STERILE COMPOUNDING REVIEW

Contents

Community Pharmacy Standards of Practice

Reference	Requirement(s)
HPA Bylaws Schedule F Part 1 s. 9.2(1)	A registrant must comply with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time.

Hospital Pharmacy Standards of Practice

Reference	Requirement(s)
HPA Bylaws Schedule F Part 2 s. 3(3)	Sterile compounds must be prepared and distributed in an environment that is in accordance with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time.
HPA Bylaws Schedule F Part 2 – Hospital Pharmacy Standards of Practice s. 3(4) 	Hazardous drugs must be handled and prepared in accordance with the Requirements for the Safe Handling of Antineoplastic Agents in Health Care Facilities published by the Workers Compensation Board of British Columbia and such other published standards approved by the board from time to time.

Residential Care Facilities and Homes Standards of Practice

Reference	Requirement(s)
HPA Bylaws Schedule F Part 3 s. 6.3(1)	A registrant must comply with the National Association of Pharmacy Regulatory Authorities standards as approved by the board from time to time.

Requirements for Pharmacy Compounding of Sterile Preparations

Pursuant to section 18(9) of the *PODSA* Bylaws, "a direct owner, manager, directors and officers must ensure compliance with the *National Association of Pharmacy Regulatory Authorities Standards* as approved by the board from time to time, applicable to the operation of a pharmacy."

The following requirements apply to any community, hospital or residential care pharmacy that compounds sterile preparations. This review form is based on, and references requirements outlined in the NAPRA *Model Standards for Pharmacy Compounding of Non-Hazardous and Hazardous Sterile Preparations*. Please refer to these Model Standards for complete lists of requirements and guidelines.

In the tables, items marked with  apply only to non-hazardous sterile compounding and items marked with  apply only to hazardous sterile compounding. All other items apply to both, non-hazardous and hazardous sterile compounding.

- ***"NAPRA Non-Hazardous"*** refers to *NAPRA's Model Standards for Pharmacy Compounding Non-Hazardous Sterile preparations (2016)* and
- ***"NAPRA Hazardous"*** refers to *NAPRA's Model Standards for Pharmacy Compounding Hazardous Sterile preparations (2016)*.

Regulatory Framework

Requirement(s)
Pharmacy compounding must always be carried out within a prescriber–patient–pharmacist relationship.
In situations involving requests to compound preparations outside of a prescriber–patient–pharmacist relationship, in the absence of a patient-specific prescription, the preparation activities fall under the federal legislative framework. ***Registrants should review Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051).***
Individuals who do not have the knowledge, training, expertise, facilities, or equipment required to compound sterile products must refer patients to a colleague who does have the competencies and facilities required to do so or, where permitted by provincial/territorial legislation, ask another pharmacy to compound the product for them.
If a sterile product is commercially available, compounding personnel must not use non-sterile ingredients to compound a sterile preparation.
Pursuant to the NAPRA Model Standards, sterility is also required for the reconstitution and certain manipulations (according to manufacturers' instructions) of sterile products approved by Health Canada and for the repackaging of approved sterile products, regardless of the route of administration.

Sterile Compounding Supervisor Responsibilities

Reference	Requirement(s)
5.1.1.2 Sterile compounding supervisor	The sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of sterile preparations. These responsibilities are assigned by the pharmacy manager.
5.1.2.3 Competency assessment program: Sterile compounding supervisor - Qualifications	The sterile compounding supervisor must have successfully completed training (i.e., courses) in the compounding of sterile preparations, maintained up-to-date knowledge and demonstrated the required competencies.
	The sterile compounding supervisor must also have the competency required to manage a safe, high-quality area for compounding sterile preparations.
5.1.2.3 Competency assessment program: Sterile compounding supervisor - Frequency of assessment	The sterile compounding supervisor must be evaluated for knowledge and abilities, at the same frequency as compounding personnel, by a third party (an evaluator with expertise in the compounding of sterile preparations, at arm's length from the facility/pharmacy and free of any real or perceived conflict of interest with the individual being evaluated).
5.1.2.3 Competency assessment program: Pharmacist who never compounds sterile preparations but whose role includes supervising pharmacy technicians and pharmacy assistants	A pharmacist whose activities are limited to supervising a pharmacy technician or pharmacy assistant during the compounding of sterile preparations may be exempted from the practical section of the assessment of competency in aseptic compounding, the media fill test and GFS; must possess a good understanding of the policies and procedures related to sterile compounding and demonstrate the ability to determine whether the pharmacy technicians and pharmacy assistants are complying with aseptic processes, in order to quickly detect any risk of error and possible contamination; must pass the practical section of the training program regarding assessment of the aseptic compounding process, the media fill test and GFS, if there is a possibility that this pharmacist will compound sterile preparations on an occasional basis.

