Newfoundland & Labrador Pharmacy Board

Pharmacy Quality Assurance Self-Assessment

(Sterile Compounding –Non-Hazardous and Hazardous)

Contact Information	
Pharmacy:	**License #:**
Address:	**PO Box:**
City/Town:	**Postal Code:**
Phone #:	**Fax #:**
Email Address:	**Website:**

Hours of Operation			
Mon-Fri:	**Sat:**	**Sun:**	**Holidays:**

Type of Sterile Compounding Provided	
❑ **Non-hazardous**	❑ **Hazardous**

Pharmacy Staff		
Position:	**Name:**	**License Number (if applicable):**
Pharmacist-in-Charge		
Compounding Supervisor		
Additional Compounding Personnel:		

Advancing Pharmacy Care for a Safe and Healthy Community

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
Standard 5.1- Personnel (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
The pharmacist-in-charge, as licence holder for the pharmacy, understands the high-level responsibility for the operation of the pharmacy, including full implementation of sterile compounding standards.					
A pharmacist or pharmacy technician with the required training has been designated as the sterile compounding supervisor and is responsible for developing, organizing, and supervising all activities related to pharmacy compounding of sterile preparations.					
	The sterile compounding supervisor understands and has committed to the responsibilities as outlined in Section 5.1 of the Standards.				
All compounding personnel have reviewed and understand the applicable sterile compounding standards, and are committed to meeting their roles and responsibilities.					
Training and assessment:					
A training and assessment program is in place.					
Compounding supervisor					
	Has successfully completed training (i.e. courses) in the compounding of sterile preparations, maintains up-to-date knowledge and demonstrates required compounding and managerial competencies.				
	Is evaluated for knowledge and ability by an appropriate third party that has expertise in sterile compounding and is not affiliated with the facility or individual being evaluated.				
Compounding personnel:					
	Theoretical training and assessment of required knowledge of policies and procedures, as well as the aseptic compounding process, is included in the training process for personnel.				
	Training for personnel includes practical training and assessment in the clean room to demonstrate compliance with operating procedures and knowledge of aseptic compounding processes (gloved fingertip sampling and media fill testing).				
	Personnel must pass gloved finger tip sampling and media fill testing for various types of sterile preparations to be compounded before working in the compounding area for sterile compounding.				
	Knowledge and competency assessments take place at least once per year for those involved in low ro medium-risk level sterile compounding and twice per year for those involved in high-risk level sterile compounding.				

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
Cleaning and disinfecting personnel:					
	Initial training includes theoretical training and assessment that covers the issues and particularities of cleaning and disinfecting the premises and equipment, and practical training and assessment in the areas reserved for compounding sterile preparations.				
	All cleaning and disinfecting personnel are evaluated at least once per year.				
Other personnel:					
	Persons entering the sterile compounding area or involved in sterile compounding processes (such as volunteers, employees, or contractors) are adequately trained and follow established policies and procedures.				
	Pharmacists who **do not compound** but are responsible for supervising compounding personnel, have completed theoretical training components of the sterile compounding training program and have a solid understanding of policies and procedures related to sterile compounding.				
The results of all assessments are noted in the given employees files and are retained in a retrievable manner for the purposes of audit.					
In the event of an unsuccessful written or practical evaluation, personnel immediately stop performing compounding or cleaning/disinfecting activities and redo training; activities are not resumed until an individual passes evaluation.					
Standard 5.2- Policies and Procedures (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
Policies and procedures covering all sterile compounding procedures are developed with a plan in place to review and update at least once every 3 years and upon Standard changes (see Appendix I of each set of standards for a full list of suggested policies and procedures).					
	Compounding supervisor establishes content and holds staff accountable for consistent application and compliance.				
	A standard format is used to develop clear policies and procedures (Appendix 4 of Standards).				
	Records of policy and procedure revisions include the date of each change and the names of authors and reviewers.				
Standard 5.3- Facilities and Equipment (<u>NON-HAZARDOUS</u> STERILE COMPOUNDING AREA)					
The sterile compounding facilities are designed and built by qualified engineering and construction companies, and meet the requirements of pharmacy regulatory standards, provincial regulations, health facility requirements and any other applicable standards for the construction of buildings. [NOTE: It is the responsibility of pharmacy owners and management to ensure this and NLPB requires supporting documentation to this effect].					

Please indicate compliance by checking the appropriate space below.					
Criteria	**Compliant**			**Action Timeline/Comments**
	Yes	**No**	**N/A**	
Areas for sterile compounding are large enough to facilitate compounding; allow cleaning and disinfecting without constraint; and ensure good flow of people, equipment and materials.				
Lighting of the sterile compounding area is sufficient and fixtures are located so as to facilitate the sterile compounding process and verification of all stages of compounding.				
The facility's heating, ventilation and air conditioning system (HVAC) is designed to minimize risk of airborne contamination in controlled rooms, and achieve and maintain the appropriate ISO class for clean rooms and anterooms.				
An air-conditioning system is included in the HVAC system for the comfort of staff wearing personal protective equipment (PPE) that are working in sterile compounding areas.				
There are no windows or doors in the controlled rooms that open directly to the exterior of the building (In the case that windows and doors to the exterior are present, they are sealed. **Please indicate if this is the case in "comments"**).				
Air supplied to sterile compounding areas passes through a high-efficiency particulate air (HEPA) filter; air is supplied from the ceiling via diffusers fitted with a terminal HEPA filter.				
Efficiency of filters is tested at least every 6 months and filters are periodically replaced, as per manufacturer recommendations.				
Particle counts of the controlled rooms are performed by trained quality personnel or a qualified certifier at least every 6 months. This includes: non-viable particles per cubic metre of air, viable particles per cubic metre of air, and viable surface particles.				
All sources that generate particles are controlled in order to maintain required ISO classification.				
Air quality requirements must be met under dynamic conditions and verification exercises take place while compounding activities are being performed.				
Return air intakes should be installed at the bottom of walls, forcing particles to flow downward (if not, airflow analysis must take place under dynamic operating conditions to ensure the location of the return air intakes does not hinder the compounding process-supporting documentation must be retained and available for review).				
Sterile compounding areas have two controlled rooms, a clean room and anteroom, that are enclosed and physically separated by a wall. (If no high risk compounding is performed compounding area and ante-area do not need to be separated by a wall, but there must be a displacement airflow of 40 feet per minute from clean-area to ante-area. **Please specify if this is the case under "comments"**).				

