Guidelines for Outsourcing Pharmaceutical Compounding Services:

A Tool for Healthcare Organizations

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1.0 Introduction

In September of 2013, the Government of Ontario, through the Ministry of Health and Long-term Care, established the Implementation Taskforce to oversee the implementation of the 12 recommendations made in Dr. Jake Thiessen's report "A Review of the Oncology Under-Dosing Incident" (Report August 7, 2013). At the same time, the Government of Ontario also established several Sub-taskforce groups to develop strategies for implementing specific Report recommendations.

This document was developed by a Working Group, under the direction of the Procurement Sub-taskforce of the Implementation Taskforce. Individuals who contributed to the development of this document are gratefully acknowledged in Appendix D.

The Canadian Society of Hospital Pharmacists has agreed to make the document available. This publication is available at: http://www.cshp.ca.

The intent of this document is to provide guidance to healthcare organizations when turning to outsourcing arrangements for pharmaceutical compounding services.

The key aspects of this tool include:

a. Ensure that patient safety and risk mitigation is considered as the highest priority;
b. Identify best practices to support the establishment of pharmaceutical compounding services under contract;
c. Leverage an existing assessment tool developed by the American Society of Health-System Pharmacists (ASHP);
d. Provide guidance on three stages of the procurement competitive bid process including the **competitive bid document** with suggestions for weighting and scoring for award; **post award verification,** including contract finalisation and contract implementation with subsequent product and/or service provider conversion; and **continuous improvement** and related monitoring;
e. Address aseptic and nonaseptic compounding specifications;
f. Provide the suggested risk matrix to categorize preparations and services (Appendix B);
g. Recognize the need for contingency planning in the event of a drug shortage;
h. Ensure that this is a living document that will evolve over time as regulations change; and
i. Establish an understanding that this document is specific to the province of Ontario.

What is compounding?

Compounding is the preparation of drug preparations pursuant to or in anticipation of a prescription.

Compounding is within the scope of practice and a professional standard of pharmacists and pharmacy technicians registered with the Ontario College of Pharmacists (OCP) and is carried out at various compounding sites or facilities including pharmacy departments in hospitals, retail pharmacy businesses, and Drug Preparation Premises (DPPs).

Regulations support the assurance of safety and quality at compounding sites/facilities. The OCP is authorized to inspect any compounding site or facility where pharmacists and pharmacy technicians engage in or supervise drug

preparation activities, including DPPs. The inspection criteria are based on an existing accepted standard of practice for compounding of drug preparations. Any DPP that has passed an OCP inspection has met the currently accepted standard for quality of facility, procedures, and service. (Further definitions are provided in Appendix A.)

2.0 Purpose and Organization of the Document

Compounding services are contracted by group purchasing organizations (GPOs), shared services healthcare organizations (SSOs) and individual hospitals/healthcare organizations (collectively, "contractors") from service providers that can include DPPs, other hospitals, and service providers. This document is intended to guide contractors in their review of their processes for contracting, awarding, and performance monitoring for compounding services. The scope of the document includes contracting for nonaseptic compounding and aseptic compounding of drugs for parenteral administration using two or more commercially manufactured sterile drugs. The scope of the document does not include aseptic compounding from a nonaseptic active pharmaceutical ingredient (API), or contracting for procurement from contract manufacturers.

Contractors should include language, as part of the terms and conditions, which allows for the application and/or modification of the practices herein to meet their specific needs. At all times, close attention should be paid to those preparations included in the highest risk category as these likely present the greatest risk for negative patient outcomes. (See Appendix B.)

Inspections of DPP ensure acceptable service. The purpose of the contractor's competitive bid document is to measure the ability of one service provider to provide a service and value for money relative to others.

Guidance is provided for evaluation and monitoring of:

Section	Number	Example of Weighting of Non-Financial Evaluation Criteria
3.0	Regulatory Compliance	PASS/FAIL + 10%
4.0	Scope of Preparation and Service Specifications	10%
5.0	Quality and Safety	50%
6.0	Medication Administration Safety	30%

Each section identifies recommended competitive bid process goals and objectives, evaluation criteria, scoring, post-award contract verification actions, and ongoing audit and monitoring activities.

Evaluation criteria are presented in a tabular format and classified as follows:

- M – Mandatory;
- K – Key (very important but not mandatory);
- D – Desired;
- S – The service provider submits evidence in the bid response;
- V – The contractor conducts a post-award verification process with the service provider; and
- A – Audits are conducted by the contractor and service provider during the contract period.

In the competitive bid process, mandatory requirements result in a pass/fail score for the service provider, whereas other criteria are evaluated and scored based on objective criteria pre-defined by the contractor.

Evidence of the service provider's ability to meet requirements should be included within their submitted proposals. For other important information which may be considered proprietary, the competitive bid document should ask the service provider to describe their processes, service capabilities/limits, and service levels. The contractor should then conduct a post-award verification of the actual processes. The timelines for the post-award verification period should be stipulated in the competitive bid documents**.** Upon contractor/buyer/end-user verification that actual processes align with the proposal, should any changes be required, the successful bidder will have 30 days to provide an acceptable solution, or the contractor reserves the right to terminate the arrangement in whole or in part.

3.0 Regulatory Compliance

The contractor must confirm that the service provider meets regulatory requirements for the province in which the healthcare organization/buyer operates. In Ontario, there are currently two types of regulated drug preparation facilities:

- a pharmacy (hospital or retail based) with a valid certificate of accreditation in accordance with applicable governing legislation in a province or territory of Canada; or
- Drug Preparation Premise (DPP) where a pharmacist engages in drug preparation activities, or where drug preparation activities take place that a pharmacist supervises and that has passed an inspection in Ontario.

The contractor must confirm that the service provider, whose compounding activities are conducted under the supervision of a licensed pharmacist, employs pharmacists with valid licences or registration within Ontario. These criteria should be evaluated on a pass/fail basis.

The competitive bid process should further be structured to acquire evidence to determine:

- the service provider's level of quality achieved during regulatory assessments; and
- that the service provider employs and maintains qualified personnel.

These criteria should be scored.