5.1.2.4 Management of the competency assessment program: Sterile compounding supervisor and delegation of employee training	The sterile compounding supervisor is responsible for the training of and competency assessment program for all employees involved in the compounding of sterile preparations.
5.1.2.2 Initial training and assessment program: cleaning and disinfecting personnel	The sterile compounding supervisor must ensure appropriate training of all new cleaning and disinfecting personnel.
5.2 Policies and procedures	The sterile compounding supervisor must establish the content of policies and procedures, providing detailed descriptions of all activities in the pharmacy's compounding of sterile preparations. The supervisor must also ensure application of and compliance with these policies and procedures.
5.2 Policies and procedures	The sterile compounding supervisor must ensure that all established policies and procedures are promptly updated whenever there is a change in practice or in standards. In addition, policies and procedures must be reviewed at least every 3 years.
7. Quality Assurance Program	The sterile compounding supervisor must establish a quality assurance program to ensure the clear definition, application and verification of all activities that will affect the quality of compounded sterile preparations and the protection of personnel.
7.5 Quality assurance of compounded sterile preparations	The sterile compounding supervisor must establish a quality assurance program to ensure that sterile preparations are compounded in compliance with established procedures. The program must monitor, among other things, • the presence of a compounding protocol for each compounded sterile preparation; • compliance of the preparation with the prescription issued; • compliance of labels affixed to containers with legislation and regulations; • compliance with required documentation in the compounded sterile preparations log for individual patients and the batch compounded sterile preparations log, ensuring the performance of all verification steps required during and after compounding.
5.3.3 Equipment	The sterile compounding supervisor must ensure that PEC/C-PEC maintenance and certification have been performed. The supervisor must review the results or ensure that the results have been reviewed and corrective measures taken, as appropriate. The supervisor must sign the maintenance form or log.
7.3.2.3 Sampling of non-viable particles in air	The sterile compounding supervisor must ensure the competency of the certifier and the personnel chosen to conduct the sampling. *** Note: Appendix 5 and 6 in NAPRA Non-Hazardous and NAPRA Hazardous list the responsibilities of the certifier and certifications required for controlled areas and PECs/C-PECS. This information is provided for the benefit of the sterile compounding supervisor to include in the Quality Assurance Program and to allow assessment of the services provided during certification of controlled areas and equipment.*
7.6 Documentation of quality control activities	The sterile compounding supervisor must • investigate missing documentation, situations of non-compliance (where action is required) and deviations from protocols;

	• identify trends concerning microbial load in controlled areas and types of microorganisms found; • consult a microbiology specialist, if necessary; • take corrective and preventive actions
7.3.2.3 Sampling of viable particles in air and on surfaces	If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism must be identified. Corrective and preventive actions (e.g., cleaning, disinfecting) will be based on this information.
7.3.2.3 Environmental verification: Compliance with specifications for environmental parameters of facilities and proper operation of devices	The sterile compounding supervisor must ensure that all personnel on site know the procedure to be followed in case of non-compliance with respect to air pressure and temperature.
7.6 Documentation of quality control activities	Written documentation related to the quality assurance program must be verified, analyzed and signed by the sterile compounding supervisor and retained for a period designated in federal/provincial/territorial regulations.
5.1.1.2 Sterile compounding supervisor	All records required by the Model Standards are completed, maintained and readily available for audit and inspection purposes.

Personnel – Training and Competency Assessment

Compounding Personnel

Reference	Requirement(s)
***NAPRA Non-Hazardous* 5.1.2.1 Conditions** NH	All new personnel involved in compounding sterile preparations must successfully complete a workplace training and competency assessment program pertinent to the type of preparations to be produced.
***NAPRA Hazardous* 5.1.2.1 Conditions** H	Before compounding any hazardous sterile preparations, employees must receive specific training in the workplace and must undergo and pass an assessment of their competency.
	All personnel (pharmacists, pharmacy technicians and pharmacy assistants) must know and apply safe-handling procedures for the receipt, storage, distribution and disposal of hazardous products and hazardous waste, as well as the procedures for dealing with accidental exposure and spills.
***NAPRA Hazardous* 6.11.2 Spills: Training and garb** H	Employees who clean up spills must have received adequate training, must wear appropriate garb while cleaning up a spill.
5.1.2.2 Initial training and assessment program: Compounding personnel	The initial training and assessment program for compounding personnel must have the following components: • reading and understanding the policies and procedures related to compounded sterile preparations; • theoretical training, with assessment covering various topics; • individualized practical training and assessment in the workplace clean room; • assessment of aseptic techniques, based on gloved fingertip sampling (GFS) and a media fill test, for the various types of sterile preparations to be

Reference	Requirement(s)
	compounded.
	Personnel must pass GFS and a media fill test before working in the compounding area for sterile products.
***NAPRA Non-Hazardous* 5.1.2.3 Competency assessment program: Compounding personnel - Content of assessment** 	A competency assessment program for all compounding personnel must be implemented in the workplace. This program must include the following: • a theoretical test measuring required knowledge of policies and procedures, the aseptic compounding process, • a practical test in the workplace clean room (including GFS and a media fill test to evaluate compliance with operating procedures and knowledge of aseptic compounding processes.
***NAPRA Hazardous* 5.1.2.3 Competency assessment program: Compounding personnel - Content of assessment** 	A competency assessment program for all compounding personnel (pharmacists, pharmacy technicians and pharmacy assistants) must be implemented in the workplace. This program must include the following: • a theoretical test measuring required knowledge of policies and procedures, the aseptic compounding process, and accidental exposure and spills; • a practical test in the workplace clean room (including GFS and a media fill test, with simulations involving a hazardous product) to evaluate compliance with operating procedures and knowledge of aseptic compounding processes.
5.1.2.3 Competency assessment program: Compounding personnel- Frequency of assessment	All personnel assigned to the compounding of sterile preparations must undergo assessment at the following frequencies: • at least once a year in the workplace for preparations with low or medium risk level; • at least twice a year in the workplace for preparations with high risk level.
5.1.2.3 Pharmacist on duty in a health care facility	Any pharmacist on duty in a health care facility where a pharmacist will be expected to compound sterile preparations must receive the same training as a compounding pharmacist and must undergo annual assessment of competency in sterile-preparation compounding.
5.1.2.1 Conditions	The assessment results and any corrective measures imposed must be recorded, and these records must be retained.

