug Use Control 2008 (4.18.2)
	☐	☐	☐	☐	**52**	No expired products are found in inventory.		DPRA R.S.O. 1990, c. H.4 Part IX, s.50 (7) (8) AC Med Mgmt 2017 (12.7, 12.10)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**53**	The DPP has an established procedure for proper destruction of unusable medications and devices.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.3.2) Benzodiazepines and other Targeted Substances Regulations s.2 (2) (3) CSHP Guidelines for Drug-Use Control 2008 (4.3.6)
	☐	☐	☐	☐	**54**	Medications and components intended for internal use are stored separately from medications and components intended for external use.		NAPRA Resources for Pharmacy Operators 2009 CSHP Guidelines for Drug-Use Control 2008 (4.3.5.2.2) CSHP Compounding Guidelines 2014 (9.3)
	☐	☐	☐	☐	**55**	Storage of poisons and flammable compounds follow appropriate WHMIS, legislative guidelines/ requirements and standards.		WHMIS NAPRA Resources for Pharmacy Operators 2009 CSHP Guidelines for Drug-Use Control 2008 (4.3.5.2.2) CSHP Compouding Guidelines 2014 (9.3)
	☐	☐	☐	☐	**56**	Hazardous drugs are stored separately from other inventory to prevent contamination.		NAPRA Resources for Pharmacy 2009 CSHP Compounding Guidelines 2014 (10.2.3, 11.3.5)
	☐	☐	☐	☐	**57**	The DPP has a policy and procedure to ensure appropriate barcoding of the medication throughout the medication use process (if applicable).		AC Med Mgmt 2017 (6.3, 18.1) ISMO Bar Coding Resource Guide 2013
A.7 NARCOTICS AND CONTROLLED SUBSTANCES								
	☐	☐	☐	☐	**58**	A random narcotic count performed during the OCP assessment reveals no errors.		NCR s.42, s.43 Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.4) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012
	☐	☐	☐	☐	**59**	The DPP meets the Controlled Drugs and Substances Act legislative requirements.		NCR s.43 Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.4, 5.4.3) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012 (Managing Inventory)
	☐	☐	☐	☐	**60**	Narcotic and controlled drugs are stored in a segregated and secured DPP narcotic room that meets Health Canada standards.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.3.2) Guidelines for the Physical Security of Drugs Stored in Hospitals, Bureau of Dangerous Drugs, 1985

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**61**	The DPP has policies and procedures to identify and resolve discrepancies for Narcotic and controlled drugs.		NCR s.43 Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.4.3) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012 (Managing Inventory)
	☐	☐	☐	☐	**62**	The DPP meets the Benzodiazepines and Other Targeted Substances Regulation, Legislative Requirements and standards.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.4, 5.4.3) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012 (Managing Inventory)
	☐	☐	☐	☐	**63**	Benzodiazepines and other targeted substances are stored in a segregated and secured DPP narcotic room that meets Health Canada standards.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.3.2) Guidelines for the Physical Security of Drugs Stored in Hospitals, Bureau of Dangerous Drugs, 1985
	☐	☐	☐	☐	**64**	The DPP has policies and procedures to identify and resolve discrepancies for benzodiazepine and other targeted substances.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (5.4.3) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012 (Managing Inventory)
	☐	☐	☐	☐	**65**	The DPP has a policy and procedure to perform random audits and verifications of purchase orders, receipts, dispensing as well as perpetual inventory record of narcotics and controlled drugs, benzodiazepines and other targeted substances regularly.		Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals 1990 (9.2) OCP Fact Sheet Narcotic Reconciliation and Security Aug 2012 (Managing Inventory)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
B. ORDER PROCESSING, VERIFICATION, DISPENSING, AND DISTRIBUTION **B.1 GENERAL**								
	☐	☐	☐	☐	**66**	There is a tracking or audit trail that logs the process for drug preparation activities.		