3.0 Evaluation Criteria for Regulatory Compliance *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
3.1	Provide evidence of qualification to provide service by submitting supporting documentation (copies are accepted): Pharmacy provides: • Certificate of accreditation or equivalent for Ontario DPP provides: • Most recent DPP inspection result from Ontario College of Pharmacists	 **M** **M**	 S S	

3.0 Evaluation Criteria for Regulatory Compliance *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
3.2	Provide evidence in the form of a copy of qualification inspection results: Pharmacy provides: • Most recent accreditation report the Ontario College of Pharmacists DPP provides: • Complete inspection report for evaluation against DPP Inspection Criteria, and activities and timeline taken to address any conditions or areas for improvement	 D D	 S S	 A A
3.3	Provide evidence in the form of a copy of a narcotic dealer's licence for narcotics and controlled substances for all facility sites associated with the provision of the service that involves controlled substances.	**M**	S	A
3.4	Provide a description of the service provider's process for validation of appropriate licence or registration of all employees involved in compounding at time of hire and the process for revalidation annually.	D	V	A

3.0 Scoring of Regulatory Compliance Criteria		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
3.1	Provided evidence of qualification to provide service.	**Pass/Fail**
3.2	Provided evidence of qualification to provide compounding services without conditions.	Y/N
3.3	Narcotic dealers licence for preparations containing narcotics and controlled substances.	**Pass/Fail**
3.4	Process for validation of appropriate licence or registration of employees involved in compounding at time of hire and annually thereafter.	Y/N

3.0 Post-Award Verification of Regulatory Compliance Submissions **(with successful candidate)**	
Corresponding Evaluation Criterion	*Obtain and review:*
3.4	Process for validation of appropriate licensing and registration and ensure it requires employees to submit evidence of qualification at the time of hire and on an annual basis.
3.4	Report on current licensing and registration qualifications of employees.

3.0 Auditing Requirements for Regulatory Compliance Criteria		
Corresponding Evaluation Criterion	*Service provider should submit:*	Frequency
3.2	Copy of most recent accreditation report/inspection report.	Annually
3.3	Copy of all business addresses and associated narcotic dealer's licences.	Annually
3.4	Report on current licensing and registration qualifications of employees.	Annually

4.0 Scope of Preparation & Service Specifications

The competitive bid document should specify the needs of the buyers and their end-users for compounded preparations and service. The competitive bid process is the vehicle used to assess the service providers' ability to meet these needs.

Specified Preparation List

The contractor and buyers will together create a Specified Preparation List that clearly describes the list of preparations required from the service provider.

The buyer will have confirmed with the end-users the requirements for:

- ingredient product(s) at the exact concentration including any tolerance limits for the concentration;
- base solutions and required volumes or identified restrictions;
- final volume and any allowable deviation (including manufacturer's overfill and additive volume);
- beyond-use stability dating;
- interface with specific equipment (e.g., syringe, tubing);
- drug delivery device (e.g., large or small volume intravenous bag with type of plastic specified, if needed, syringe, container); and
- special labelling, if required.

The buyer will have confirmed with the end-users how the preparation will be subsequently used specifying:

- patient specific dose administered to patient including route and dose limits;
- pharmacy bulk package from which patient specific doses will be withdrawn; or
- base preparation to which other products will be added.

From this information the Specified Preparation List will be created for the competitive bid document. The Specific Preparation List will state the concentration of ingredient(s) in final volume (with or without tolerable deviation) of a drug delivery device (with specified base solution, if applicable), any required special labelling, and a brief description of how the preparation will subsequently be used.

Using the Risk Matrix (Appendix B), the contractor and buyers should identify into which section of the Risk Matrix the preparations will be placed.

It may be appropriate to consider a market approach that segregates preparations in the higher risk area of the matrix. Consideration may be given to awarding the contract to more than one service provider for risk mitigation reasons (i.e., aseptic compounding to one service provider and nonaseptic compounding to another service provider).

Specified Service Terms:

The competitive bid document should include Specified Service Terms that should be developed by the contractor and buyer to specify the basic service requirements, which may include:

- regular hours of service and after hours support;
- order placement process for regular preparations and preparations that contain controlled substances;
- emergency orders;
- guaranteed turn-around time from order placement to delivery of preparations;
- shipping and storage requirements (e.g., adherence to cold chain);
- return policy and process;
- use of products at contractor normal acquisition cost;
- business operations: invoicing, terms of payment, late payment charge, etc.;
- delivery location and timeframes; and
- direct access by the healthcare organization to a licensed pharmacist and/or pharmacy technician responsible for the compounding service.

The contractor and buyer may consider the extent and manner of including these provisions in the contract:

- healthcare organization has the right to bring compounding of any preparations in house without prior notification and without penalty;
- healthcare organization has the right to visit site and review operations with agreed upon notification period within the contract; and
- healthcare organization has the right to terminate the contract if quality assurance deficiencies are not addressed within an acceptable time frame.

The competitive bid process should be structured to obtain evidence that the service provider demonstrates capability to consistently deliver a full range of quality services for:

- the required range of specified service and preparations, including controlled substances, in a variety of formats to meet current and future needs;
- traceability of all preparations compounded by the service provider;
- communication and management of issues or complaints;
- contingency plans to minimize disruption to supply, including drug shortage events; and
- effective change control processes.

Legend for Evaluation Criteria:

Evaluation Level:	**Evidence Required:**
M – Mandatory	**S** – With Submission
K – Key	**V** – Post-Award Verification
D – Desired	**A** – Audit During Contract

4.0 Evaluation Criteria for Scope of Preparation and Service Specifications *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
4.1	Submit evidence of experience or capability in producing compounded preparations for: 3.1.1 Nonaseptic: • Tablets or Capsules (for research) • Oral liquids • Formulations for pediatric patients and adult patients who have difficulty swallowing (or at risk of choking) • Suppositories • Topical formulations • Other formulations 3.1.2 Aseptic: • Anti-infectives • Antinauseants • Cardioplegia solutions • Chemotherapy • Continuous nerve blocks • Continuous renal replacement therapy preparations • Controlled substances • Corticosteroids • Electrolyte solutions • Drugs administered into the central nervous system space (e.g., epidural, intrathecal) • Medications for pediatric patients • Nebulised solutions • Oxytocin solutions • Patient–controlled analgesia • Parenteral nutrition	D	S	
4.2	Submit evidence of experience or capability in producing compounded preparations in a full range of final product containers, including but not limited to: • Mini-bags • Pump specific cassettes • Syringes • Elastomeric pumps • Large– volume infusion bags	D	S	
4.3	Submit a list of Canadian references for nonaseptic and aseptic compounding services or similar services involving sterile preparations.	D	S	