Cleaning and Disinfecting Personnel

Reference	Requirement(s)
5.1.2.2 Initial training and assessment program: cleaning and disinfecting personnel	The initial training and assessment program for cleaning and disinfecting personnel must have the following components: • theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding sterile preparations; • practical training and assessment in the areas reserved for the compounding of sterile preparations.
5.1.2.3 Competency assessment program: cleaning and disinfecting personnel - Content of assessment	A competency assessment program for cleaning and disinfecting personnel must be implemented in the workplace.

Reference	Requirement(s)
5.1.2.3 Competency assessment program: cleaning and disinfecting personnel - Frequency of assessment	All cleaning and disinfecting personnel must be evaluated at least once a year in the workplace.
	The results of these assessments should be noted in each employee's file and must be retained.

Other Persons

Reference	Requirement(s)
5.1.2.2 Initial training and assessment program: Other persons	Any other person (whether an employee or not) who enters the sterile compounding area or who is involved in sterile compounding processes must be adequately trained and must follow and comply with specific policies and procedures. This requirement covers contractors, volunteers and employees, whether they are students, interns, equipment maintenance personnel or any other type of personnel.

Mandatory References

Reference	Requirement(s)
Mandatory References	The sterile compounding supervisor must make available a recent edition of the following publications: • Standards, guidelines, and policies from the College of Pharmacists of BC; • Trissel LA. Handbook on injectable drugs, • United States Pharmacopeial USP General Chapter <797>: Pharmaceutical Compounding — Sterile Preparations.
***NAPRA Non-Hazardous* Mandatory References** NH	The sterile compounding supervisor must make available a recent edition of NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations.
***NAPRA Hazardous* Mandatory References** H	The sterile compounding supervisor must make available a recent edition of: • NAPRA's Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations; • National Institute for Occupational Safety and Health (NIOSH). NIOSH list of antineoplastic and other hazardous drugs in healthcare settings; • United States Pharmacopeia USP Chapter: <800> Hazardous drugs - handling in healthcare settings).
***NAPRA Hazardous* 5.3.1.3 NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings** H	A list of hazardous drugs used must be available at the pharmacy and must be reviewed at least every 12 months. Each of these drugs must be handled and disposed of properly.
***NAPRA Hazardous* 6.11.1 Accidental exposure** H	For products with material safety data sheets, those documents must be accessible in the workplace.
NAPRA Non-Hazardous 5.3.4.2 NAPRA Hazardous 5.3.4.3 Disinfectant	The material safety data sheets for disinfectants used in the facility must be available on site and easily accessible.

Policies and Procedures

Reference	Requirement(s)
5.2 Policies and procedures	Procedures must be clear, must follow a standard format and must include an index for easy access to information when it is needed.
	The drafting and revision dates, the date of each change and the names of authors and reviewers must be included in each policy or procedure.
	Where compounding is undertaken by another pharmacy, as permitted by provincial/territorial legislation, the pharmacist or pharmacy technician at the dispensing facility should include in its general procedures manual information about policies and procedures for acquiring compounded sterile preparations for patients (originating pharmacy, entry in the file, delivery, etc.).
5.1.1.3 Compounding personnel – Responsibilities	When a sterile preparation is prepared on behalf of another facility/pharmacy (where permitted by provincial/territorial legislation), provide, orally and in writing, any information required for storing and transporting such medications (storage method, precautions, suggested BUD, etc.) to the pharmacist or pharmacy technician at the facility/pharmacy where the preparation will be dispensed.
	When a sterile preparation has been prepared on behalf of another facility/pharmacy (where permitted by provincial/territorial legislation), ensure that effective communication and collaboration occur between the pharmacists and pharmacy technicians at both facilities to clarify who is responsible for which aspects of patient care and to ensure continuity of care.
Required Policies and procedures: PERSONNEL	• Obligations of personnel ○ Attire and dress code (e.g., personal clothing, jewelry, makeup, hairstyles) ○ Health conditions (reasons for temporary withdrawal from compounding activities) ○ Expected behaviour in controlled areas (e.g., no drinking, eating or other activities not related to compounding; expectation that procedures will be followed; avoidance of unnecessary conversations)
	• Delegation of activities ○ Delegation of technical activities to persons other than pharmacists or pharmacy technicians
	• Training and assessment of personnel ○ Initial training and competency assessment program, (including details of compounding hazardous products, if applicable) ○ Program to assess maintenance of competency, including the characteristics of compounding sterile preparations ○ Training and assessment of cleaning and disinfecting personnel (including cleaning in the context of compounding hazardous sterile preparations, if applicable)
Required Policies and procedures: FACILITIES	• Facilities and equipment ○ Access to controlled areas ○ Facilities and equipment necessary for the compounding of sterile preparations,