	☐	☐	☐	☐	**67**	For each medication prepared there is a system of auditability and traceability.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30, 36) Supplement: Requirements to Support NAPRA Standards of Practice: Requirement #36) OCP Record Retention, Disclosure, and Disposal Guideline OCP Guidelines for Compounding Preparations
B.2 INVESTIGATIONAL DRUGS								
	☐	☐	☐	☐	**68**	There are policies, procedures to ensure study drugs are handled properly.		AC Med Mgmt 2017 (2.1) CSHP Clinical Trials: Guidelines for Pharmacies in Healthcare Institutions 2013 (4.3) CSHP Guidelines for Drug Use Control 2008 (4.1.8.3, 4.4.2.2)
	☐	☐	☐	☐	**69**	Investigational medications are stored separately from other medications and supplies.		CSHP Clinical Trials: Guidelines for Pharmacies in Healthcare Institutions 2013 (6.1)
	☐	☐	☐	☐	**70**	Investigational drugs are stored under appropriate environmental control.		CSHP Clinical Trials: Guidelines for Pharmacies in Healthcare Institutions 2013 (5, 6.2) CSHP Guidelines for Drug Use Control 2008 (4.3.5, 4.4.9.3)
	☐	☐	☐	☐	**71**	Investigation drug records are maintained in accordance with legislative requirements.		CSHP Clinical Trials: Guidelines for Pharmacies in Healthcare Institutions 2013 (7.1, 8.2) CSHP Guidelines for Drug Use Control 2008 (4.4.8.3 e)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
B. 3 MEDICATION DELIVERY								
	☐	☐	☐	☐	**72**	The DPP has policies and procedures to ensure medications are transported/ delivered to the customer securely under environmental control.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(1) NIOSH 2014 (pg 5) NAPRA Non-Hazardous Sterile Preparations 2015 (6.9) NAPRA Non-Sterile Preparations 2016 (7.9) NAPRA Hazardous Sterile Preparations 2016
RETURN OF MEDICATION								
	☐	☐	☐	☐	**73**	Drugs and compounded preparations that have left the direct control of the DPP are not re-issued.		NAPRA Non-Sterile Preparations 2016 (7.9) NAPRA Sterile Preparations 2016 (6.9) NAPRA Hazardous Sterile Preparations 2016 AC Med Mgmt 2017 (20.4) CSHP Guidelines Drug-Use Control 2008 (4.5, 4.8.1.)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
C. PREPARATION, PACKAGING AND LABELLING OF MEDICATION **C.1 PREPARATION**								
	☐	☐	☐	☐	**74**	A member provides oversight for DPP operations including all drug preparation, repackaging and labelling activities.		Pharmacy Act 1991, S.O. 1991 c. 36 Sect 3 (a), 4(1) 1 DPRA R.S.O. 1990, c. H.4 Part VI 119 (1)
	☐	☐	☐	☐	**75**	In DPP's using bar-coding technology the DPP has policies and procedures to ensure a safe and consistent process.		CSHP Drug-Use Guidelines 2008 (2.4.4 C)
C.2 PACKAGING								
	☐	☐	☐	☐	**76**	The DPP has policies and procedures on the appropriate selection of packaging material.		DPRA s 156(3) NAPRA R Ph. MSOP (1.40)
	☐	☐	☐	☐	**77**	Records are retained for 10 years		DPRA and Regulation Sect IV 21 (3j) PHIPA 13 (2) Records Section OCP Record Retention, Disclosure, and Disposal Guideline
	☐	☐	☐	☐	**78**	For each repackaged product there is a system of auditability and traceability. A separate production record is kept for each compounded bulk product and includes: a) date of compounding, b) lot or batch number assigned to the compounded product, c) manufacturer name and lot number for each raw material used, d) process including weights and measures performed, e) results of all quality control testing, f) statement of the final yield, g) sample label, and h) beyond use date of the product.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice Requirement #36)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
C.3 LABELLING								
	☐	☐	☐	☐	**79**	The DPP has a policy in place to ensure that labels are consistent and comply with standards. A label is affixed to the finished bulk/batch repackaged or bulk compounded drug and contains: a) generic name(s) of the drug, b) strength and quantity of ingredients, c) final concentration of active ingredients and base solutions/diluents, d) dosage form, e) total amount/volume of final product, f) beyond use date of the compound, g) manufacturer identification and lot number or DPP control number, h) storage conditions, if applicable, i) auxiliary labels, if applicable, and j) name of the DPP.		DPRA 161 (l) and R.S.O. 1990, c. H.4, s. 156 (3). Accreditation Canada (ROP) AC Med Management Std (2.2, 17.2 & 17.3) CSHP Repackaging: Guidelines for Healthcare Facilities (1998) (s. 6.0)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
D. PHARMACEUTICAL COMPOUNDING **D.1 NON-STERILE PREPARATIONS** **GENERAL**								
	☐	☐	☐	☐	**80**	A member provides oversight for DPP operations.		Pharmacy Act: OReg 202/94: Part IX: Inspection of Drug Preparation Premises, Pharmacy Act 1991, S.O. 1991 c. 36 Sect 3 (a), 4(1) 1 DPRA R.S.O. 1990, c. H.4 Part VI 119 (1)
	☐	☐	☐	☐	**81**	The DPP has a system to assess and update policies and procedures to ensure consistency with current standards and best practices for compounding non-sterile products.		NAPRA Non-Sterile Preparations 2016 (Responsibilities) NIOSH OHSA
	☐	☐	☐	☐	**82**	The DPP adheres to health, safety and environmental standards when compounding non-sterile products.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1) DPRA R.S.O. 1990, c. H.4 s.21 NAPRA Non-Sterile Preparations 2016 OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**83**	The DPP ensures that ingredients used for compounding are of acceptable standards and quality.		NAPRA Non-Sterile Preparations 2016 (7.3) OCP Policy on Procurement and Inventory Management 2014