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
The cleanroom:					
	Has primary engineering controls (PECs) installed within the room. (eg. laminar air flow workbench [LAFW] or compounding aseptic isolator [CAI])				
	Is kept under positive pressure relative to the anteroom (pressure differential ≥ 5.0 Pa).				
	Maintains ISO class 7 air quality under dynamic conditions.				
	Experiences at least 30 air changes per hour (ACPH). (Note: depending on size of the room and personnel present at one time this may need to be larger)				
	Has its temperature maintained at ≤ 20ºC and is continuously monitored.				
	Has access restricted to personnel with specific clean room responsibilities.				
	Has one or more observation windows to allow supervision of compounding activities.				
The anteroom:					
	Is separated by a line of demarcation to identify "clean" area and "dirty" area.				
	Is used for high particulate activates (garbing, handwashing, labelling, staging of components, etc.)				
	Is kept under positive pressure compared to non-controlled areas (pressure differential ≥ 5.0 Pa)				
	Maintains ISO class 8 air quality under dynamic conditions.				
	Experiences at least 20 air changes per hour (ACPH). (Note: depending on size of the room and personnel present at one time, more may be required)				
	Has its temperature maintained at ≤ 20ºC and is continuously monitored.				
	Each door to the ante-area has a window.				
	A process is defined so that the door to the ante-area from the uncontrolled space, and the door to the clean room from the ante-area, are not open at the same time.				
	Contains appropriate amount of PPEs: -Hands-free sink of adequate size -Soap dispenser -Nail picks -Alcohol-based hand rub with persistent activity -Hand drying system (dryer or lint-free towels preferred) -Mirror -Clock -Waste container -Eyewash station -Pass through window or designated "clean" cart.				
	Has its sink located on the "clean" side of the anteroom.				
	Activity and personnel within the area is limited to what is essential.				

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Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
	There is an area outside the anteroom for unpacking supplies.				
	Supplies are removed from cardboard boxes outside the anteroom and disinfected with sporical agent before being brought into the anteroom.				
In the event the anteroom is shared between non-hazardous and hazardous cleanrooms (not recommended), requirements outlined in Section 5.3.2.6 of NAPRA Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations are met.					
	Appropriate "dirty", "clean", chemically contaminated" designations.				
	Activities in a shared anteroom are limited to handwashing and donning of PPE. **No drug storage**.				
	Shared anteroom is positive pressure relative to both the clean room for hazardous drugs and non-controlled areas.				
	ISO class 7 air quality is maintained under dynamic conditions.				
	There are at least 30 ACPH. More may be required depending on size of room and number of personnel.				
	Temperature is maintained at ≤ 20ºC and is continuously monitored.				
	Air diffusers are positioned so that particle stream is directed toward the dirty area of anteroom.				
	Air is exhausted to the exterior of the building and is not recycled.				
Functional parameter control systems:					
	Control systems indicating the temperature and differential pressure of controlled areas are in the same place, where they can be easily monitored by pharmacy personnel.				
	Control systems are connected to a notification system to alert personnel when parameters are outside accepted limits.				
	A policy and procedure is in place to have controls calibrated **once yearly.**				
Pressure monitors are in place to alert personnel of deviations in the pressure differential from specifications.					
ALL surfaces (ceilings, walls, floors, fixtures, carts, shelving, counters, pass through window, cabinets, etc.) in the controlled areas are smooth, impervious, non-porous, waterproof, free from cracks and crevices (sealed), non-shedding and resistant to sanitizing agents.					
Floors in the controlled areas extend 10-15 cm up the walls.					
There are no carpets, rugs, or mats in controlled areas.					
Any holes, cracks, or breakage in ceiling and walls are repaired and sealed at the earliest opportunity.					
Ceiling fixtures in the controlled areas are recessed and flush mounted, and are washable, smooth, and sealed.					