	○ Maintenance of facilities and equipment, ○ Cleaning and disinfecting activities for facilities and equipment
Required Policies and procedures: COMPOUNDED STERILE PREPARATIONS	• Determining beyond-use dates of products used in a preparation • Determining beyond-use dates of final preparations • Hand and forearm hygiene • Garbing in compounding areas and for compounding • Cleaning and disinfecting the PEC • Bringing equipment and products into the clean room and PEC/C-PEC • Aseptic techniques (with details for each of the techniques used) • Preparation of injectable products outside regular operating hours of the compounding department of a health care facility • Verification of the compounding process (including validation of calculations by a pharmacist) and of final preparations • Labelling of final compounded sterile preparations • Packaging of final compounded sterile preparations • Storage of final compounded sterile preparations • Recording of preparations in the patient file • Transport and delivery of final compounded sterile preparations (to the patient, to patient care units or to the dispensing pharmacist) • A policy for return of expired or unused compounded sterile preparations from the patient's home or the patient care unit in a health care facility. • Biomedical waste management (e.g., at the pharmacy, returns from patients or patient care units, instructions to patients) • Recall of products or final compounded sterile preparations
Required Policies and procedures: QUALITY ASSURANCE PROGRAM	• Verification and maintenance of equipment • Environmental control of facilities and containment primary engineering control (e.g., pressure verification, air and surface sampling plan) ○ A procedure must be developed to outline and explain the actions to be taken should the pressure differential deviate from specifications. • Quality assurance of aseptic process for personnel (e.g., gloved fingertip sampling, media fill tests) • Quality assurance of compounded sterile preparations (e.g., existence of a protocol, compliance with prescription, documentation in logs)
***NAPRA Hazardous* Required Policies and procedures: COMPOUNDED STERILE PREPARATIONS** 	• Receiving and unpacking of hazardous sterile products • Storage of hazardous sterile products • Decontamination, deactivation, and disinfection of the C-PEC • Aseptic techniques for compounding hazardous sterile preparations • Accidental exposure of personnel to hazardous products (e.g., eyewash station, log) • Spills (e.g., spill management, use of chemical cartridge respirator, kit) • Hazardous waste management (e.g., at the pharmacy, returns from patients or patient care units, instructions to patients)
***NAPRA Hazardous* Required Policies and procedures: ENVIRONMENTAL MONITORING PROGRAM** 	Environmental monitoring for chemical contamination

Quality Assurance Program

Reference	Requirement(s)
7.1 Program content	The quality assurance program must have four components: 1. verification of equipment, including the PEC/C-PEC; 2. verification of controlled areas (clean room and anteroom); 3. verification of aseptic compounding processes; 4. verification of final preparations. ** For more information, refer to section 7 and Appendix 12 Components of a Quality Assurance Program in NAPRA Non-Hazardous ***and*** NAPRA Hazardous***.***
7.2 Results and action levels	For each of the specified components, the sterile compounding supervisor must establish a verification process, the results of which are assigned one of three levels: • Compliance (no action required): mandatory specifications have been attained. • Alert (tendency toward non-compliance): increased vigilance is required to prevent non-compliance. • Action required (non-compliant): more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non-compliance.
7.1 Program content	Each component of the quality assurance program and its activities must be documented.
7.4. Quality assurance of personnel involved in aseptic compounding	The quality assurance program for the aseptic compounding process for personnel must include GFS and a media fill test, which are the two final steps of initial and periodic qualification of personnel.
7.6 Documentation of quality control activities	All completed documentation concerning the quality assurance program for personnel involved in the aseptic compounding process (by GFS and media fill test), including nutrient medium readings, should be retained and made accessible.

Certification, Environmental Monitoring and Maintenance of Controlled Areas and Equipment

*** Note: Appendix 5 and 6 in NAPRA Non-Hazardous and NAPRA Hazardous list the responsibilities of the certifier and certifications required for controlled areas and PECs/C-PECS.*

Reference	Requirement(s)
7.3.2.1 Verification of Controlled Rooms and the PEC/C-PEC: Certification	The controlled areas of facilities and the PEC/C-PEC must be certified by a recognized organization • at least every 6 months; • during installation of new equipment or a new controlled area; • during maintenance or repair of equipment (repair of PEC/C-PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall, etc.) that might alter environmental or operational parameters; • when investigation of a contamination problem or a problem involving non-compliance in the aseptic compounding process requires exclusion of malfunctioning facilities.

Reference	Requirement(s)
	The program for monitoring facilities and the PEC must include a plan for sampling viable and nonviable particles.
7.3.2.3 Sampling specifications	Samples (non-viable particles in the air, viable particles in the air and viable surface particles) must be obtained at least every 6 months from the air in controlled areas and in the PEC/C-PEC and every time that the following conditions are present: • during installation of new equipment or a new controlled area; • during maintenance or repair of equipment (repair of PEC/C-PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall); • during investigation of a contamination problem or a problem involving non-compliance of personnel with aseptic processes.
	Samples for determining the number of non-viable particles per cubic metre of air, viable particles per cubic metre of air and viable surface particles must always be obtained under dynamic operating conditions during each facility and PEC/C-PEC certification.
***NAPRA Non-Hazardous* 5.3.3.1 Location of PEC and other furniture** 	During certification, a smoke test under dynamic conditions must be used to validate proper operation
***NAPRA Hazardous* 5.3.3.1 Location of C-PEC and other furniture** 	During certification, a smoke test under dynamic conditions may be used to validate proper operation.
5.3.3.1 Maintenance of PEC/C-PEC	PECs/C-PECs must be maintained in accordance with the manufacturer's recommendations but certified according to the testing standards detailed in the Controlled Environment Testing Association (CETA) application guides CAG-003, CAG-005 and CAG-002-2006 (current versions).
5.3.2.12 Filters and pre-filters	The efficiency of HEPA filters in the ventilation system must be tested during facility certification (at least every 6 months), and filters must be replaced periodically as recommended by the manufacturer.
	PEC/C-PEC pre-filters must be accessible. Washable pre-filters must not be used.
***NAPRA Hazardous* 5.3.2.12 Filters and pre-filters** 	Filters used to exhaust air from clean rooms or C-PECs must be considered contaminated and must be handled with a level of care appropriate to protecting personnel and the environment.
7.3.1.1 Verification of equipment supporting compounding activities: Certification	Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, must be certified with respect to its installation and operation and must be calibrated before being put into service and thereafter as recommended by the manufacturer.
7.3.1.1 Verification of equipment supporting compounding activities: Certification	A regular maintenance plan must be established, taking into account the manufacturer's recommendations for each device. If no manufacturer's recommendations are available, maintenance activities must be performed at least once a year by a qualified technician.
5.3.3 Equipment	Preventive maintenance for PEC/C-PECs and other equipment must be performed when no compounding is in progress, before cleaning and disinfection operations.