	☐	☐	☐	☐	**84**	The DPP has policies and procedures for assessing inventory and handling and storage of bulk chemicals used in non-sterile compounding.		AC Med Mgmt 2017 (13.1) ISMP MSSA 2011 page 31 NAPRA Non-Hazardous Sterile Preparations 2015 WHMIS
	☐	☐	☐	☐	**85**	Staff members wear appropriate PPE when preparing all non-sterile compounded products.		OHSA R.S.O. 1990, CHAPTER O.1 s.27(1), 28(1b) DPRA O. Reg. 58/11: GENERAL Part IV s.24 6(d) NAPRA Non-Sterile Preparations 2016 (8.2.3.4) WHMIS
	☐	☐	☐	☐	**86**	If technology/ equipment/ automated compounders are utilized, policies, procedures and operational guidelines ensure the safe and optimal performance of the equipment.		DPRA O. Reg. 58/11: GENERAL Part IX s.50 (2) NAPRA Non-Sterile Preparations 2016 (Appendix 6 section A, 4.3)
	☐	☐	☐	☐	**87**	The DPP has the appropriate equipment needed to compound the required products.		DPRA R.S.O. 1990, c. H.4 s.24 (6) WHMIS NAPRA Non-Sterile Preparations 2016 (6.3.6) OCP Guidelines for Compounding Preparations OCP Record Retention, Disclosure, and Disposal Guidelines
	☐	☐	☐	☐	**88**	The master formula record is developed by a pharmacist and maintained for each non–sterile compounded drug product.		OHSA WHMIS NAPRA Non-Sterile Preparations 2016 (6.3.6) OCP Guidelines for Compounding Preparations OCP Record Retention, Disclosure, and Disposal Guidelines

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**89**	Records are retained for 10 years.		DPRA and Regulation Sect IV 21 (3j). PHIPA 13 (2) Records Section NAPRA Non-Sterile Preparations 2016 (9.6) OCP Guidelines for Compounding Preparations OCP Record Retention, Disclosure, and Disposal Guidelines OHSA
	☐	☐	☐	☐	**90**	For each non-sterile compounded product there is a system of auditability and traceability and a record that provides: a) the identification of each person involved in each step of the compounding process, and b) the identification of individual(s) providing final verification and authorization for release.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice:Requirement #36) NAPRA Non-Sterile Preparations 2016 (9.6) OCP Record Retention, Disclosure, and Disposal Guideline OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**91**	Written policies and procedures to ensure labels of non-sterile compounded products are consistent and comply with standards. A label is affixed to the finished bulk/batch repackaged or bulk compounded drug and contains: a) generic name(s) of the drug, b) strength and quantity of ingredients , c) final concentration of active ingredients and base solutions/diluents, d) dosage form, e) total amount of final product, f) beyond use date of the compound, g) manufacturer identification and lot number or DPP control number, h) storage conditions, if applicable, i) auxiliary labels, if applicable, and j) operating name of the DPP.		NAPRA Non-Sterile Preparations 2016 (9.4) NIOSH (pg.4) OCP Guidelines to Compounding Preparations

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
NON-STERILE PREPARATIONS & MANIPULATION OF HAZARDOUS DRUGS								
	☐	☐	☐	☐	**92**	Compounding and product manipulation of hazardous drugs is performed within a BSC/CACI.		NAPRA Non-Sterile Preparations 2016 (6.3.4, 8.2.3.1) NIOSH (pg 7 and Table 7)
	☐	☐	☐	☐	**93**	For DPP's that compound both sterile and non-sterile hazardous drugs, the respective BSC/CACIs are placed in segregated rooms separate from each other		NAPRA Non-Sterile Preparations 2016 (8.2.2) Health Canada Policy 0051 AC Med Mgmt (16.4)
	☐	☐	☐	☐	**94**	For occasional non-sterile hazardous drug compounding and manipulation, the BSC/CACI for sterile compounding may be used.		NAPRA Non-Sterile Preparations 2016 (8.2.3.1) NIOSH
	☐	☐	☐	☐	**95**	The appropriate PPE is worn when handling hazardous drugs for non-sterile compounding and manipulation.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) DPRA O. Reg. 58/11: GENERAL Part IV s.24 6(d) NAPRA Non-Sterile Preparations 2016 (8.2.3.4)
	☐	☐	☐	☐	**96**	Equipment is dedicated for use in compounding and manipulation of hazardous drugs		NAPRA Non-Sterile Preparations 2016 (8.2.3.2)
	☐	☐	☐	☐	**97**	The process for labelling the final compound/product ensures contamination is not introduced into the non-hazardous drug areas.		NAPRA Non-Sterile Preparations 2016 (8.1 General statement)
	☐	☐	☐	☐	**98**	The DPP has a policy and procedure to ensure protection of the product, personnel and environment during transport of hazardous drugs.		NAPRA Non-Sterile Preparations 2016 (8.1) WHMIS Transportation of Dangerous Goods Act and Regulations
	☐	☐	☐	☐	**99**	All hazardous drugs are labelled with a warning label stating the need for special handling and disposal.		NAPRA Non-Sterile Preparations 2016 (8.2.1.3) WHMIS Transportation of Dangerous Goods Act and Regulations
	☐	☐	☐	☐	**100**	Hazardous waste is handled separately from other trash and in compliance with regulations for handling, storing and transporting hazardous waste.		NAPRA Non-Sterile Preparations 2016 (8.4) WHMIS Transportation of Dangerous Goods Act and Regulations

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
D.2. STERILE COMPOUNDING IN DPP NON-HAZARDOUS STERILE PREPARATIONS General								