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
There are no water sources, sinks or drains in the clean room.					
Movable furniture is cleaned and disinfected before entering the clean room.					
Each room is identified with appropriate signage (e.g. pictograms indicating hazards, restricted access, dress code, etc.)					
Equipment:					
Primacy Engineering Control (PEC); e.g. LAFW, CAI, is:					
	located in the clean room;				
	installed according to manufacturer's recommendations and certified by a qualified certifier and in accordance with Controlled Environment Testing Association (CETA) Standards (Appendix 5 of the Standards);				
	cleaned appropriately (see standard 6.6.4);				
	operated continuously during every sterile compounding activity. (If the PEC has been turned off, it must be allowed to run for at least 30 minutes, or as recommended by the manufacturer, before cleaning, disinfection and compounding of sterile preparations are undertaken.)				
	a work area that meets at least ISO Class 5 under dynamic conditions with unidirectional airflow;				
	positioned to avoid interference with facility ventilation systems and to allow sufficient clearance for cleaning and disinfecting activities;				
	recertified every 6 months, when relocated, after major repairs, and when viable air sampling indicates it may not be in compliance with specifications.				
	equipped with accessible pre-filters, inspected every 6 months, and replaced when necessary.				
	HEPA filters are verified and certified during installation of PEC.				
If a CAI is used, manufacturer recommended recovery time is observed after placing materials, before starting compounding.					
If LAFW used, it is not positioned near doors or drafts that may affect airflow.					
If multiple LAFW, they are positioned to prevent interference with each other.					
All necessary equipment, devices, instruments, and accessories are cleaned and disinfected with germicidal detergent, followed by sterile 70% isopropyl alcohol (IPA) before being placed in a controlled area.					
Automated Compounding Device (ACD) and balance:					
	is positioned in the PEC so that all critical sites are exposed to first air;				
	if a peristalic pump is used, it is calibrated between batches;				
	ACD is calibrated at least once daily after cleaning, then as needed according to manufacturer recommendations;				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
	The balance is calibrated before each use, after it is moved, after cleaning and as needed (in accordance with manufacturer recommendations);				
	Calibration results are recorded in a readily retrievable manner.				
Carts:					
	separate carts are designated for the "clean" and "dirty"				
	are made of stainless steel or high-quality plastic;				
	are cleaned and disinfected daily;				
	supplies are disinfected when placed on the "clean" cart;				
	if used to bring materials from outside the controlled area, remain on the "dirty" side of the line of demarcation. Clean carts used to bring materials from the anteroom to the cleanroom remain on the "clean" side of the line of demarcation;				
	if the anteroom is shared, one cart is reserved for the "clean but chemically contaminated" side and one for the "clean and not chemically contaminated" area.				
Refrigerators and freezers used to store compounded sterile products (CSPs) are:					
	commercial biomedical grade units;				
	not used to store food;				
	located outside the controlled areas, if possible;				
	continuously monitored for temperature using accurate temperature probes (calibrated once per year). Temperature readings are recorded, and a notification system is in place to alert personnel to temperature excursions.				
Incubators are:					
	used to maintain a constant temperature to culture microorganisms;				
	temperature controlled according to culture medium and incubation period;				
	monitored for temperature, with temperatures read and recorded at least once daily when in operation;				
	calibrated and maintained as per manufacturer recommendations;				
	not located in the cleanroom or anteroom.				
If cameras, computer equipment, or a communication system is placed in controlled rooms they are conducive to cleaning procedures and "hands free" use.					
Controlled areas have a sufficient number of easy-to-clean waste containers with plastic bag liners.					

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
Facility has an appropriate amount of PPE that is appropriately donned for compounding of sterile products:					
	Shoe covers or dedicated shoes;				
	Hair covers;				
	Beard covers (if applicable);				
	Surgical masks;				
	Non-shedding protective gown that is enclosed at the neck and snug fitting sleeves;				
	Non-powdered sterile gloves that fit over the sleeves of gown.				
Cleaning Procedures:					
Only trained and qualified cleaning and disinfecting personnel are allowed to clean the controlled area.					
A germicidal disinfectant is used to disinfect all surfaces in the clean room and anteroom [SPECIFY AGENT IN COMMENTS].					
The germicidal disinfectant is augmented with the use of a weekly (or monthly) sporicidal agent.					
Material safety data sheets are available for the disinfectants used in the facility.					
Specific cleaning equipment is designated for non-hazardous and hazardous compounding areas.					
Non-shedding equipment is used for controlled areas.					
Where possible, disposable cleaning equipment is used.					
When reusable equipment is used, it is washed and dried after each use and appropriately stored in a cabinet in or near the antearea.					
Separate cleaning equipment is designated for ISO- Class 5 areas, and ISO Class 7 and 8 areas.					
Cleaning and disinfecting personnel comply with handwashing and garbing protocols including donning of gloves.					
Cleaning equipment is disinfected before it enters the cleanroom.					
PEC, counters, carts, floors, surfaces that are frequently touched (e.g. door knobs, light switches, chairs, etc.) are cleaned **daily**.					
Walls, ceiling, shelves, and outer surfaces of PEC are cleaned **monthly.**					
Cleaning is performed from the "cleanest" area to the "dirtiest" area.					
A policy is in place for the documentation of cleaning and disinfecting procedures and associated records are stored in a readily retrievable manner.					

Please indicate compliance by checking the appropriate space below.					
Criteria	**Compliant**			**Action Timeline/Comments**
	Yes	**No**	**N/A**	
Standard 5.3- Facilities and Equipment (<u>HAZARDOUS</u> STERILE COMPOUNDING AREA)				
The sterile hazardous compounding facilities are designed and built by qualified engineering and construction companies, and meet the requirements of pharmacy regulatory standards, provincial regulations, health facility requirements and any other applicable standards for the construction of buildings. [NOTE: It is the responsibility of pharmacy owners and management to ensure this and NLPB requires supporting documentation to this effect].				
A list of hazardous drugs used is maintained and reviewed at least every 12 months.				
Areas for sterile hazardous compounding are large enough to facilitate compounding; allow cleaning and disinfecting without constraint; and ensure good flow of people, equipment and materials.				
Lighting of the compounding area is sufficient and fixtures are located so as to facilitate the sterile compounding process and verification of all stages of compounding.				
The facility's heating, ventilation, and air conditioning system (HVAC) is designed to minimize risk or airborne contamination in controlled rooms and achieve and maintain the appropriate ISO class for clean rooms and anterooms.				
An air-conditioning system is included in the HVAC system for the comfort of staff wearing personal protective equipment (PPE) that are working in sterile compounding areas.				
There are no windows or doors in the controlled rooms that open directly to the exterior of the building (In the case that windows and doors to the exterior are present, they are sealed. **Please indicate if this is the case in "comments"**).				
Air supplied to sterile compounding areas passes through a high-efficiency particulate air (HEPA) filter; air is supplied from the ceiling via diffusers fitted with a terminal HEPA filter.				
Efficiency of filters is tested at least every 6 months and filters are periodically replaced as per manufacturer recommendations.				
Particle counts of the controlled rooms are performed by trained quality personnel or a qualified certifier at least every 6 months. This includes: non-viable particles per cubic metre of air, viable particles per cubic metre of air, and viable surface particles.				
All sources that generate particles are controlled in order to maintain required ISO classification.				
Air quality requirements must be met under dynamic conditions and verification exercises take place while compounding activities are being performed.				