Reference	Requirement(s)
5.3.2.9 Functional parameter control systems	Instruments for measuring differential pressure between controlled areas must be calibrated at least once a year or as recommended by the manufacturer.
7.3.2.3 Sampling of non-viable particles in air	Calibration certificates for the equipment used to conduct the certification must accompany the report prepared after each certification.
7.6 Documentation of quality control activities	All completed documentation concerning components of environmental verification of controlled areas, the PEC/C-PEC and supporting equipment must be filed and retained with other compounding records.
7.6 Documentation of quality control activities	Documents concerning purchase, organization and certification of the PEC/C-PEC must be accessible throughout the entire service life of the facility and the PEC/C-PEC.
5.4 General maintenance log	The general maintenance log (paper-based or computerized) includes all records or forms regarding the following activities: • cleaning and disinfecting, • certification and maintenance of the facility as a whole, • certification and maintenance of the PEC/C-PEC and maintenance of other equipment; • verification of proper operation of equipment and instruments (calibration, refrigerator temperatures, etc.).

Environmental Monitoring Program – Sampling Plan

Reference	Requirement(s)
7.3.2.3 Sampling of viable, non-viable and surface particles in controlled areas and the PEC/C-PEC	A written sampling plan for controlled areas and the PEC/C-PEC must be established.
7.3.2.3 Sampling plan	The air and surface sampling plan must include, for each controlled area (clean room and anteroom), • sampling site diagram; • type of sampling to be done; • sampling methods to be used; • number of samples to be obtained at each site; • frequency of sampling; • number of colony-forming units (CFUs) triggering action.
	The sampling plan must allow for three types of samples: • non-viable particles per cubic metre of air; • viable particles per cubic metre of air; • viable surface particles.
***NAPRA Hazardous* 7.3.2.3 Hazardous drug contamination and wipe sampling** 	The level of hazardous drug contamination should be measured at least every 6 months or more frequently if any major change is made in placement of furniture, aseptic processes, or cleaning and disinfecting practices.
***NAPRA Hazardous* 7.3.2.3 Hazardous drug contamination and wipe sampling** 	Surface contamination by hazardous antineoplastic drugs, as determined by environmental monitoring, must be recorded in the general maintenance log.

Beyond-use Dates

Reference	Requirement(s)
6.1.1 Beyond-use dates for preparations	The BUD must not exceed the earliest of the dates established by the following two criteria: • expiration date based on chemical and physical stability according to reference texts • storage time related to risk of microbial contamination
	To establish a longer BUD, sterility tests must be performed for a given preparation or batch. Preparations must be quarantined while awaiting the results of sterility tests. Preparations may be released once the results of sterility testing are obtained.
	The pharmacy's operating procedures must describe the risk assessment process used to establish the BUD and the storage conditions.
6.1.2.1 Single-dose vial	If the vial is punctured in a PEC/C-PEC that maintains ISO Class 5 air quality, the BUD is 6 hours.
	Six hours after initial needle puncture, the vial can no longer be used. Once the vial is removed from the ISO Class 5 PEC/C-PEC, it must be discarded.
	To properly manage risk, a label must be affixed to the vial indicating the time of initial needle puncture.
	The contents of a vial cannot be divided for the sole purpose of extending stability.
	If the vial or another single-dose container is opened or punctured in an environment with air quality worse than ISO Class 5, the BUD is 1 hour.
6.1.2.2 Open ampoule	No storage of an open ampoule is permitted; as such, no BUD applies.
6.1.2.3 Multiple-dose container (e.g., vial)	The BUD is 28 days, unless otherwise specified by the manufacturer.
	If there is visible contamination before 28 days (or the manufacturer's expiry date), the container must be discarded.
6.8 Storage	A procedure for verifying the BUDs of stored compounded sterile preparations and the expiration dates of commercial products must be developed and implemented to ensure that products and compounded sterile preparations that have become unusable are quickly discarded. Preparations that have exceeded their BUDs must be discarded promptly.

Low Risk Preparations

Reference	Requirement(s)
6.1.3 Beyond-use dates according to risk of microbial contamination: Low Risk Preparations	**Low Risk Preparations** • Final product compounded using up to 3 "sterile units" • No more than 2 septum punctures at the injection site for each sterile unit • Simple aseptic transfer technique Drug prepared for one patient (patient-specific dose)

Reference	Requirement(s)
	BUD without sterility testing **Risk of contamination: Low** • At controlled room temperature BUD must be no more than 48 hours • With storage in refrigerator BUD must be no more than 14 days • With storage in freezer BUD must be no more than 45 days

Medium Risk Preparations

Reference	Requirement(s)
6.1.3 Beyond-use dates according to risk of microbial contamination: Medium Risk Preparations	**Medium Risk Preparations** • Final product compounded using 4 or more "sterile units" • Complex manipulations • Prolonged preparation time • Batch preparations (preparing more than one unit of the same composition during one compounding session)
	BUD without sterility testing **Risk of contamination: Medium** • At controlled room temperature BUD must be no more than 30 hours • With storage in refrigerator BUD must be no more than 9 days • With storage in freezer BUD must be no more than 45 days

High Risk Preparations

Reference	Requirement(s)
6.1.3 Beyond-use dates according to risk of microbial contamination: High Risk Preparations	**High Risk Preparations** • Non-sterile ingredients or equipment used before terminal sterilization • Non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization • Improper garbing or gloving by compounding personnel
	BUD without sterility testing **Risk of contamination: High** • At controlled room temperature BUD must be no more than 24 hours • With storage in refrigerator BUD must be no more than 3 days • With storage in freezer BUD must be no more than 45 days
	High-risk preparations must always be sterilized.
6.1.3 Sterility test and bacterial endotoxin test	A sterility test via membrane filtration and a bacterial endotoxin test must be performed for high-risk sterile preparations (see Table 6) in the following situations: • when sterile preparations are compounded in batches of over 25 identical units; • when there has been more than 12 hours of exposure time at a temperature between 2°C and 8°C before sterilization; • when there has been more than 6 hours of exposure time at a temperature above 8°C before sterilization.