4.4	Describe any additional customer services or service features included in the offer.	D	V	
4.5	Describe the business continuity plan to be followed in the event of a disaster or any unanticipated disruption in service, with specific reference to aseptic compounding (e.g., drug shortages, following equipment failure, pandemic, environmental emergencies).	D	V	
4.6	Describe how complaints are managed for: • Product concerns (final preparation, label, packaging, etc.) • Medication or compounding errors • Quality production questions (one-offs, leaking product, etc.) • Customer service	D	V	
4.7	Describe, in detail, the investigation process that is undertaken when a medication error or deviation from internal quality standard occurs (including accountabilities).	K	S	
4.8	Describe the notification process and requirements (e.g., what action is taken and what documentation is made) when an adverse event occurs, including steps for timely contact with contractor and/or buyer and confirmation of receipt of information.	K	S	
4.9	Describe the process of how and when the involved compounded preparation will be identified when a recall or any other event occurs that requires traceability of a preparation.	D	V	
4.10	Describe the protocol for change control and notification to contractor/buyer for: • Change in process • Preventative maintenance activity • Software upgrade	D	S	
4.11	Describe the protocol for change control and notification including how prior contractor/buyer approval is achieved when there is: • Valid reason to change from an original Health Canada approved primary master product (e.g., during a drug shortage) • Change from primary Master Production Formula to pre-approved contingency formula	D	S	
4.12	Describe the process for the addition of new items to the Specified Preparation List.	D	S	
4.13	Describe how the guidelines (ASHP, NAOSH, NIOSH, and USP Chapter 797) for handling and shipping of hazardous agents are met.	D	S	
4.14	Describe the process and validation for external decontamination of oncology preparations.	D	V	
4.15	Provide the names and locations of all facilities involved in the provision of this service and describe procedure for notification to the contractor/buyer of any changes.	K	S	A
4.16	Describe a plan for contract implementation or conversion strategy.	D	V	
4.17	Describe how the service provider stays up to date with evolving regulations and standards.	D	V	

4.0 Scoring of Scope of Preparation and Service Specification Criteria		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
4.1 & 4.2	Experience or capability to compound items on Specified Preparation List.	Some items/ All items/ More than listed items
4.3	Submitted names and information of suitable contacts that provided acceptable references.	Y/N
4.4	Additional Customer Service features related to: • Training • On site assistance • Response time for recalls • Other specific to customer service	Y/N
4.5	Business continuity plan to be followed in the event of a disaster or any unanticipated disruption in service, with specific reference to aseptic compounding (e.g., drug shortages, following equipment failure, pandemic, environmental emergencies).	Y/N
4.6	Complaints management procedure that addresses: • Preparations • Medication errors • Production quality • Customer service	Y/N
4.7	Detailed investigation procedure that demonstrates due diligence and rigor for: • Medication errors • Deviations from quality standards	Y/N
4.8	Process for notification of adverse events.	Y/N
4.9	Process of how and when a compounded preparation will be identified when a recall or any other event occurs that requires traceability of that preparation: • In machine—AND human—readable format • Is acted on within "X" hours of notification (including outside of regular hours)	Y/N
4.10	Protocol for change control and notification to contractor/buyer for: • Change in existing aseptic compounding production procedures • Preventative maintenance activity • Software upgrade (except where pre-approval exists for a brand product change)	Y/N
4.11	Protocol for change control and notification including how prior contractor/buyer approval is achieved when there is:	Y/N

	• Valid reason to change from an original Health Canada approved primary master product (e.g., during a drug shortage) • Change from primary Master Production Formula to pre-approved contingency formula	
4.12	Process to add new items to the Specified Preparation List.	Y/N
4.13	Described how the guidelines (ASHP, NAOSH, NIOSH, and USP Chapter 797) for handling and shipping of hazardous agents are met.	Y/N
4.14	Process for external decontamination of oncology preparations and process for validation and verification of cleaning procedures.	Y/N
4.15	Provided the names and locations of all facilities involved in the provision of this service and describe procedure for notification to the contractor/buyer of any changes.	Y/N
4.16	Plan for contract implementation or conversion strategy if applicable.	Y/N
4.17	Plan to stay up to date with evolving regulations and standards.	Y/N

4.0 Post-Award Verification of Scope of Preparation and Service Specification Submissions (with successful candidate)	
Corresponding Evaluation Criterion	*Obtain and review:*
4.4	Features of additional customer service and consider inclusion in final contract.
4.5	Business continuity plan to be followed in the event of a disaster or any unanticipated disruption in services, with specific reference to aseptic compounding (e.g. drug shortages, following equipment failure, pandemic, environmental emergencies).
4.6	Complaints management procedure that addresses: • Preparations • Medication errors • Production quality • Customer service
4.7	Detailed investigation procedure that demonstrates due diligence and rigor for medication error management.
4.7	Detailed investigation procedure that demonstrates due diligence and rigor for responding to deviation(s) from quality standards.
4.8	Process for notification of adverse events.
4.9	Process of how and when the involved compounded preparation will be identified when a recall or any other event occurs that requires traceability of a preparation: • In machine—AND human—readable format • Is acted on within “X” hours of notification (including outside of regular hours)
4.11	Protocol for change control and notification including how prior contractor/buyer approval is achieved when there is: • Valid reason to change from an original Health Canada approved primary master product (e.g., during a drug shortage)

4.0 Post-Award Verification of Scope of Preparation and Service Specification Submissions (with successful candidate)	
	• Change from primary Master Production Formula to pre-approved contingency formula
4.14	Process for external decontamination of oncology preparations and process for validation and verification of cleaning procedures.
4.16	Plan for contract implementation and conversion strategy if applicable is compatible with the exit strategy of the incumbent service provider.
4.17	Plan to stay up to date with evolving regulations and standards.

4.0 Auditing Requirements of Scope of Preparation and Service Specification Criteria		
Corresponding Evaluation Criterion	*Service provider should submit:*	Frequency
4.15	Names and locations of all facilities involved in the provision of this service and describe procedure for notification to the contractor/buyer of any changes. If a change has occurred within the last 12 months: • Date(s) of change(s) • Details of change(s)	Annually

5.0 Quality and Safety

The contractor should determine that the service provider delivers compounded preparations to the buyer/end-user that are produced by a rigorous, controlled process and that consistently meet established, high standards for stability and sterility.

The contractor should determine that the service provider uses only Health Canada approved products or products that comply with the current standard.

The contractor should determine that the service provider's evidence supports the competency of their personnel to correctly perform and document the assigned aseptic and nonaseptic compounding functions, and that they are adequately skilled, educated, instructed, and trained to do so.

Section 5.1 and 5.2 apply for nonaseptic preparations. Sections 5.1 and 5.3 apply for aseptic preparations.

5.1 Preparation Stability and Integrity

The contractor should determine that the service provider can substantially support the stated **stability and integrity** of compounded preparation, in the container in which it is packaged, for the beyond-use date for both Primary Master Formula preparations, or for any preparations produced under a contingency plan, as a result of drug shortages or any other reason.