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
Return air intakes should be installed at the bottom of walls, forcing particles to flow downward (if not, airflow analysis must take place under dynamic operating conditions to ensure the location of the return air intakes does not hinder the compounding process- supporting documentation must be retained and available for review).					
Sterile compounding areas have two controlled rooms, a clean room and anteroom, that are enclosed and physically separated by a wall.					
The cleanroom:					
	Is used to compound hazardous sterile products ONLY;				
	Primary engineering controls (PECs) are installed in the clean room- eg. Biological safety cabinet (BSC) or a compounding aseptic containment isolator (CACI).				
	The clean room is kept under **negative** pressure relative to the anteroom (pressure differential **≥ -2.5 Pa**)				
	ISO class 7 air quality is maintained under dynamic conditions.				
	There are at least 30 air changes per hour (ACPH). (Note: depending on size of the room and personnel present at one time may need to be more)				
	Temperature is maintained at ≤ 20ºC and is continuously monitored.				
	Return air from the clean room is exhausted to the exterior of the building.				
	Access to the clean room is restricted to personnel with specific clean room responsibilities.				
	The clean room has one or more observation windows to allow supervision of compounding activities.				
The anteroom:					
	Is separated by a line of demarcation to identify "clean" area and "dirty" area.				
	Is used for high particulate activates (garbing, handwashing, labelling, staging of components, etc.)				
	Is kept under positive pressure compared to non-controlled areas (pressure differential ≥ 5.0 Pa)				
	ISO class 7 air quality is maintained under dynamic conditions.				
	There is at least 30 air changes per hour (ACPH). Note: depending on size of the room and personnel present at one time, more may be required.				
	Temperature is maintained at ≤ 20ºC and is continuously monitored.				
	Each door to the ante-area has a window.				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
	A process is defined so that the door to the ante-area from the uncontrolled space, and the door to the clean room from the ante-area, are not open at the same time.				
	The anteroom contains PPE, hands-free sink of adequate size, soap dispenser, nail picks, alcohol-based hand rub with persistent activity, hand drying system (dryer or lint-free towels[PREFERRED), mirror, clock, **cytotoxic** waste containers, eyewash station, and pass through window or designated "clean" cart.				
	The sink is located on the "clean" side of the anteroom.				
	Activity and personnel within the area is limited to what is essential.				
Area for unpacking hazardous products:					
	There is an area outside the anteroom for unpacking supplies.				
	Supplies are removed from cardboard boxes outside the anteroom and disinfected with sporical agent before being brought into the anteroom.				
	If the product is in a damaged state when received it is unpacked in a C-PEC.				
Area for storing hazardous products:					
	is a dedicated room separate from the unpacking area.				
	is maintained under **negative pressure (-2.5 Pa)** relative to surrounding areas.				
	has at least **12 ACPH**, with **air exhausted to the exterior.**				
	has shelves with lips to prevent products from falling and breaking				
	is identified with proper signage that indicates presence of hazardous products.				
Functional parameter control systems:					
	Control systems indicating the temperature and differential pressure of controlled areas are in the same place, where they can be easily monitored by pharmacy personnel.				
	Control systems are connected to a notification system to alert personnel when parameters are outside accepted limits				
	A policy and procedure is in place to have controls calibrated **once yearly.**				
Pressure monitors are in place to alert personnel of deviations of pressure differential from specifications.					
ALL surfaces (ceilings, walls, floors, fixtures, carts, shelving, counters, pass through window, cabinets, etc.) in the controlled areas are smooth, impervious, non-porous, waterproof, free from cracks and crevices (sealed), non-shedding and resistant to sanitizing agents.					

Please indicate compliance by checking the appropriate space below.					
Criteria	**Compliant**			**Action Timeline/Comments**
	Yes	**No**	**N/A**	
Pass throughs have an interlocking system or a door opening procedure is in place.				
Floors in the controlled areas extend 10-15 cm up the walls.				
There are no carpets, rugs, or mats in controlled areas.				
Any holes, cracks, or breakage in ceiling and walls are repaired and sealed at the earliest opportunity.				
Ceiling fixtures in the controlled areas are recessed and flush mounted, and are washable, smooth, and sealed.				
There are no water sources, sinks or drains in the clean room.				
Movable furniture is cleaned and disinfected before entering the clean room.				
Each room is identified with appropriate signage (e.g. pictograms indicating **cytotoxicity**, hazards, restricted access, dress code, etc.)				
All required PPE is worn by those carrying out facility maintenance.				
HEPA filters that are being replaced are considered contaminated and are handled and disposed of cautiously.				
Equipment:				
Containment Primacy Engineering Control (C-PEC) (e.g. Class II or III BSC or CACI) is:				
located in the clean room;				
installed according to manufacturer's recommendations and certified by a qualified certifier and in accordance with Controlled Environment Testing Association (CETA) Standards (Appendix 5 of the Standards);				
exhausted to the exterior;				
cleaned appropriately (see standard 6.6.4);				
operated continuously;				
a work area that meets at least ISO Class 5 under dynamic conditions with unidirectional airflow;				
positioned to avoid interference with facility ventilation systems and to allow sufficient clearance for cleaning and disinfecting activities;				
recertified every 6 months, when relocated, after major repairs, when viable air sampling indicates it may not be in compliance with specifications.				
equipped with accessible pre-filters, inspected every 6 months, and replaced when necessary.				
HEPA filters are verified and certified during installation of PEC.				
If a CACI is used, manufacturer recommended recovery time is observed after placing materials, before starting compounding.				
If BSC is used, it is not positioned near doors or drafts that may affect airflow.				