Immediate-use Preparations

Reference	Requirement(s)
***NAPRA Non-Hazardous* 6.1.4 Beyond-use dates for immediate-use preparations** 	Compounded sterile preparations prepared for immediate use is performed only when the situation is critical, with a requirement for immediate administration to the patient. The preparation does not exceed 3 "sterile units," does not contain any hazardous drugs (e.g., chemotherapeutic agents), for each sterile unit used, there are no more than two entries into any one container, package or administration container/device, aseptic technique does not require more than 1 hour of continuous preparation and is rigorously applied. Administration of the preparation must begin within 1 hour after the start of compounding; otherwise, the preparation must be discarded. **BUD without sterility testing** **Type of contamination: Immediate-use preparation** • At controlled room temperature: 1 hour • With storage in refrigerator: 1 hour • With storage in freezer: not applicable
***NAPRA Hazardous* 6.1.4 Beyond-use dates for immediate-use preparations** 	Hazardous sterile preparations do not qualify as immediate-use preparations.

Patient File

Reference	Requirement(s)
6.4 Patient file	For any compounded sterile preparation that has already been dispensed, all information required for review and assessment of the preparation by pharmacists and for subsequent treatment of the patient must be recorded in the patient file.
	Information recorded in the patient file must allow users to accurately reproduce the prescribed preparation at a later date and identify the compounding personnel, if necessary.
	The origin of the compounded sterile preparation dispensed to the patient must be recorded in the patient file in cases where the preparation was made by another pharmacy, as permitted by provincial/territorial legislation.
	Any pharmacy (in the health care facility or the community) must be able to track information related to preparations that it dispenses, even if those preparations were made by another pharmacy.

Recall of Sterile Products or Final Compounded Sterile Preparations

Reference	Requirement(s)
5.1.1.3 Compounding personnel – Responsibilities	When a preparation must be recalled, notify the pharmacist or pharmacy technician at any pharmacy/facility where the product was dispensed.
6.10 Recall of sterile products or final compounded sterile preparations	When information obtained by a community or hospital pharmacy as a result of internal control, a complaint or a product recall shows that the grade or quality of a product or preparation does not meet requirements, the pharmacist or pharmacy technician must be able to

Reference	Requirement(s)
	• identify patients who have received the compounded sterile preparation; • notify patients or their caregivers that there is a problem with the preparation; • perform the necessary follow-up if the preparation has been administered.
	The information about individual units or batches of compounded sterile preparations recorded in the patient's file and the preparation log must be sufficient to allow users to track recipients of compounded sterile preparations.
	In health care facilities, the pharmacist or pharmacy technician must follow the established recall procedure, remove products already in circulation and follow up appropriately with patients likely to have used them.
	The causes of the problem leading to the recall must be reviewed, and corrective and preventive measures must be identified and implemented, regardless of the location of the pharmacist's or pharmacy technician's practice.

Compounded Sterile Preparation Protocols

Reference	Requirement(s)
6.2 Compounded sterile preparation protocols	Protocols for the compounding of sterile preparations must include all of the information required to prepare the compound: • name of preparation • pharmaceutical form • ingredients required • quantity, concentration and source of ingredients • necessary equipment • compounding procedure • storage method • BUD • References • draft and revision date • pharmacist's signature
	All protocols for pharmacy-compounded sterile preparations must be stored together and must be readily available for quick consultation.
	The protocols must be reviewed and approved by the sterile compounding supervisor or delegate.

Compounded Sterile Preparation Log

Reference	Requirement(s)
6.3 Compounded sterile preparation log	A compounded sterile preparation log must be completed during the compounding process.

6.3.1 Compounded sterile preparation log for one patient (individual preparations)	The compounded sterile preparation log for an individual patient must contain the following information:
	• patient's name
	• prescription number (if compounded in a community pharmacy)
	• patient's identification number (if compounded in a health care facility)
	• preparation identification (official or assigned name, strength and dosage of the preparation)
	• compounding procedure (master formulation record reference)
	• for each ingredient (including primary and secondary diluents),
	  ○ name
	  ○ source
	  ○ quantity/volume measured
	  ○ batch number
	  ○ drug identification number and lot number, as applicable
	  ○ expiration date
	• compounding date
	• total quantity compounded
	• preparation BUD
	• identity of compounder and verifier at each stage of the process, as well as identity of the person who approved the preparation
	• duplicate label, as described in the master formulation record
	• description of final preparation
	• results of quality control procedures
	• documentation of any quality control issues and any adverse reactions or preparation problems

6.3.2 Compounded sterile preparation log for batch preparations	The log for compounded sterile preparations prepared in batches must contain the following information:
	• preparation identification (official or assigned name, strength and dosage form of the preparation)
	• compounding procedure (master formulation record reference):
	  ○ equipment needed to prepare the preparation, as appropriate
	  ○ mixing instructions, including order of mixing, mixing temperatures or other environmental controls, duration of mixing and other factors pertinent to replication of the preparation as compounded
	• for each ingredient (including primary and secondary diluents),
	  ○ name
	  ○ source
	  ○ quantity/volume measured
	  ○ calculations needed to determine and verify quantities of ingredients and doses of active
	  ○ pharmaceutical ingredients
	  ○ compatibility and stability information, including references when available
	  ○ batch number
	  ○ drug identification number and lot number, as applicable
	  ○ expiration date
	• compounding date