The competitive bid process should be structured to acquire evidence that a service provider:

- uses Health Canada approved products or products that comply with appropriate standards;
- employs trained personnel with technical ability to adequately serve all assigned levels of compounding: nonaseptic as per USP <795> standard or acceptable Canadian equivalent, aseptic as per USP <797> risk level standard or acceptable Canadian equivalent; Hazardous Drugs as per USP <800> or acceptable Canadian equivalent;
- employs adequate number of personnel with the necessary qualifications including practical experience appropriate to their responsibilities who are available on site;
- has contingency plans to ensure the different risk levels of aseptic compounding are always conducted by appropriately trained personnel;
- provides mandatory regular re-testing of appropriate knowledge and skills; and
- maintains a Master Formulation Record on each specified compounded preparation that contains evidence the delivered preparation meets the quality standards until the labelled beyond-use date including:
  - citations of published data for product-specific stability validation;
  - citations for related stability validation studies that have been used to extrapolate stability;
  - evidence of unpublished validated stability data where the study has been validated and is accurate, reproducible, and specific as per accepted reference standards; and
  - information on content of latex, DEHP (DI (2-ethyl hexyl) phthalate), preservatives, or any other excipient as requested by buyer.

5.1 Evaluation Criteria for Quality and Safety: Stability and Integrity *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
5.1.**1**.1	Provide an attestation that the service provider solely uses ingredients that are approved by Health Canada in compounding preparations, other than for any identified exceptions.	K	S	
5.1.**1**.2	Identify nonaseptic compounded preparations from the Specified Preparation List where any products not approved by Health Canada are an ingredient. Furthermore, identify those ingredients and include the standard for those ingredients, or identify if no standard exists.	K	V	A
5.1.**1**.3	Identify aseptic compounded preparations from the Specified Preparation List where non-Health Canada approved products are an ingredient. Furthermore, identify those ingredients and include the standard for those ingredients, or identify if no standard exists.	K	V	A
5.1.**2**.1	Describe the process to ensure that employees achieve and maintain competency in site specific aseptic and nonaseptic compounding and describe the competency assessments used.	D	V	A
5.1.**2**.2	Describe key topics covered in employee orientation and training program.	D	V	
5.1.**2**.3	Describe the activities and resources available for employee/staff development, education, and training including: • Orientation to basic therapeutic knowledge covering preparations included in the service portfolio • Mandatory and optional education related to skills requirements	D	V	A

5.1 Evaluation Criteria for Quality and Safety: Stability and Integrity *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
	• Access to approved medication information, current protocols, clinical guidelines, and dosing regimens			
5.1.**3.**1	Provide an attestation statement that there is acceptable stability data to substantiate the stability and integrity of their preparations to the labelled beyond-use date.	K	S	
5.1.**3**.2	Provide a list of any preparations on the Specified Preparation List that have product-specific published stability data available.	K	V	
5.1.**3**.3	Provide a list of any preparations where stability data for the brand of product designated in the dossier that is not published and alternate stability data is available through: • Extrapolation from published brand data • Unpublished validated stability data where the study has been validated and is accurate, reproducible, and specific as per accepted reference standards. (See Appendix C)	K	V	
5.1.**3**.4	Describe, for preparations where stability data is unavailable (new product or product change), the proposed approach for establishing validated stability data and how the costs of obtaining such data will be handled.	D	V	
5.1.**4**.1	Provide an attestation statement of compliance with Health Canada Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069).	K	S	
5.1.**4**.2	Describe the processes for temperature monitoring during preparation, storage, and transportation that includes monitoring frequency.	D	V	
5.1.**4**.3	Describe the process for management of incidents when temperature excursions occur.	D	V	A
5.1.**5**.1	Describe the process for ensuring the expiry dates of original ingredients do not compromise beyond-use date of the compounded preparation.	D	V	

5.1 Scoring of Quality and Safety Criteria: Stability and Integrity		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.1.**1**.1	Attestation that the service provider solely uses Health Canada approved ingredient products in compounding preparations, other than for any identified exceptions.	Y/N
5.1.**1**.2	Identified nonaseptic compounded preparations from the Specified Preparation List where non-Health Canada approved products are an ingredient, as well as identified the ingredients and included the standard for those ingredients, or identified if no standard exists. • Any non-Health Canada approved active ingredient products have acceptable standard or, if it is an excipient product, the absence of a standard is acceptable	Y/N Y/N
5.1.**1**.3	Identified aseptically compounded preparations from the Specified Preparation List where non-Health Canada approved ingredient products	Y/N

5.1 Scoring of Quality and Safety Criteria: Stability and Integrity		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
	are an ingredient, as well as identified the ingredients and included the standard for those ingredients, or identified if no standard exists. • Any non-Health Canada approved active ingredient products have acceptable standard or, if it is an excipient product, the absence of a standard is acceptable	Y/N
5.1.**2**.1	Process to assess employee competency and to ensure maintenance of competency in site specific aseptic and nonaseptic compounding preparations.	Y/N
5.1.**2**.1	Orientation and training for each risk level of aseptic preparation, based on <797> standard or acceptable equivalent, which includes initial assessment and on-going assessment at appropriate intervals, for competency to manipulate sterile preparations aseptically, and assessment of competency through use of media-fill test procedures and glove fingertip sampling.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent
5.1.**2**.2	Orientation and training process with: • Antiseptic hand cleansing • Disinfection of nonaseptic compounding surface • Appropriate donning of protective garb • Achieving and maintaining sterility of ISO class 5 environment (Primary Engineering Control) • Achieving and maintaining protection of personnel and compounding environments from contamination by radioactive, cytotoxic, and chemo toxic drugs • Identifying, weighing, and measuring ingredients • Performing aseptic technique to manipulate sterile products • Labelling compounded preparations • Inspecting quality of compounded preparations	Y/N
5.1.**2**.3	Activities and resources available for employee/staff development, education and training that include the aspects in the evaluation criteria.	Y/N
5.1.**3**.1	Attestation statement that there is acceptable stability data to substantiate the stability and integrity of their preparations to the labelled beyond-use date.	Y/N
5.1.**3**.2	Identified items on Specified Preparation List that have product-specific published stability data available.	Y/N
5.1.**3**.3	Identified any preparations where stability data for the brand of product designated in the dossier that is not published and alternate stability data is available through: • Extrapolation from published brand data • Unpublished validated stability data where the study has been validated and is accurate, reproducible, and specific as per accepted reference standards. (See Appendix C)	Y/N

5.1 Scoring of Quality and Safety Criteria: Stability and Integrity		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.1.**3**.4	Process to establish validated stability data where no stability data is available and how costs of obtaining such data will be handled.	Y/N
5.1.**4**.1	Attestation statement of compliance to Health Canada Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069).	Y/N
5.1.**4**.2	Complies with Health Canada Guidelines for Temperature Control of Drug Products during Storage and Transportation.	Does not meet/ meets/ exceeds
5.1.**4**.3	Process for management of incidents when temperature excursions occur with sterile preparations.	Y/N
5.1.**5**.1	Process for ensuring expiry dates of original ingredients do not compromise beyond-use date of the compounded preparation.	Y/N