	☐	☐	☐	☐	**101**	The DPP does not manufacture drug products or otherwise prepare drug products pursuant to a prescription.		Food and Drug Act Health Canada Policy 0051 (3.0, 4.2, 5.2)
	☐	☐	☐	☐	**102**	A member provides oversight for DPP operations of all sterile drug compounding activities.		Pharmacy Act 4 (1.1) DPRA section 149 (1)
	☐	☐	☐	☐	**103**	The DPP has a system to assess and update policies and procedures to ensure consistency with current standards and best practices for sterile compounding of non-hazardous drugs.		NAPRA Non-Hazardous Sterile Preparation 2015 (5.1.1.2) AC Med Mgmt 2014 (6.3) OCP Guidelines for Compounding Preparations NIOSH (pg 4)
	☐	☐	☐	☐	**104**	The DPP has a policy in place to specify the dating of single dose and multi-dose vials in the compounding of sterile products.		NAPRA Non-Hazardous Sterile Preparation 2015 (5.1.1.2, 6.1.2.1, 6.1.2.3)
	☐	☐	☐	☐	**105**	The DPP ensures that ingredients used for sterile compounding are of established quality and standards.		Health Canada Policy 0051 (4.1, 5.1 section J) OCP Policy/Guideline - Medication Procurement and Inventory Management
	☐	☐	☐	☐	**106**	The DPP personnel receive appropriate orientation and the required training to premises-specific procedures and equipment, relevant to the services provided.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(2a), s. 26 (1l) s.27(1) NAPRA Non-Hazardous Sterile Preparation 2015 (5.1.1.2, 5.1.2.2. 5.1.2.3)
	☐	☐	☐	☐	**107**	The DPP provides staff with access to appropriate medication information resources, current protocols, clinical guidelines and dosing recommendations required for sterile compounding of non-hazardous drugs.		AC Med Mgmt 2014 (6.3) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**108**	Staff members wear appropriate PPE in accordance with standards required for sterile compounding of non-hazardous drugs.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) DPRA O. Reg. 58/11: GENERAL Part IV s.24 6(d) NAPRA Non-Hazardous Sterile Prep 2015 (6.6.2.2)
	☐	☐	☐	☐	**109**	The DPP has a policy in place to ensure the use of Sterile Isopropyl Alcohol (IPA) for the disinfection of surfaces/ equipment/ supplies used in the compounding of sterile products.		NAPRA Non-Hazardous Sterile Prep 2015 (5.3.3.2, 6.6.4, 6.6.5, Table 9)
	☐	☐	☐	☐	**110**	The DPP has a policy for the cleaning and disinfection of sterile compounding areas in accordance with established standards.		NAPRA Non-Hazardous Sterile Preparation 2015 Appendix 1 (B6) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**111**	Cleaning staff are trained prior to performing cleaning and disinfection activities in sterile compounding areas in accordance with established standards.		NAPRA Non-Hazardous Sterile Preparation 2015 (5.3.4.1)
	☐	☐	☐	☐	**112**	The DPP has a policy and procedure for quality assurance and environmental verification in accordance with established standards.		NAPRA Non-Hazardous Sterile Preparation 2015 (5.3.3.1) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**113**	The DPP is able to provide rationale and supporting records related to all site-specific environmental control measures undertaken.		NAPRA Non-Hazardous Sterile Preparation 2015 (7.6)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
COMPOUNDED STERILE PRODUCT (CSP) PREPARATION								
	☐	☐	☐	☐	**114**	A master formula record developed by a pharmacist is retained for each sterile compounded drug product.		NAPRA Sterile Preparations 2015 (5.1.1.2, 6.2, 6.3.1 and 6.3.2) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**115**	Records are retained for 10 years.		DPRA and Regulation Sect IV 21. PHIPA 13 (2) Records Section NAPRA Sterile Preparations 2016 (5.1.1.2, 5.4) OCP Guidelines for Compounding Preparations OCP Record Retention, Disclosure, and Disposal Guidelines OHSA
	☐	☐	☐	☐	**116**	The DPP ensures a system of auditability and traceability for each CSP and a record that provides: a) the identification of each person involved in each step of the compounding process, and b) the identification of individual(s) providing final verification and authorization for release.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice:Requirement #36) NAPRA Sterile Preparations 2015 (5.1.1.2, 6.4) OCP Record Retention, Disclosure, and Disposal Guideline OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**117**	Written policies and procedures are in place for CSP labels that comply with standards and are consistent. A label is affixed to the finished bulk/batch repackaged or bulk compounded drug and contains: a) generic name(s) of the drug, b) strength and quantity of ingredients , c) final concentration of active ingredients and base solutions/diluents, d) dosage form, e) total amount of final product, f) beyond use date of the compound, g) manufacturer identification and lot number or DPP control number, h) storage conditions, if applicable, i) auxiliary labels, if applicable, and j) operating name of the DPP.		WHMIS NAPRA Sterile Preparations 2015 (5.2, Appendix 1) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**118**	The DPP has quality control mechanism in place for the final product.		OCP Guidelines for Compounding Preparations NAPRA Sterile Preparations 2015 (7.5)
	☐	☐	☐	☐	**119**	The DPP performs and documents periodic audits of the sterile compounding and distribution processes.		NAPRA Sterile Preparations 2015 (7.4)