Reference	Requirement(s)
	• total quantity compounded • identity of compounder and verifier at each stage of the process, as well as identity of the person who approved the preparation • description of the final preparation • container used for dispensing • sample labelling information, which shall contain, in addition to legally required information, generic name and quantity or concentration of each active ingredient, preparation BUD, storage conditions and prescription or control number (batch number), as applicable • packaging and storage requirements results of quality control procedures
6.3.2 Compounded sterile preparation log for one patient (individual preparations) and batch preparations	The pharmacy must keep a log for each individual patient, as well as a log for sterile preparations made in batches. The log (paper-based or computerized) must be filed and retained for future reference.

Facilities

*** Note: this section is not applicable to SCAs or C-SCAs. Refer to sections (Non-Hazardous) Segregated Compounding Areas (SCA) or (Hazardous) Containment Segregated Compounding Areas (C-SCA) for requirements.***

Reference	Requirement(s)
***NAPRA Non-Hazardous* 5.3 Facilities and equipment** 	Sterile-preparation compounding facilities must be designed and built in accordance with these Model Standards, with provincial/territorial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings.
***NAPRA Hazardous* 5.3 Facilities and equipment** 	Facilities for the compounding of hazardous sterile preparations must be designed and built in accordance with these Model Standards, with provincial/territorial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings.
5.3.2.1 Dimensions	Areas reserved for the compounding of sterile preparations must be large enough to facilitate compounding; allow cleaning and disinfecting without constraint; and ensure good flow of people, equipment and materials.
5.3.2.3 Heating, ventilation and air conditioning system for controlled rooms (clean room and anteroom)	The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter.
	An air conditioning system must be included in the HVAC system to help ensure the comfort of personnel wearing personal protective equipment (PPE).
5.3.2.3 Heating, ventilation and air conditioning system for controlled rooms (clean room and anteroom) 	Return air intakes should be installed at the bottom of walls, forcing the particles to flow downward. In older facilities, an airflow analysis must be performed under dynamic operating conditions (using the air speed achieved at the front of the PEC) to ensure that the location of the return air intakes does not hinder the compounding process.

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.2.3 Heating, ventilation and air conditioning system for controlled rooms (clean room and anteroom)** 	Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward. In older facilities, an airflow analysis must be performed under dynamic operating conditions (using the air speed achieved at the front of the C-PEC) to ensure that the location of the return air exhausts does not hinder the compounding process.
	The return air from the clean room must be exhausted to the exterior of the building.
5.3.2.4 Windows and openings	Controlled rooms must not have windows or doors opening directly to the exterior of the building. If any windows are present, they must be sealed.
	If any doors lead to the outside or to a non-controlled area (other than the doors designated for accessing the room), they must be sealed.
5.3.2.8 Materials and finishes	The surfaces of ceilings, walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, non-porous and resistant to damage from cleaning and disinfecting products.
	Dust-collecting overhangs, such as door sills, utility pipes, windowsills, window curtains and window blinds, must be avoided.
5.3.2.8 Ceilings in controlled areas (clean room and anteroom)	All ceiling joints must be sealed.
	In the clean room and the anteroom, joints between the ceiling and walls should be free of sharp corners where foreign substances could accumulate. This can be achieved by coving the ceiling to the wall or by caulking.
	If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room.
	If a conventional recessed panel ceiling is installed, the panels must be impregnated with polymer to make them impermeable and hydrophobic, and the edges must be coated with clean room silicone to seal them to the support frame. The tiles on this type of ceiling require periodic preventive sealing because the sealer eventually dries out. When facilities undergo certification, this type of ceiling must be tested to ensure no increase in viable and non-viable particles. This type of ceiling is not recommended for new facilities.
	In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in ceilings must be repaired and sealed at the earliest opportunity.
5.3.2.8 Walls in controlled areas (clean room and anteroom)	All wall joints must be sealed.
	In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in walls must be repaired and sealed at the earliest opportunity.
5.3.2.8 Floors in controlled areas (clean room and anteroom)	Flooring must be flat, smooth, impervious, non-friable, non-porous, sealed and resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed immediately.
	In the clean room and anteroom, the floor must be coved to the side wall, at least 10–15 cm.

Reference	Requirement(s)
	There must be no carpets, rugs, "sticky mats" or anti-fatigue mats.
5.3.2.9 Ceiling fixtures	In controlled areas (clean room and anteroom), ceiling fixtures must be recessed and flush mounted. Their external surfaces, whether made of glass or other material, must be washable, smooth and sealed.
5.3.2.9 Plumbing	Water sources, sinks and drains must not be located in a clean room but are permitted in the anteroom.
5.3.2.9 Functional parameter control systems	Control systems (e.g. indicating temperature and differential pressure) must be connected to a notification system to alert personnel when operating parameters are outside pre-set limits.
***NAPRA Non-Hazardous* 5.3.2.5 Compounding areas** NH	Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the PEC (e.g., laminar airflow workbench [LAFW], compounding aseptic isolator [CAI]) is located, and an anteroom, located next to the clean room.
***NAPRA Hazardous* 5.3.2.5 Compounding areas** H	Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the C-PEC (e.g., BSC or CACI) is located, and an anteroom, located next to the clean room.
***NAPRA Non-Hazardous* Table 3; 4; 5.3.2.5 Clean room; *NAPRA Hazardous* Table 2**	The temperature in the controlled rooms (anteroom and cleanroom) must be less than or equal to 20°C.