5.1 Post-Award Verification of Quality and Safety Submissions: Stability and Integrity (with successful candidate):	
Corresponding Evaluation Criterion	*Obtain and review:*
5.1.**1**.2 & 5.1.**1**.3	Nonaseptic and sterile items on Specified Preparation List where any non- Health Canada approved products are an ingredient.
5.1.**2**.1 & 5.1.**2**.2	Process to assess employee competency and to ensure maintenance of competency in site specific sterile and nonaseptic compounding preparations. Orientation and training for each risk level of sterile preparation, based on <797> standard or acceptable equivalent, which includes initial assessment and on-going assessment at appropriate intervals, for competency to manipulate sterile preparations aseptically, and assessment of competency through use of media-fill test procedures and glove fingertip sampling.
5.1.**2**.3	Activities and resources available for employee/staff development, education and training that include the aspects in the evaluation criteria.
5.1.**3**.2	Identified items on Specified Preparation List that have product-specific published stability data available.
5.1.**3**.3	Identified any preparations where stability data for the brand of product designated in the dossier that is not published and alternate stability data is available through: • Extrapolation from published brand data • Unpublished validated stability data where the study has been validated and is accurate, reproducible, and specific as per accepted reference standards. (See Appendix C)

5.1 Post-Award Verification of Quality and Safety Submissions: Stability and Integrity (with successful candidate):	
5.1.**3**.4	Process to establish validated stability data where no stability data is available and how costs of obtaining such data will be handled.
5.1.**4**.2 & 5.1.**4**.3	Processes for temperature monitoring during preparation, storage, and transportation that includes monitoring frequency. Process for management of incidents when temperature excursions occur with sterile preparations.
5.1.**5**.1	Process for ensuring expiry dates of ingredients do not compromise beyond-use date of preparation.

5.1 Auditing Requirements for Quality and Safety Criteria: Stability and Integrity		
Corresponding Evaluation Criterion	*Service provider submits:*	Frequency
5.1.**1**.2 & 5.1.**1**.3	Nonaseptic and sterile items on Specified Preparation List with exceptions to Health Canada approved ingredients and the standard for those ingredients or if no standard exists.	Annually
5.1.**2**.1	Results and dates of most recent media-fill tests and glove fingertip sampling for personnel involved in aseptic compounding (without personal information).	Annually
5.1.**2**.3	Documents of evidence of annual training and education completed.	Annually
5.1.**4**.3	Records of number of incidents of temperature excursions and actions taken.	Quarterly

5.2 Nonaseptic Preparations

The contractor should determine that the service provider uses production procedures to deliver **nonaseptic** preparations with consistent quality with low variability from label description.

The competitive bid process should be structured to acquire evidence that:

- the service provider has Master Production Formula for each nonaseptic item on Specified Preparation List and accompanying procedures based on <795> standard or acceptable equivalent;
- for simple nonaseptic compounding, as defined by <795>, the Master Production Formula is based on a pharmaceutical standard or published formulation with acceptable detailed production processes and procedures that:
  - are followed and documented for every production;
  - identify the purity and quality of compounding ingredients;
  - include primary production process and also include reference to pre-approved contingency production sheets, production processes and procedures;
  - include verification of critical processes including, but not limited to, weighing, measuring, and mixing;

- document the number of units , lot, expiry, GTIN, and brand of drug products used;
- include particulars of packaging and labelling;
- include assessment of final product (e.g., mass, uniformity of mixing, clarity, odour, colour, consistency, and pH as appropriate); and
- include identification of date, time, and personnel conducting the procedure; and

- The service provider follows regularly validated procedures and documents the verification processes.

5.2 Evaluation Criteria for Quality and Safety: Nonaseptic Preparations *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
5.2.1	Provide a copy of the sample Master Production Formula sheet for each category of nonaseptic compounding, represented on the Specified Preparation List, based on <795> standard or acceptable equivalent.	K	S	
5.2.2	Describe the process for verifying that production procedures are being followed for different formats (e.g., ointments, capsules, liquids, eye drops, etc.) and the frequency of verification.	D	V	
5.2.3	Describe the assessment (e.g., mass, uniformity of mixing, clarity, odour, colour, consistency, pH, as appropriate) of final preparation.	D	V	
5.2.4	Describe the process used to address any variability observed from any verification or monitoring process during production, post-production, and final preparation assessment.	D	V	A
5.2.5	Describe any other quality assurance activities not specifically requested in other parts of the competitive bid document that exceed <795> standard or acceptable equivalent.	D	V	

5.2 Scoring of Quality and Safety Criteria: Nonaseptic Preparations		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.2.1	Master Production Formula for each category of nonaseptic compounding, represented on the Specified Preparation List, based on <795> standard or acceptable equivalent.	Y/N
5.2.2	Process that verifies that production procedures are being followed for different formats (e.g. ointments, capsules, liquids, eye drops, etc.), based on risk mitigation, and documents the verification process, particularly as it relates to weights and measures, that meets <795> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <795> standard or acceptable equivalent
5.2.3	Assessment of final preparation that meets <795> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <795> standard or acceptable equivalent
5.2.4	Process to address any variability observed from any verification or monitoring process during production, post-production, and final preparation assessment.	Y/N

5.2 Scoring of Quality and Safety Criteria: Nonaseptic Preparations		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.2.5	Other quality assurance activities that exceed <795> standard or acceptable equivalent.	Y/N

5.2 Post Award Verification of Quality and Safety Submissions: Nonaseptic Preparations (with successful candidate):	
Corresponding Evaluation Criterion	*Obtain and review:*
5.2.1	Copy of Master Production Formula sheet for each nonaseptic compounding, represented on the Specified Preparation List: • Demonstrates preparations are based on acceptable pharmaceutical standards or published formulations; • Includes production procedures for key steps; and • Includes criteria for assessment of final preparation and verification of such assessment. Approve acceptability of including these preparations in final contract.
5.2.2	Process that verifies that production procedures are being followed for different formats (e.g. ointments, capsules, liquids, eye drops, etc.), based on risk mitigation, and documents the verification process, particularly as it relates to weights and measures, that meets <795> standard or acceptable equivalent.
5.2.3	Assessment of final preparation that meets <795> standard or acceptable equivalent.
5.2.4	Process to address any variability observed from any verification or monitoring process during production, post-production, and final preparation assessment.
5.2.5	Other policies governing quality assurance activities that exceed <795> standard or acceptable equivalent. Consider including in final contract.