	☐	☐	☐	☐	**120**	Staff performance is assessed for continued ongoing competency and after return to work from an extended leave.		NAPRA Sterile Preparations 2015 (5.1.2.3, 7.4)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**121**	The DPP has a system to report, investigate and follow up on medication incidents, drug related incidents and adverse drug reactions related to CSPs.		NAPRA MSOP RPh. (3.10 - 3.16 inclusive) OCP Guidelines for Compounding Preparations (7.2.6) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Quality Control/Final Verification of Manually Prepared Product Section)
	☐	☐	☐	☐	**122**	A designated staff member in a management role reviews all incidents and adverse drug reactions related to compounded sterile drug products in a timely manner to determine patterns and causal factors that contribute to patient risks.		AC ROP 2016 (ADR reporting) NAPRA MSOP RPh. (3.15, 3.16) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Quality Control/Final Verification of Manually Prepared Product Section)
	☐	☐	☐	☐	**123**	Education is provided to DPP staff about incidents related to compounded sterile preparations.		AC ROP 2016 (ADR reporting) NAPRA MSOP RPh. (3.14, 3.16)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
SPECIALIZED STERILE COMPOUNDING General								
	☐	☐	☐	☐	**124**	DPP maintains a list of specialized CSPs		
	☐	☐	☐	☐	**125**	Compounding personnel preparing specialized CSPs receive specialized training to obtain the required competencies.		Health Canada Policy 0051 (section 5.1 K) OHSA 26 (K)
	☐	☐	☐	☐	**126**	Policies and procedures for compounding all CSPs are sufficiently detailed to prevent process variation in practice among compounding personnel.		OCP Guidelines for Compounding Preparations (7.2.1 a) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Compounding Section)
	☐	☐	☐	☐	**127**	Master formula records are standardized, developed by a pharmacist and are used to guide the compounding of specialized CSPs		OCP Guidelines for Compounding Preparations (3.4) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013
	☐	☐	☐	☐	**128**	For DPP's using IV workflow software, there are policies and procedures that ensure that the final check of the programming has been completed by a pharmacist who is an expert or super user, prior to using the program for dispensing.		ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (IV Workflow Software Section)
	☐	☐	☐	☐	**129**	For DPP's using automated IV compounding devices, there are standard operating procedures.		ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Automated IV Compounding Devices Section)
	☐	☐	☐	☐	**130**	There is a policy and procedure for final verification of all CSP.		NAPRA Sterile Preparations 2015 (6.6.6.5)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
TOTAL PARENTERAL NUTRITION (TPN)								
	☐	☐	☐	☐	**131**	A TPN formulation sheet is prepared by a pharmacist prior to compounding.		OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**132**	TPN formulations undergo a safety review by a pharmacist for ingredient compatibility and admixture stability.		OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**133**	The DPP has policies and procedures in place for preparing TPN manually.		NAPRA Sterile Preparations 2015 (5.1.1.2)
	☐	☐	☐	☐	**134**	The DPP has policies and procedures in place for the use of technology/ automated compounders to prepare TPN.		NAPRA Sterile Preparations 2015 (5.1.1.2, 5.3.3.2)
	☐	☐	☐	☐	**135**	Operation of the compounding process must be routinely observed by a pharmacist in a management role, for procedural compliance.		NAPRA Sterile Preparations 2015 (5.1.1.1)
	☐	☐	☐	☐	**136**	The DPP has a policy for TPN and IV fat emulsion labels to ensure consistency and to comply with standards.		NAPRA Sterile Preparations 2015 (7.5, Appendix 1, Section B 9)
	☐	☐	☐	☐	**137**	For each compounded TPN admixture records are retained for 10 years.		DPRA and Regulation Sect IV 21. PHIPA 13 (2) Records Section OCP Record Retention, Disclosure, and Disposal Guideline
	☐	☐	☐	☐	**138**	For each compounded TPN admixture, the DPP ensures a system of auditability and traceability and a record that provides: a) the identification of each person involved in each step of the compounding process, and b) the identification of individual(s) providing final verification and authorization for release.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice Requirement #36)
	☐	☐	☐	☐	**139**	The DPP has a policy and procedure to address and communicate TPN component shortages and backorders to customers.		AC Med Mgmt 2017 (2.14)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
FACILITIES REQUIREMENTS - NON-HAZARDOUS DRUGS								
	☐	☐	☐	☐	**140**	Hazardous and non-hazardous drug compounding take place in two separate rooms.		NAPRA Sterile Preparations 2015 (5.3.2.5) Note "exception" in NAPRA Sterile Preparations 2015 (5.3.2.6) AC Med Mgmt 2014 (16.4)
	☐	☐	☐	☐	**141**	An anteroom is present.		NAPRA Sterile Preparations 2015 (5.3.2.5)
	☐	☐	☐	☐	**142**	A sink for hand washing and an eye-wash station are installed before entrance to ISO Class 7 clean room.		DPRA O. Reg. 58/11, s. 23. NAPRA Sterile Preparations 2015 (5.3.2.5)
	☐	☐	☐	☐	**143**	The direct compounding area (LAFW/CAI) maintains an ISO Class 5 environment.		NAPRA Sterile Preparations 2015 (5.3.3.1)