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Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
If multiple BSC, they are positioned to prevent interference with each other.					
All necessary equipment, devices, instruments and accessories are cleaned and disinfected with germicidal detergent, followed by sterile 70% isopropyl alcohol (IPA) before being placed in a controlled area.					
Automated Compounding Device (ACD) and balance:					
	Is positioned in the PEC so that all critical sites are exposed to first air.				
	If a peristalic pump is used, it is calibrated between batches.				
	ACD is calibrated at least once daily after cleaning, then as needed according to manufacturer recommendations.				
	The balance is calibrated before each use, after it is moved, after cleaning and as needed (in accordance with manufacturer recommendations)				
	Calibration results are recorded in a readily retrievable manner.				
Carts:					
	Separate carts are designated for the "clean" and "dirty" area of the anteroom.				
	Are made of stainless steel or high-quality plastic.				
	Are cleaned and disinfected daily.				
	Supplies are disinfected when placed on the "clean" cart.				
	Carts used to bring materials from outside the controlled area remain on the "dirty" side of the line of demarcation. Clean carts used to bring materials from the anteroom to the cleanroom remain on the "clean" side of the line of demarcation.				
	If the anteroom is shared, one cart is reserved for the "clean but chemically contaminated" side and one for the "clean and not chemically contaminated" area.				
Refrigerators and freezers used to store hazardous compounded sterile products (CSPs) are:					
	commercial biomedical grade units;				
	not used to store food or other drugs;				
	continuously monitored for temperature using accurate temperature probes (calibrated once per year), with temperature readings recorded. A notification system is in place to alert personnel to temperature excursions.				
Incubators are:					
	used to maintain a constant temperature to culture microorganisms;				
	temperature controlled, according to culture medium and incubation period;				
	monitored for temperature and temperatures are read and recorded at least once daily;				

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Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
	calibrated and maintained as per manufacturer recommendations;				
	not located in the cleanroom or anteroom.				
If cameras, computer equipment, or a communication system is placed in controlled rooms, they are conducive to cleaning procedures and preference is given to equipment that is able to operate "hands free".					
Controlled areas have a sufficient number of easy-to-clean and decontaminate hazardous waste containers that are closable to prevent spread of vapours and labelled with hazardous materials symbols.					
Personal Protective equipment and clothing:					
	Gloves are non-powdered, ASTM compliant.				
	Two pairs of ASTM gloves are worn during unpacking hazardous drug, cleaning and disinfecting clean room and C-PEC, compounding, managing a spill, disposing of hazardous product.				
	The first (inner) pair of gloves are worn under the sleeves of the gown. The second (outer) pair is pulled up over the gown cuffs.				
	Outer gloves are sterile.				
	Gloves are discarded and replaced at the earliest of manufacturer's recommendations, 30 minutes, or when torn or contaminated.				
	Gowns are impermeable to hazardous products, tie in the back, and have fitted wrist cuffs.				
	Gowns are discarded and replaced at the earliest of manufacturer's recommendations, 2-3 hours, when removed, or when torn or contaminated.				
	Personnel wear appropriate masks based on the compounding related-activity (N95, N100, or chemical cartridge respirators; see Table 5) that are fit-tested.				
	Masks are changed at the earliest of manufacturer recommendation, 3.5 hours of continuous compounding, after each removal, or if contaminated.				
	Goggles and a face shield or a full piece respirator are used when working eye level, when cleaning under the C-PEC work surface, when cleaning a spill or when there is a risk of splashes.				
	Clean room scrubs are worn.				
	Two pairs of disposable shoe covers are required at all times in the clean area of the anteroom and in the clean room, even if dedicated shoes are worn.				

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
	Shoe covers are changed after each removal or in the event of contamination, spill or breakage. Shoe covers worn in hazardous drug compounding areas are not worn outside the controlled area.				
	Beard covers are worn, if applicable.				
Cleaning Procedures:					
Only trained and qualified cleaning and disinfecting personnel are allowed to clean the controlled area.					
A decontaminant, deactivation product, germicidal disinfectant is used to decontaminate and disinfect all surfaces in the clean room and anteroom [SPECIFY AGENTS USED IN COMMENTS].					
The germicidal disinfectant is augmented with the use of a weekly (or monthly) sporicidal agent.					
Material safety data sheets are available for the disinfectants used in the facility.					
Specific cleaning equipment is designated for hazardous compounding areas.					
Non-shedding equipment is used for controlled areas.					
Disposable cleaning equipment is used. If reusable accessories are used, they must be washed and dried after each use and must be stored in a clean cabinet dedicated to storing this equipment.					
Separate cleaning equipment is designated for ISO- Class 5 areas and ISO Class 7 areas.					
Cleaning and disinfecting personnel comply with handwashing, PPE, and garbing protocols including donning of gloves.					
Cleaning equipment is disinfected before it enters the cleanroom.					
C-PEC, counters, carts, floors, surfaces that are frequently touched (e.g. door knobs, light switches, chairs, etc.) are cleaned **daily**.					
Walls, ceiling, shelves, and outer surfaces of C-PEC are cleaned **monthly.**					
Cleaning is performed from the "cleanest" area to the "dirtiest" area.					
A policy is in place for the documentation of cleaning, decontamination and disinfecting procedures and associated records are stored in a readily retrievable manner.					
Standard 6.1- Beyond-use Date and dating methods (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
The pharmacy's policy and procedures for sterile compounding include a section on the assignment of BUD's.					
BUDs are assigned based on chemical and physical stability and storage time, based on risk of microbial contamination.					