5.2 Audit of Quality and Safety Submissions: Nonaseptic Preparations		
Corresponding Evaluation Criterion	*Service provider submits:*	Frequency
5.2.4	Report of variability excursions identified in production process or post-production and final preparation assessment.	Quarterly

5.3 Sterile Preparations

The contractor should determine that the service provider uses production procedures to deliver **sterile products** with consistent quality with low variability from label description.

The competitive bid process should be structured to acquire evidence that the service provider:

- has a Master Production Formula for each sterile item on the Specified Preparation List with acceptable detailed production processes and procedures that:
  - are followed and documented for every production and include equipment and personnel preparation compliant with <797> standard risk levels or acceptable equivalent;
  - ensure identity, quality, and purity of compounding ingredients including integrity of partially used compounding ingredients;
  - include primary production processes and procedures; and also include reference to pre-approved contingency production processes;
  - include verification of critical processes;
  - document the number of units, lot, expiry, GTIN, and brand of drug products used;
  - include particulars of packaging and labelling;
  - include specific reference to accommodation of overfill in administration containers (e.g., bag or vial);
  - include inspection and assessment of final product for colour, particulate matter, leakage, and sterility, as appropriate; and
  - identify date, time, and personnel conducting the procedure;
- validates major changes related to environment, cleaning, and equipment (e.g., changes to heating, ventilation and air conditioning systems, cleaning procedures, and equipment);
- follows regularly verified procedures and documents the verification processes; and
- regularly tests for sterility of final products, where required to be compliant with risk level identified in <797> standard or acceptable equivalent.

5.3 Evaluation Criteria for Quality and Safety: Sterile Preparation *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
5.3.1	Provide a copy of sample Master Production Formula sheet for each aseptic compounding risk level category represented on Specified Preparation List, based on <797> standard or acceptable equivalent.	K	V	
5.3.2	Describe the process for verifying that production procedures are being followed for each aseptic compounding risk level category represented on Specified Preparation List, including frequency of verification, based on <797> standard or acceptable equivalent.	D	V	
5.3.3	Describe how the process for assessment of final preparation meets <797> standard or acceptable equivalent, including final concentration variance.	D	V	A
5.3.4	Describe the process used to address any variability observed from any verification or monitoring process (i.e., during production and post-production and final preparation assessment).	D	V	A
5.3.5	Describe how production formulas and labelling of final product address specific references to accommodation of overfill in drug delivery device.	D	V	
5.3.6	Describe how the preparation procedure for equipment and personnel prior to each product batch meets <797> standard or acceptable equivalent.	D	V	

5.3 Evaluation Criteria for Quality and Safety: Sterile Preparation *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
5.3.7	Describe how the process of routine environmental quality inspections and monitoring of compounding surfaces for microbiological growth (e.g., spores and fungal), and environmental air sampling meets <797> standard or acceptable equivalent.	D	V	A

5.3.8	Describe and provide evidence of how the facility and equipment meet the requirements for:
	• ISO Standard 14644
	  ○ Class 7 for clean rooms
	  ○ Class 5 for laminar flow hoods and biological safety cabinets
	• Separate clean room for hazardous and non-hazardous drugs
		D	V	

5.3.9	Describe the preventative maintenance program for equipment.	D	V	
5.3.10	Describe preparation procedures when there have been changes introduced into the facility, equipment, process, or products. Include the notification process for service provider staff and contractors/buyers.	D	V	
5.3.11	Describe any other quality assurance activities not specifically requested in other parts of the competitive bid document that exceed <797> standard or acceptable equivalent.	D	V	
5.3.12	Describe how post-production sterility testing meets <797> standard or acceptable equivalent.	D	V	
5.3.13	Describe how the process used to address any failures in sterility testing meets <797> standard or acceptable equivalent. Provide a copy of sterility failures that occurred in most recent "X" month period for high volume or high risk products.	D	V	A

5.3 Scoring of Quality and Safety: Sterile Preparation		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.3.1	Master Production Formula sheet for each aseptic compounding risk level category represented on the Specified Preparation List, based on <797> standard or acceptable equivalent.	Y/N
5.3.2	Process for verifying that production procedures are being followed for each aseptic compounding risk level category represented on Specified Preparation List, including frequency of verification, based on <797> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent
5.3.3	Process for assessment of final preparation meets <797> standard or acceptable equivalent, including final concentration variance.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent

5.3 Scoring of Quality and Safety: Sterile Preparation		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
5.3.4	Process to address any variability observed from any verification or monitoring process (i.e. during production, post-production, and final preparation assessment).	Y/N
5.3.5	Production formulas and labelling of final product that address specific references to accommodation of overfill in drug delivery devices.	Y/N
5.3.6	Procedure for preparation of equipment and personnel prior to each product batch that meets <797> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent
5.3.7	Procedure for routine inspections to assess the quality of the environment, including compounding surfaces and environmental air that meets <797> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent

5.3.8	Evidence is provided that the facility and equipment meet the requirements for:
	• ISO Standard 14644
	  ○ Class 7 for clean rooms
	  ○ Class 5 for laminar flow hoods and biological safety cabinets
	• Separate clean room for hazardous and non-hazardous drugs
		Y/N

5.3.9	Program for routine maintenance for equipment.	Y/N
5.3.10	Preparation procedures for when there have been changes introduced into the facility, equipment, process, or products are addressed. Process includes notification for service provider's staff and contractor/buyer.	Y/N
5.3.11	Other quality assurance activities not specifically requested in other parts of the competitive bid document that exceed <797> standard or acceptable equivalent.	Y/N
5.3.12	Process for post-production sterility testing that meets <797> standard or acceptable equivalent.	Does not meet/ meets/ exceeds <797> standard or acceptable equivalent
5.3.13	Process used to address any failures in sterility testing that complies with <797> standard or acceptable equivalent. Provided copy of results in most recent "X" month period for high volume or high risk products.	Does not meet/ meets/ exceeds <797> standard or acceptable

5.3 Scoring of Quality and Safety: Sterile Preparation		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
		equivalent Y/N

5.3 Post Award Verification of Quality and Safety Submissions: Sterile Preparations (with successful candidate):	
Corresponding Evaluation Criterion	*Obtain and Review:*
5.3.1	Copy of Master Production Formula sheet for each item on Specified Preparation List, including: • Production procedures for key steps; and • Criteria for assessment of final preparation and verification of such assessment. Approve acceptability of including these preparations in final contract.
5.3.2	Policy for routine validation of production procedures.
5.3.3	Policy for routine post-production and final preparation assessment.
5.3.4	Policy for addressing and managing any variability from production procedures and/or from assessment of post-production and final preparation.
5.3.5	Master Production Formula sheet and confirm that production formulas and labelling of final product account for accommodation of overfill in drug delivery devices.
5.3.6	Policy for preparation of equipment and personnel prior to each product batch and confirm that the policy meets <797 standard or acceptable equivalent.
5.3.7	Policy for routine environmental quality inspections, including compounding surfaces and environmental air.