	☐	☐	☐	☐	**144**	Certification of each PEC (LAFW/CAI) is performed at least every six months and whenever the LAFW/CAI is relocated.		NAPRA Sterile Preparations 2015 (5.3.3.1)
	☐	☐	☐	☐	**145**	The clean room/ buffer area does not contain sources of water.		NAPRA Sterile Preparations 2015 (5.3.2.9)
	☐	☐	☐	☐	**146**	The clean room/ buffer area maintains an ISO Class 7 environment.		NAPRA Sterile Preparations 2015 (5.3.2.5 Table 3)
	☐	☐	☐	☐	**147**	Certification of the clean room/ buffer area is performed at a frequency as per standards.		NAPRA Sterile Preparations 2015 (5.3.3.1)
	☐	☐	☐	☐	**148**	HEPA-filtered air is introduced at the ceiling with returns to be low mounted on the wall to create a top-down dilution.		NAPRA Non-Hazardous Sterile Compounding 2015 (5.3.2)
	☐	☐	☐	☐	**149**	Clean room/ buffer area air pressure is positive relative to all adjacent spaces.		NAPRA Sterile Preparations 2015 (5.3.2.5 Table 2)
	☐	☐	☐	☐	**150**	Differential pressures are monitored daily.		NAPRA Sterile Preparations 2015 (5.3.2.5 Table 2 and 3)
	☐	☐	☐	☐	**151**	Ceiling/flooring/equipment/chairs shall be non-porous, smooth, free of cracks, non-shedding, cleanable and disinfectable.		DPRA R.S.O. Reg. 58/11, s. 23. NAPRA Sterile Preparations 2015 (5.3.2.8)
	☐	☐	☐	☐	**152**	Dust-collecting overhangs, such as ceiling pipes and window-sills are not in evidence		NAPRA Sterile Preparations 2015 (5.3.2.8)
	☐	☐	☐	☐	**153**	The DPP has policies and procedures in place to address equipment and facility alarms.		NAPRA Non-Hazardous Sterile Compounding 2015 (5.3.2.5 Table 3)
	☐	☐	☐	☐	**154**	Equipment and system malfunctions are documented and reviewed by the DPP administrator/designate on a routine basis.		NAPRA Non-Hazardous Sterile Compounding 2015 (7.6)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
D3. HAZARDOUS STERILE PREPARATIONS **General**								
	☐	☐	☐	☐	**155**	The DPP does not manufacture drug products or otherwise prepare drug products pursuant to a prescription.		Health Canada Policy 0051 (5.1, 5.2)
	☐	☐	☐	☐	**156**	A member provides oversight for DPP operations for all hazardous sterile drug compounding activities.		Drug and Pharmacies Regulation Act: OReg 58/11: Part IV: Standards for Accreditation and Operation s.23, Pharmacy Act: OReg 202/94: Part IX: Inspection of Drug Preparation Premises, Section 3 and 4
	☐	☐	☐	☐	**157**	The DPP has a policy specifying which parenteral medication products must be prepared by DPP staff in a BSC/CACI.		OHSA R.S.O. 1990, c. O.1, s. 37 (3)
	☐	☐	☐	☐	**158**	The DPP has a system to assess and update policies and procedures to ensure consistency with current standards and best practices for sterile compounding of hazardous drugs.		AC Med Mgmt 2014 (2.2) NAPRA Hazardous Sterile Preparations 2016 OHSA NIOSH
	☐	☐	☐	☐	**159**	The DPP has a policy in place to specify the dating of single dose and multi-dose vials in the compounding of hazardous sterile products.		WHMIS NAPRA Hazardous Sterile Preparations 2016 NAPRA Non-Hazardous Sterile Preparations 2015
	☐	☐	☐	☐	**160**	The DPP personnel receive appropriate orientation and the required training to premises-specific procedures and equipment, relevant to the services provided		Health Canada Policy 0051 (section 5.1 K) OHSA R.S.O. 1990, c. O.1, s. 37 (3) NAPRA Hazardous Sterile Preparations 2016 OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**161**	The DPP provides staff with access to appropriate medication information resources, current protocols and clinical guidelines required for sterile compounding of hazardous drugs.		OHSA R.S.O. 1990, c. O.1, s. 37 (3) AC Med Mgmt 2014 (6.3, 13.2)
	☐	☐	☐	☐	**162**	The DPP ensures that ingredients used for sterile compounding of hazardous drugs are of established quality and standards.		OHSA R.S.O. 1990, c. O.1, s. 37 (1) OCP Guidelines for Compounding Preparations

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**163**	Staff members wear appropriate PPE in accordance with standards required for sterile compounding of hazardous drugs.		OHSA R.S.O. 1990, CHAPTER O.1 s.25(1), s.27(1), 28 (1b) DPRA O. Reg. 58/11: GENERAL Part IV s.24 6(d) NAPRA Hazardous Sterile Preparations 2016 OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**164**	The DPP has a policy in place to ensure the use of Sterile Isopropyl Alcohol (IPA) for the disinfection of surfaces/ equipment/ supplies used in the compounding of hazardous sterile products.		NAPRA Non-Hazardous Sterile Prep 2015 (5.3.3.2, 6.6.4, 6.6.5, Table 9) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**165**	The DPP has a policy for the deactivation, decontamination, cleaning and disinfection of the sterile compounding area in accordance with established standards.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**166**	Cleaning staff are trained prior to performing the deactivation, decontamination, cleaning and disinfection activities in sterile compounding areas in accordance with established standards.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**167**	The DPP has a policy and procedure for quality assurance and environmental verification in accordance with established standards.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**168**	The DPP is able to provide rationale for and supporting records related to all site-specific environmental control measures undertaken.		NAPRA Sterile Preparations 2015 (Section 7) NAPRA Hazardous Sterile Preparations 2016