Please indicate compliance by checking the appropriate space below.

Criteria	Compliant			Action Timeline/Comments
	Yes	No	N/A	
When performing stability testing to establish a longer BUD, preparations are quarantined until the results are obtained.				
Sterile commercial products are used wherever possible.				
BUD's are appropriately specified for single dose and multi-dose vials in the compounding of sterile products.				
CSP`s are appropriately classified as low, medium, or high risk with a BUD is assigned accordingly.				
CSP packaging labels include BUD (in addition to mandatory drug label information).				
Administration of the CSP begins before the BUD has passed.				
High-risk compounds are always sterilized.				
Sterility testing via membrane filtration and bacterial endoxin testing is performed for high-risk sterile preparations when CSPs are prepared in batches greater than 25 units, > 12 hours exposure time between 2-8ºC or > 6 hours exposure above 8ºC.before sterilization.				
A BUD of 12 hours or less is assigned for preparations compounded in segregated areas.				
Segregated compounding areas are appropriately placed to reduce the risk of contaminations and personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.				
Standard 6.2, 6.3, 6.4- Compounded sterile preparation protocols, compounded sterile preparation log, and patient file (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)				
Written protocols for CSPs contain all of the information required to prepare the compound (see Appendix 7, NAPRA *Model Standards for Pharmacy Compounding of Non-hazardous/Hazardous Sterile Preparations*).				
Protocols are reviewed and approved by a sterile compounding supervisor or delegate.				
Protocols are readily available to compounding personnel for quick consultation.				
A compounded sterile preparation log is completed during the compounding process for both individual patients and batches.				
Logs for individual preparations and batches contain all information required by the Standards.				
Logs (paper-based or computerized) are filed in a readily retrievable manner and retained for 10 years.				
All information related to the review and assessment of each preparation, and the subsequent treatment of the patient is recorded in the patient's file; all CSP's are auditable and traceable to the patient.				
The pharmacy has a policy and procedure for recall of compounded CSPs.				

Please indicate compliance by checking the appropriate space below.					
Criteria	**Compliant**			**Action Timeline/Comments**	
	Yes	**No**	**N/A**		
Standard 6.5- Conduct of personnel in areas reserved for the compounding of sterile preparations (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
Personnel behave in a professional manner and follow all policies and procedures.					
Personnel afflicted with conditions that can affect quality of CSPs (eg. skin infections, burns (including sunburn), cold sores, eye infections, active respiratory infections, fresh piercings or tattoos) are excluded from compounding areas and activities until the condition has been resolved.					
Pharmacy personnel prepare for entering the controlled areas by removing outer lab jackets, makeup and jewellery, nail polish or synthetic nails, personal electronic devices such as cell phones or ipods.					
Pharmacy personnel tie up long hair, keep natural nails short and trimmed, ensure hands and skin or forearms are undamaged.					
Food, drinks, chewing gum, candy are not permitted in controlled areas.					
All access doors to the controlled areas are kept closed.					
Access to controlled areas is restricted to personnel with specific responsibilities in the controlled area.					
All personnel in the controlled areas must follow specified hand hygiene and garbing procedures.					
Only essential conversation is permitted in the controlled areas to limit particulate contamination.					
Standard 6.6- Aseptic Compounding (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
The number of people in the cleanroom and anteroom are limited to the minimum number required to perform aseptic compounding activities.					
Hand and Forearm Hygiene:					
Pharmacy personnel use nail picks to remove debris from nails, thoroughly scrub hands and arms to the elbow with an antimicrobial cleanser and dry hands with air dryer or disposable towels.					
Hands and forearms are covered with alcohol based hand rub (ABHR) with persistent activity in the anteroom as well as when entered the clean room.					
Garbing:					
Pharmacy personnel wear dedicated, low shedding apparel, pants that fully cover the legs, closed shoes and socks.					
Pharmacy personnel select and appropriately don gowns and PPE in the antearea.					
Hair nets, beard covers and face masks are donned on the "dirty" side of the anteroom.					