5.3.8	Evidence that the facility and equipment meet the requirements for:
	• ISO Standard 14644 for the numbers of particle size greater than 0.5 µm or larger per cubic metre
	  ○ Class 7 for clean rooms
	  ○ Class 5 for laminar flow hoods and biological safety cabinets
	• Separate clean room for hazardous and non-hazardous drugs

5.3.9	Policy for routine preventative maintenance for equipment.
5.3.10	Policy for management of changes to facility, equipment, and processes that includes notification for service provider's staff. Policy for management of product changes, including notification for service provider's staff and prior notification for contractor/buyer. Ensure final contract includes appropriate notification process and tracking of changes to products over the life of the contract.
5.3.11	Policies for other quality assurance activities not specifically requested in other parts of the competitive bid document that exceed <797> standard or acceptable equivalent.

5.3 Post Award Verification of Quality and Safety Submissions: Sterile Preparations (with successful candidate):	
Corresponding Evaluation Criterion	*Obtain and Review:*
	Consider including in final contract.
5.3.12	Policy for post-production sterility testing.
5.3.13	Policy for managing failures in sterility testing. Review results of items on Specified Preparation List for sterility failures that occurred in most recent "X" month period.

5.3 Audit of Quality and Safety Submissions: Sterile Preparations		
Corresponding Evaluation Criterion	*Service provider submits:*	Frequency
5.3.3	Report of excursions during assessment of final preparation.	Monthly
5.3.13	Report of excursions identified for final product sterility testing.	Monthly
5.3.4	Report of excursions identified in production process, post production assessment, and final preparation assessment.	Quarterly
5.3.7	Report of excursions for routine quality monitoring and inspections.	Quarterly

6.0 Medication Administration Safety

The contractor should determine that the service provider labels products in a manner that clearly identifies the product and features of the product that are essential to patient safety throughout every step in the supply chain and supports full tracking and traceability of the product.

The competitive bid process should be structured to acquire evidence that the service provider:

- identifies each unit of preparation provided to the end-user with a label that:
  - meets Ontario DPP requirements or other applicable provincial or federal regulatory requirements;
  - meets ISMP-Canada guidance document for labelling of compounded products for patient safety (when it becomes available); and
  - will remain readable and endure throughout the supply chain;
- identifies each unit of preparation provided to the end-user with a label that clearly identifies:
  - the generic name of the drug and assists in differentiating it from other generic drugs;
  - Total drug amount, volume, and concentration (with full consideration of any overfill of original products or additive volume);
  - How to trace the preparation to original Health Canada approved products either by machine and human readable bar codes or other acceptable process;
  - Information placement for patient safety at end point of use (e.g., infusion pumps); and

- If the drug is a hazardous product;

- Identifies each unit of product issued to the end-user with packaging that clearly provides:
  - Tamper evidence;
  - Need for protection from light (as relevant); and
  - Any other applicable storage conditions.

6.0 Evaluation Criteria for Medication Administration Safety *As part of the competitive bid process, a service provider should:*		M/K/D	S/V	A
6.1	Demonstrate, by submitting sample labels generated from current system, how labelling for compounded preparations for **nonaseptic** categories complies with Ontario DPP requirements and ISMP-Canada guidance document.	K	V	
6.2	Demonstrate, by submitting sample labels generated from current system, how labelling for compounded preparations for **sterile** categories: • Complies with DPP requirements; • Complies with ISMP-Canada guidance document and any Cancer Care Ontario guidance, particularly related to final concentration of active ingredients and base AND total amount/total volume of final product; and • Demonstrates that concentrations of sterile preparations in delivery devices are clear and appropriate to end use.	K	V	
6.3	Describe the process and procedure for any changes in labelling. Include requirements for signed off pre-approval from buyer.	K	V	

6.0 Scoring of Criteria for Medication Administration Safety		
Corresponding Evaluation Criterion	*Service provider has:*	Scoring Methodology
6.1	Labelling for compounded preparations for **nonaseptic** categories complies with: • Ontario DPP requirements; and • ISMP-Canada guidance document.	 Y/N Y/N
6.2	Labelling for compounded preparations for **sterile** categories complies with: • DPP requirements; and • ISMP-Canada and Cancer Care Ontario guidance, including final concentration of active ingredients and base AND total amount/total volume of final product.	 Y/N Y/N Y/N
6.2	Labelling of concentrations of sterile preparations in delivery devices is clear and appropriate for end use.	Y/N
6.3	Process for any changes in labelling that includes signed off pre-approval from buyer.	Y/N

6.0 Post Award Verification of Medication Administration Safety (with successful candidate):	
Corresponding Evaluation Criterion	*Obtain and Review:*
6.1	Master Production Formula for labelling specifications for each item on Specified Preparation List, but with particular attention to highest risk preparations.
6.2	Approve all labels for sterile preparations on Specified Preparation List.
6.3	Policy governing any changes to labels. Ensure prior approval and sign-off from contractor/buyer of any label change is part of final contract.

7.0 Final Contract Preparation

After verification of the related policies and procedures referred to in the competitive bid document, the final contract needs to address:

- items from Specified Preparation List to be included in final contract;
- any requirements from the contractor that are changes to service provider's normal service;
- where additional clarity is required in the service relationship;
- confirmation of change control process;
- appropriate product change notification process and tracking of changes to products and preparations over the life of the contract;
- confirmation of continuous improvement audits;
- final sign off from buyers that production process and label meets Specified Preparation List requirements;
- final sign off from buyers on sample final product. This is required for all preparations in highest risk areas (see Risk Matrix, Appendix B); and
- final sign off from buyers of first preparation received under the new contract, whether or not it is a new service provider.