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
HAZARDOUS STERILE COMPOUND PREPARATION								
	☐	☐	☐	☐	**169**	The DPP has policies, procedures, and operational guidance describing the requirements for handling hazardous drugs.		DPRA: OReg 58/11 s. 23 NIOSH 2014 NAPRA Hazardous Sterile Preparations 2016 OHSA AC med Mgt (16.3) ISMP International Medication Safety Self Assessment for Oncology 2012 CAPhO: Standards of Practice for Oncology Pharmacy in Canada 2009 Transportation of Dangerous Goods Act
	☐	☐	☐	☐	**170**	Hazardous drugs are stored separately from other inventory to prevent contamination.		NAPRA Hazardous Sterile Preparations 2016 NAPRA Non-Sterile Preparations 2016 (8.2.2.5 Table 2)
	☐	☐	☐	☐	**171**	The refrigerator used for hazardous drug storage is located in hazardous drug storage room, buffer room or containment segregated compounding area (C-SCA) (i.e. under negative pressure conditions)		NAPRA Hazardous Sterile Preparations 2016 NAPRA Non-Sterile Preparations 2016 (8.2.2.5 Table 2)
	☐	☐	☐	☐	**172**	All hazardous drugs are labelled with a warning label stating the need for special handling and disposal.		WHMIS OHSA NAPRA Non-Sterile Preparations 2016 (7.7.1.1 and 7.7.1.2) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**173**	Standardized guidelines and procedures are readily available for reconstituting, diluting, preparing, verifying and administering commonly used hazardous agents.		NAPRA Hazardous Sterile Preparations 2016 (Appendix 2) OCP Guidelines for Compounding Preparations
	☐	☐	☐	☐	**174**	DPP personnel are oriented, trained, and demonstrate competency in the accurate and safe preparation of hazardous drugs in accordance with established standards .		OHSA (section 41) NAPRA Non-Sterile Preparations 2016 (6.1.2) NAPRA Hazardous Sterile Preparations 2016 USP 800 section 9
	☐	☐	☐	☐	**175**	DPP personnel demonstrate knowledge of appropriate procedures to be followed in case of accidental skin or eye contact with hazardous drugs.		OHSA WHMIS NAPRA Non-Sterile Preparations 2015 (8.3.2) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**176**	Chemo spill kits are available in all areas where chemotherapy is received, stored, compounded, and during transportation.		AC Med Mgmt 2014 (20.3) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**177**	A master formulation record developed by a pharmacist is retained for each hazardous sterile compounded drug product.		NAPRA Hazardous Sterile Preparations 2016 OCP Guidelines for Compounding Preparations

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**178**	Records are retained for 10 years.		DPRA and Regulation Sect IV 21. PHIPA 13 (2) Records Section NAPRA Sterile Preparations 2016 (5.1.1.2, 5.4) OCP Guidelines for Compounding Preparations OCP Record Retention, Disclosure, and Disposal Guidelines OHSA
	☐	☐	☐	☐	**179**	The DPP ensures a system of auditability and traceability for each hazardous CSP and a record that provides: a) the identification of each person involved in each step of the compounding process, and b) the identification of individual(s) providing final verification and authorization for release.		DPRA and Regulation Sect IV 20 (2) NAPRA Pharmacy Practice Management Systems 2016 (Requirement 30) Supplement: Requirements to Support NAPRA Standards of Practice:Requirement #36) NAPRA Sterile Preparations 2015 (5.1.1.2, 6.4) OCP Record Retention
	☐	☐	☐	☐	**180**	The label for the sterile hazardous drug product are consistent with policy and procedure and comply with standards. A label is affixed to the finished bulk/batch repackaged or bulk compounded drug and contains: a) generic name(s) of the drug, b) strength and quantity of ingredients , c) final concentration of active ingredients and base solutions/diluents, d) dosage form, e) total amount of final product, f) beyond use date of the compound, g) manufacturer identification and lot number or DPP control number, h) storage conditions, if applicable, i) auxiliary labels, if applicable, and j) operating name of the DPP.		WHMIS OHSA NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**181**	The process for labelling the final compound/product ensures contamination in not introduced into the non-hazardous drug areas.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**182**	The DPP has quality control mechanism in place for the final product.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**183**	The DPP performs and documents periodic audits of the hazardous sterile compounding and distribution processes.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**184**	Staff performance is assessed for continued ongoing competency .		OHSA (section 41) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**185**	The DPP has a policy and procedure to ensure protection of the product, personnel and environment during transportation of hazardous drugs.		WHMIS OHSA USP <800> (section 17) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**186**	There is a process to evaluate and address exposure to hazardous products to ensure personnel safety.		WHMIS OHSA NAPRA Hazardous Sterile Preparations 2016

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