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
	Shoe covers or dedicated shoes are donned while stepping over the line of demarcation to the "clean" side of the anteroom.				
	Dedicated shoes are easy to clean and maintain and are cleaned and disinfected weekly.				
	Gowns are closed at the neck, have elastic cuffs, and are donned on the "clean" side of the anteroom.				
	Sterile gloves are donned in the clean room after hands have been disinfected for the second time with ABHR with persistent activity.				
	Gloves cover the cuffs of non-shedding gowns.				
	Gloves are disinfected with sterile 70% isopropyl alcohol throughout the compounding process.				
Introducing products and equipment into the clean room:					
Products are removed from cardboard packaging and wiped with a sporidal agent before entering the anteroom.					
Only packaging that is required to maintain sterility remains on the product when introduced to the clean room.					
Compounding equipment and supplies are organized by patient or batch into bins to prevent errors.					
Compounding products and equipment are disinfected with sterile 70% IPA using non-shedding swabs when passing from the "dirty" cart/bin to the "clean" cart/bin at the line of demarcation.					
Cleaning and disinfecting the Primary Engineering Control:					
	PECs are cleaned, disinfected, and decontaminated (if applicable) by compounding personnel at the minimum frequencies specified in section 6.6.4 of the standards.				
	Sterile water is used to dilute cleaning solutions used inside the ISO Class 5 device.				
	Disinfectant dilutions and contact time with surfaces is according to manufacturer instructions.				
	The work surface is cleaned before starting each preparation, when contamination is suspected, when there is a spill and when aseptic technique has been breached.				
	For hazardous compounding, decontamination with an appropriate agent occurs before disinfection and deactivation is done weekly.				
Aseptic Technique:					
	Compounding occurs in the critical area of the PEC, where all sites are exposed to first air.				
	If aseptic technique is compromised at any point, the compound is discarded.				
	Gloves are disinfected with sterile 70% isopropyl alcohol before re-introduction into the PEC.				
	All equipment and products are disinfected with sterile IPA before entering the PEC.				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
	Vials are not permitted to accumulate in the PEC.				
Aspects specific to compounding hazardous preparations:					
	A ventilated system equipped with a 0.22 μm hydrophobic filter is used to dilute powder or withdraw liquids.				
	Compounders comply with the maximum fill limit of the syringe.				
	A luer-lock safety tip system is used for preparations dispensed in a syringe.				
	A closed-system transfer device is used, if possible.				
	Final preparations are placed in a sealable plastic bag before removal from the C-PEC and are labelled cytotoxic.				
Verification:					
	The sterile compounding supervisor ensures all CSPs comply with protocols, verifies the identity and volume of each ingredient, and regularly verifies the quality of manipulations. (NOTE: the compounding supervisor is not expected to perform the final check of each CSP, but rather is responsible to monitor that proper protocols exist and are followed by personnel).				
	Compounding personnel perform a visual inspection of each compound and its container, verify information on the product label, and ensure correct storage pending final check.				
	Each preparation is subject to a second check by a person other than the individual who performed the compounding.				
Labelling:					
	The pharmacy has a policy regarding the labelling of CSPs.				
	Labels meet federal and provincial legislation requirements (consult with Standards of Pharmacy Operation for general label requirements).				
	Each CSP unit is individually labelled (both preparations made for individual patients as well as each unit in a batch preparations).				
	Labels contain: pharmacy identification, drug identification (all active ingredients, source, concentration, route of administration, volume, solute and amount prepared), overfill volume, special precautions, storage method, date of compounding, BUD and batch number.				
	Product inserts contain: any required information that could not fit on the label, administration details, storage instructions, precautions for disposal/destruction and emergency contact information for the pharmacy.				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
Standard 6.7- Packaging (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
A policy and procedure is in place for packaging that contains all required information.					
Appropriate packaging is used for all preparations that ensures the safety of the patient or health care provider, and shipper.					
	Packaging used maintains the products stability, integrity and storage conditions.				
	Items with an attached needle are stored in a secondary rigid container.				
	Storage requirements and precautions are on the final packaging.				
	Transport precautions and instructions (e.g. patient name and address) are on the outside packaging.				
Standard 6.8- Storage (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
A storage procedure is in place and is adhered to at all times.					
Manufacturer product storage requirements are strictly observed.					
Storage temperature for final CSPs and products used for preparations are controlled within specified limits.					
Refrigerators and freezers used to store medications must be commerial biomedical grade units.					
Alternative appropriate storage is available in the event of an equipment malfunction or when the fridge/freezer is being cleaned.					
A procedure is in place for verified BUDs of stored CSPs and expiry dates of commercial products used in compounding.					
Requirements for the storage of hazardous drugs are adhered to.					
Standard 6.9- Transport and Delivery (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)					
The pharmacy has a policy and procedure for the transport of CSPs and delivery to patient care units, pharmacists, and patients.					
The pharmacy has a policy for the return of expired or unused CSPs from the patient or patient care unit.					
	Medications to be destroyed are kept separate from inventory.				
	Medications and sharps are destroyed safely and in accordance with environmental protection laws.				
Methods are in place to ensure temperature of CSPs has been maintained during transport (e.g. temperature maintenance indicator, min/max thermometer, certified cooler).					

Please indicate compliance by checking the appropriate space below.					
Criteria	**Compliant**			**Action Timeline/Comments**
	Yes	**No**	**N/A**	
Standard 6.10, 6.11, 6.12- Recall of sterile products of final CSPs, incident and accident management, waste management (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)				
The pharmacy has the ability to identify patients who have received a given preparation, and a procedure for notifying patients/caregivers if there is a problem with a CSP.				
A procedure is defined for determining the cause of a problem with a CSP so that corrective and preventative measures can be put in place.				
The pharmacy has an event report or explanation form (Appendix 11) available for personnel to complete in the event of an incident or accident.				
Complaints, accidents, incidents and reported side effects are evaluated to determine their cause and steps are put in place to prevent recurrence.				
A log is in place for incident reviews and the information is used for continuous quality improvement.				
Policies and procedures are in place for handling accidental exposure to hazardous products.				
Medications and sharp or pointed instruments are disposed of safely and in accordance with environmental protection laws.				
Medications to be destroyed are kept separate from inventory.				
A policy and procedure is in place for destruction of pharmaceutical waste, including specific guidance on destruction of hazardous drug, if applicable.				
Standard 7 (7.1-7.6)- Quality Assurance Program (Criteria in this section apply to both hazardous and non-hazardous sterile compounding- when completing this section you are answering for both practices, if applicable)				
A quality assurance program specific to sterile compounding is implemented and followed.				
The quality assurance program includes verification of equipment, verification of controlled areas, verification of aseptic processes, and verification of final preparations.				
Each component of the QA program has a verification process that assigns results and action levels (e.g. compliance, alert, action required).				
Verification of equipment and facilities:				
All equipment that supports compounding activities (e.g. fridges, freezers, incubators and air sampling devices) is certified upon installation and calibrated, with regular calibrations scheduled based on manufacturer recommendation.				
A regular maintenance plan is established for all equipment related to compounding.				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
	Whenever no manufacturer recommendations are available, maintenance activities are performed **at least once yearly** by a qualified technician.				
	Maintenance reports are saved in a log.				
Temperature readings:					
	If a recording device is integrated into equipment, temperatures are reviewed once daily for the previous 24 hours.				
	If a thermometer is used, temperature is read twice per day (am/pm) and thermometer calibrations and actual/min/max temperature is recorded.				
	If a computerized temperature monitoring system is used, temperature readings are recorded and stored and an alarm triggers if temperatures deviate from acceptable range.				
Verification of controlled rooms and primary engineering					
	The controlled areas and PEC are certified by a recognized organization during installation, repair, contamination problem- **and at least every 6 months.**				
	The program for monitoring facilities and PEC includes sampling of viable and non-viable particles.				
	The factory manufacturer's certificates for HEPA filters and PEC are retained in a readily retrievable manner.				
	An environmental verification program is established that includes daily temperature monitoring of controlled areas, continuous monitoring of pressure differentials (including alarm system), and daily monitoring of proper operation of devices (LAFW, BSC, CAI, CACI, automated compounding devices, etc.)				
	The air and surface sampling plan includes a sampling site diagram, type of sampling to be done, sampling methods to be used, number of samples obtained at each site, frequency of sampling; and number of colony forming units (CFUs) that trigger action.				
	Sampling plan includes: non-viable particles per cubic metre of air, viable particles per cubic meter of air, and viable surface particles.				
Non-viable particle sampling:					
	The competency of the certifier and the personnel chosen to conduct sampling is verified by the compounding supervisor.				
	Samples for particle counts are taken during installation of new equipment or a new controlled area, during maintenance or repair equipment, and during investigation of a contamination problem- **and at least every 6 months.**				
	Air samples for particle counts are taken under dynamic operating conditions.				