8.0 Additional Recommendations

Implementation of the foregoing will help to support safe contracting and acquisition of nonaseptic and aseptic compounded products and services. The process can be further strengthened through action in the following areas:

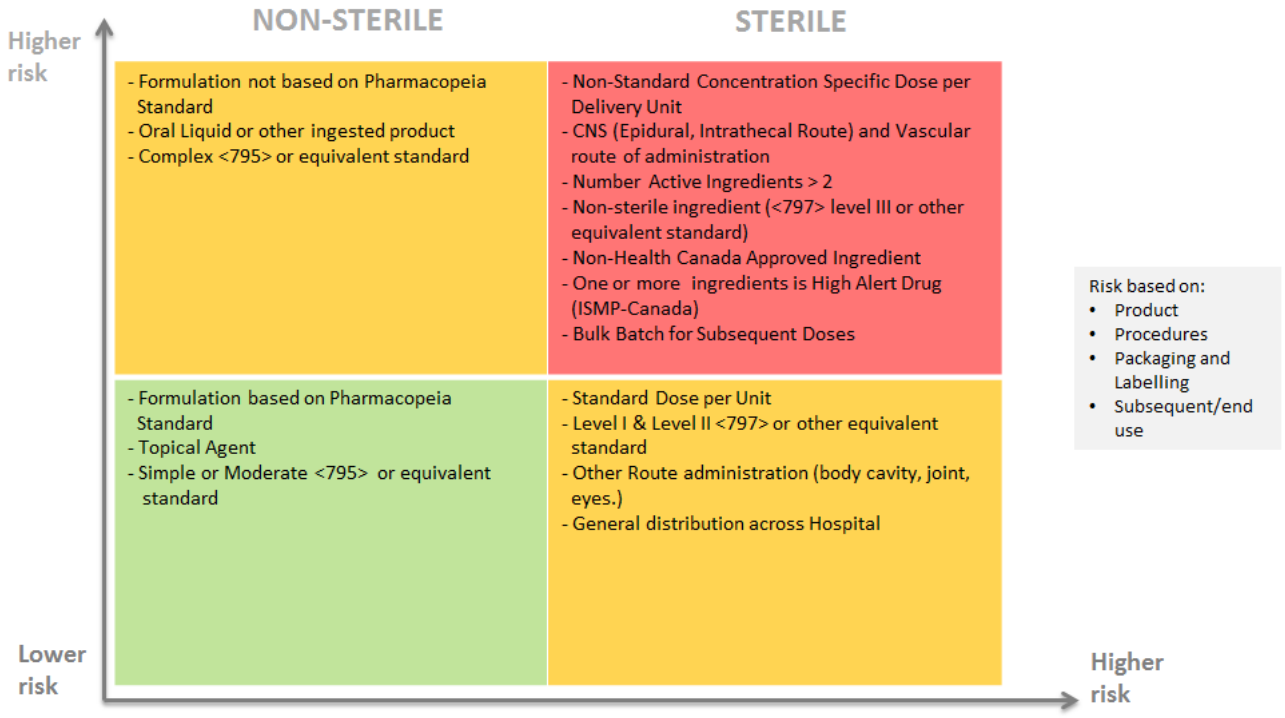
1. The scope of this document does not cover service providers in provinces other than Ontario. Health Canada should establish regulatory control and license commercial compounders to establish qualification in every province and ensure the service meets acceptable levels of standard.
2. Further clarity and consistency can be established if ISMP-Canada creates guidance document for labelling of compounded products for patient safety.
3. When Canadian equivalents to USP <797> and USP <795> become available, they must become the accepted standard.
4. Discussion and decision are required on whether preparations that are not intended for direct administration to a patient but identified for subsequent manipulation within the pharmacy should be included in the scope of the final contract.
5. Discussion and decision are required, when the scope of practice is complete, on whether compounding functions will be, or should be, limited to regulated pharmacy technicians. The recommendation is that the same standard applies whether the function is conducted within hospitals or any other location.
6. Discussion and decision are required on how compounding is managed when a compounded preparation requires final sterilisation and uses a nonaseptic API.

Appendix A: Definitions

The following definitions apply for terms used in this document; they may have different meanings in other contexts.

a) **<795>:** USP-NF General Chapter <795> Pharmaceutical Compounding-Nonaseptic Preparations
b) **<797>:** USP-NF General Chapter <797> Pharmaceutical Compounding-Sterile Preparations
c) **<795>/<797> standard or acceptable equivalent:** The standard is USP until such times as a Canadian equivalent is established.
d) **Active pharmaceutical ingredient (API):** the active ingredient in a pharmaceutical drug i.e., acetaminophen powder contained in Tylenol® tablets. It may be referred to as a bulk chemical.
e) **Beyond-use date:** the date after which a compounded preparation should not be used.
f) **Buyer:** the person or pharmacy department within the healthcare organization that procures (places the order for preparations, receives the preparations, distributes the preparations, and directly manages any changes to the preparation). In this case it is the pharmacy department and/or dedicated pharmacy personnel.
g) **Compounding:** the preparing of drug preparations pursuant to or in anticipation of a prescription.
h) **Contractor:** the entity who is conducting a competitive bid process, such as an RFP, awarding the business under a final agreement, and responsible for managing the final agreement over time. It may be an external procurement services provider, such as a group purchasing organization (GPO) or a shared service organization (SSO), or a person or department within the healthcare organization undertaking the procurement.
i) **Controlled substances:** means a substance included in schedule I, II, III, IV, or V of the Controlled Drugs and Substances Act (SC 1996 c19).
j) **End-user:** the person or department who identifies the needs of the patient for the preparations and who administers the preparations to the patient. In this case it may be physicians and nursing staff and other persons authorised to administer the compounded preparation.
k) **GTIN:** global trade item number; commonly referred to as barcode.
l) **ISMP-Canada guidance document:** a guidance document being prepared by ISMP-Canada addressing the labelling of compounded preparations.
m) **Healthcare organization:** the entity responsible for the direct delivery of healthcare to the patient e.g., the hospital.
n) **Service provider:** the entity who is responding to the competitive bid document and which may become the successful bidder.
o) **Specified Preparation List:** a detailed list of items under consideration for compounding services that contains complete information to protect patient safety at every step in the supply chain.

Appendix B: Risk Matrix



Appendix C: References

1. U.S. Pharmacopeia, USP-NF General Chapter <795> Pharmaceutical Compounding-Nonaseptic Preparations
2. U.S. Pharmacopeia**,** USP-NF General Chapter <797> Pharmaceutical Compounding-Sterile Preparations
3. Outsourcing Sterile Products Preparation Contractor Assessment Tool; www/ashpfoundation.org References for stability studies:
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8. *Controlled Drugs and Substances Act*, SC 1996, c 19.
9. Health Canada, Drug Good Manufacturing Practices Unit. *Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069)*, 2011.
10. ISO Standard 14644: Cleanrooms and associated controlled environments

Appendix D: Authors

This document was developed by a Working Group under the direction of the Procurement Sub-Taskforce of the Implementation Taskforce. Working Group Members: Kathy Boyle, (Working Group Lead), Michael Blanchard, Jimmy Fung, Nancy Giovinazzo, Sylvia Hyland, Sandy Jansen, and Allan Mills.

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