	☐	☐	☐	☐	**187**	Hazardous waste is handled separately from other trash and in compliance with regulations for handling, storing, and transporting hazardous waste.		OHSA DPRA O. Reg. 58/11: GENERAL Part IV s.24 6(c) WHMIS NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**188**	The DPP has a system to report, investigate and follow up on medication incidents, drug related incidents and adverse drug reactions related to hazardous CSPs.		NAPRA MSOP RPh. (3.10 - 3.16 inclusive) OCP Guidelines for Compounding Preparations (7.2.6) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Quality Control/Final Verification of Manually Prepared Product Section) AC ROP 2016 (ADR reporting)
	☐	☐	☐	☐	**189**	A pharmacist in a management role reviews all incidents and adverse drug reactions related to hazardous compounded sterile drug products in a timely manner to determine patterns and causal factors that contribute to patient risks.		AC Med Mgmt (25.0, 26.0) AC ROP 2016 (ADR reporting) NAPRA MSOP RPh. (3.15, 3.16) ISMP Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds 2013 (Quality Control/Final Verification of Manually Prepared Product Section)
	☐	☐	☐	☐	**190**	Education is provided to DPP staff about incidents related to hazardous compounded sterile preparations.		AC ROP 2016 (ADR reporting) NAPRA MSOP RPh. (3.14, 3.16)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Criteria Statement	Comments	References
HAZARDOUS STERILE COMPOUNDING FACILITY REQUIREMENTS								
	☐	☐	☐	☐	**191**	The anteroom is present.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**192**	A sink for hand washing, an eye-wash station and an emergency shower are installed before entrance to ISO Class 7 clean room.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**193**	The direct compounding area (BSC/CACI) maintains an ISO Class 5 environment.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**194**	Certification of each C-PEC (BSC/CACI) is performed at least every six months and whenever the BSC/CACI is relocated.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**195**	The clean room/ buffer area does not contain sources of water.		NAPRA Sterile Preparations 2015 (5.3.2.9)
	☐	☐	☐	☐	**196**	The clean room/ buffer area maintains an ISO Class 7 environment.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**197**	Certification of the clean room/ buffer area is performed at a frequency as per standards.		
	☐	☐	☐	☐	**198**	HEPA-filtered air is introduced at the ceiling with returns to be low mounted on the wall to create a top-down dilution.		NAPRA Non-Hazardous Sterile Compounding 2015 (5.3.2)
	☐	☐	☐	☐	**199**	Clean room/ buffer area air pressure is negative relative to anteroom.		AC Med Mgmt 2014 (16.3) NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**200**	Differential pressures are monitored daily.		NAPRA Sterile Preparations 2015 (5.3.2.5 Table 2 and Table 3)
	☐	☐	☐	☐	**201**	Ceiling/flooring/equipment/chairs shall be non-porous, smooth, free of cracks, non-shedding, cleanable and disinfectable.		NAPRA Hazardous Sterile Preparations 2016
	☐	☐	☐	☐	**202**	Dust-collecting overhangs, such as ceiling pipes and window-sills are not in evidence		NAPRA Sterile Preparations 2015 (5.3.2.8)
	☐	☐	☐	☐	**203**	The DPP has policies and procedures in place to address equipment and facility alarms.		NAPRA Non-Hazardous Sterile Compounding 2015 (5.3.2.5 Table 3)
	☐	☐	☐	☐	**204**	Equipment and system malfunctions are documented and reviewed by the DPP administrator/designate on a routine basis.		NAPRA Non-Hazardous Sterile Compounding 2015 (7.6)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Statement	Comments	References
E. DOCUMENTATION AND RECORD KEEPING								
	☐	☐	☐	☐	**205**	DPP related records must be retained for 10 years.		DPRA and Regulation Sect IV 21. PHIPA 13 (2) Records Section OCP Record Retention, Disclosure, and Disposal Guideline
	☐	☐	☐	☐	**206**	Pharmacists document their activities according to established DPP policy.		
	☐	☐	☐	☐	**207**	Pharmacy Technicians document their activities according to established DPP policy.		NAPRA MSOP RPhT 2009(1.37-1.44)
	☐	☐	☐	☐	**208**	DPP staff document medication incident as per DPP policies and procedures		
	☐	☐	☐	☐	**209**	A member in a management role periodically reviews documentation for all DPP personnel documented activities		CSHP Documentation of Pharmacists' Activities in the Health Record: Guidelines 2013 (10) CSHP Practice Management: Guidelines for Managing Pharmacy Practice in Healthcare Facilities 2007 (3.9.1)
	☐	☐	☐	☐	**210**	Pharmacists provide handoff communication to appropriate personnel		NAPRA MSOP R.Ph. 2009 (2.21) AC ROP 2016 (Information Transfer)
	☐	☐	☐	☐	**211**	Pharmacy Technicians provide handoff communication to appropriate personnel		NAPRA MSOP R.Ph. 2009 (2.21) AC ROP 2016 (Information Transfer)

Category	Meet	Partially Meet	Do Not Meet	N/A	Criteria #	Statement	Comments	References
E. DOCUMENTATION AND RECORD KEEPING								
	☐	☐	☐	☐	**212**	The DPP has continuous quality improvement programs in place to evaluate services related to drug use control, medication use system safety, staff competency and accuracy of duties performed.		NAPRA MSOP R. Ph 2009 (3.7-3.9) AC Med Mgmt 2017 (27.0) CSHP Guidelines for Drug-Use Control 2008 (3.2) CSHP: Guidelines for Managing Pharmacy Practice in Healthcare Facilities 2007 (3.9)
	☐	☐	☐	☐	**213**	Outcome indicators to assess quality and safety of DPP services are measured.		
	☐	☐	☐	☐	**214**	A system is in place to track and trend audits/indicators/reports for system and service improvement.		