Please indicate compliance by checking the appropriate space below.

Criteria		Compliant			Action Timeline/Comments
		Yes	No	N/A	
	Values obtained comply with ISO Standard established for the controlled area.				
	Calibration certificates are obtained for the equipment used to conduct the certification (accompanies certification report).				
Viable particle sampling:					
	A new 55 mm agar surface is used for each sample taken from established sampling sites.				
	An appropriate medium is used for plating samples (tryptic soy agar or soybean-casein digest medium for air samples; tryptic soy agar with lecithin and polysorbate for surface samples; malt extract agar or other media that supports the growth of fungi is used for sampling associated with high-risk compounding).				
	Samples are sent to a certified external laboratory or incubated at the facility in a certified incubator by trained personnel.				
	Calibration certificates are obtained for the viable air sampler.				
	The certificate for verification of the microbial proliferation capacity of each batch of nutrient medium is retained.				
	If there is growth of any viable particles the genus of the organism is identified.				
	Results are assessed based on the threshold of contamination for the ISO classification.				
Hazardous drug contamination and wipe sampling:					
	Verification of contamination is carried out on surfaces used for receipt, storage, preparation and verification of products/preparations.				
	Surface samples are taken from sites that are most likely to be contaminated.				
	The level of contamination is measured at least **every 6 months** as well as when changes are made to equipment and procedures.				
	A baseline assessment was conducted to allow for ongoing monitoring of the effectiveness of measures put in place to prevent contamination.				
QA of compounding personnel:					
Gloved fingertip sampling (GFS):					
	When conducting GFS, samples are obtained from personnel **after** appropriately donning gloves, but before application of sterile IPA.				
	A sample is obtained from personnel after the media fill test, and sterile IPA is not applied to gloves prior to sampling.				
	Tryptic soy agar plates with lecithin and polysorbate are used.				
	Samples are taken for each finger and thumb on both hands.				

Please indicate compliance by checking the appropriate space below.					
Criteria		**Compliant**			**Action Timeline/Comments**
		Yes	**No**	**N/A**	
	The samples are incubated between 30 and 35 degrees celcius and read within 48-72 hours.				
	Prior to engaging in sterile compounding for the first time, personnel are required to have 3 consecutive negative GFS results (0 CFUs)				
	GFS after the media fill test is performed **annually** for low-medium risk compounds.				
	GFS after the media fill test is performed **every 6 months** for high-risk compounds.				
	The threshold of contamination is a total of 3 CFUs in total for both hands (after which the employee and work practices are investigated).				
Media Fill testing:					
	The simulation chosen is representative of activities performed under real compounding conditions of the environment and represents the most complex preparations according to microbiological risk level.				
	Tryptic soy agar (low sulfer content) or soybean casein nutrient medium is used.				
	For high-risk compounding practices the nutrient medium is non-sterile and the testing process includes sterilization by filtration.				
	The certificate for verification of the microbial proliferation capacity of each batch of nutrient medium is retained.				
	The containers used for media fill testing are sent to a certified external laboratory or are incubated in a calibrated incubator on site with results read by trained personnel [Specify which process is used in the comments].				
	Nutrient medium containers are incubated 20-25 degress Celsius or 30-35 degrees Celsius for 14 days (if two temperatures are used the higher is applied first for 7 days and the lower for another 7 days).				
QA of compounded sterile preparations:					
	A QA program is in place for the sterile compounding supervisor to ensure compliance with established procedures (including compounding protocols, prescriptions, labels, and documentation).				
Written documentation related to the QA program is verified, analyzed, actioned, and signed by the compounding supervisor.					
All documentation must be retained in a readily retrievable manner for 10 years or for equipment throughout the service life of the facility and PEC.					

CERTIFICATION

Completed by: _____ Date: _____

I, _____, certify that:

- ❑ To the best of my knowledge, the information provided in this self-assessment accurately reflects the pharmacy's current operations and practices.
- ❑ An action plan will be put in place to fully meet the Standards for Pharmacy Compounding of Non-Sterile Preparations within a timeframe satisfactory to the NL Pharmacy Board.
- ❑ I will keep a copy of this completed self-assessment on file at the pharmacy and will present it to the NL Pharmacy Board upon request.

_____ _____

Pharmacist-in-Charge Signature Date Signed