Anteroom

*** Note: this section is not applicable to SCAs or C-SCAs. Refer to sections (Non-Hazardous) Segregated Compounding Areas (SCA) or (Hazardous) Containment Segregated Compounding Areas (C-SCA) for requirements.***

Reference	Requirement(s)
***NAPRA Non-Hazardous* 5.3.2.5 Anteroom** NH	The anteroom is separated into two spaces by a visible demarcation line: • a space or area referred to as "dirty," located at the entrance to the anteroom, in the section adjacent to the non-controlled area; • a space or area referred to as "clean," adjacent to the dirty area on one side and the clean room on the other.
***NAPRA Hazardous* 5.3.2.5 Anteroom** H	The anteroom is separated into two spaces by a visible demarcation line: • The first space or area, referred to as "dirty", is located at the entrance to the anteroom, in the section adjacent to the non-controlled area. Although this area is referred to as "dirty," it is considered to be free of chemical contamination when hazardous preparations are being compounded in the clean room. • The second space or area, referred to as "clean", is adjacent to the dirty area on one side and the clean room on the other. Although this area is referred to as "clean," it is considered to be chemically contaminated when hazardous preparations are being compounded in the clean room.
	The door between the clean room and the anteroom and the door between anteroom and the non-controlled area must have windows to prevent accidents involving personnel entering or leaving through the doors.

Reference	Requirement(s)
5.3.2.5 Anteroom - Use	Activity in the anteroom shall be kept to a minimum and shall be limited to those activities that are essential to or that directly support the work undertaken in the clean room.
	Access of supplies, equipment and personnel into the clean room shall be through the anteroom. No supplies, equipment or personnel shall enter into the clean room from a non-controlled area.

5.3.2.5 Anteroom – Contents	The anteroom must contain the following items:
	• PPE and storage space for PPE, placed in the correct order to allow users to follow the correct garbing sequence
	• hands-free sink, ideally made of stainless steel or other material not harmed by cleaning products and large enough to allow users to wash their hands and forearms without touching the sides of the sink, with minimal splashing;**
	• soap dispenser (cartridge or disposable, non-refillable unit)
	• nail picks
	• alcohol-based hand rub (ABHR) with and its dispenser
	• hand-drying system:
	  ○ lint-free towels (preferred) with a dispenser
	  ○ air hand dryer designed specifically for use in a controlled area (i.e., the anteroom)
	• mirror or other means to verify garbing
	• clock
	• waste container
	• eyewash station, if available (if not located in the anteroom, the eyewash station must be installed nearby)
	• pass-through for transferring products into the clean room and/or a cart reserved for use in the "clean" area of the anteroom and the clean room.

***NAPRA Hazardous* 5.3.2.5 Anteroom – Contents** 	The anteroom must contain a cytotoxic waste container.
***NAPRA Non-Hazardous* Table 3: Functional parameters of the anteroom for the compounding of non-hazardous sterile preparations** 	The anteroom must be kept under positive pressure relative to the non-controlled area adjacent to the anteroom.
	The pressure differential must be at least 5.0 Pa (ideally between 5.0 Pa and 12.5 Pa, equivalent to 0.02 to 0.05 inch water column) relative to the non-controlled area adjacent to the anteroom.
	A notification system must be installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.
	ISO Class 8 air quality must be maintained in the anteroom under dynamic operating conditions.
	There must be at least 20 air changes per hour (ACPH).
***NAPRA Hazardous* Table 2: Functional parameters of the anteroom for the**	The pressure differential between the anteroom and the clean room must be at least 2.5 Pa to maintain unidirectional airflow from the anteroom to the clean room.

Reference	Requirement(s)
compounding of hazardous sterile preparations 	The pressure in the anteroom must be positive. The pressure differential must be at least 5.0 Pa relative to the pharmacy adjacent to the anteroom.
	ISO Class 7 air quality must be maintained in the anteroom under dynamic operating conditions.
	There must be at least 30 air changes per hour (ACPH) in the anteroom.

Shared Anteroom

*** Note: this section is not applicable to SCAs or C-SCAs. Refer to sections (Non-Hazardous) Segregated Compounding Areas (SCA) or (Hazardous) Containment Segregated Compounding Areas (C-SCA) for requirements.***

Reference	Requirement(s)
5.3.2.6 Shared Anteroom	The anteroom is separated into two spaces (areas) by a demarcation line: • a space or area referred to as "dirty," located adjacent to the non-controlled areas, at the entrance to the anteroom; • a space or area referred to as "clean but possibly chemically contaminated," located adjacent to the clean room for the compounding of hazardous sterile preparations and the clean room for the compounding of non-hazardous sterile preparations.
	Activities in a shared anteroom are limited to hand washing and donning of PPE.
	No drugs are stored in a shared anteroom.
	All air flowing within the shared anteroom must be exhausted to the exterior of the building. The air flowing into the anteroom must not be recycled.
Table 4: Shared facilities: Functional parameters of a shared anteroom for the compounding of hazardous and non-hazardous sterile preparations	The anteroom must be kept under positive pressure relative to both the clean room for compounding of hazardous drugs and non-controlled areas adjacent to the anteroom.
	The pressure differential must be at least 5.0 Pa (equivalent to 0.02 inch water column) relative to the adjacent areas.
	A notification system must be installed in each pressure monitor to alert pharmacy personnel when pressure differentials deviate from specifications.
	ISO Class 7 air quality must be maintained in the anteroom under dynamic operating conditions.
	There must be at least 30 air changes per hour (ACPH).

Clean Room

*** Note: this section is not applicable to SCAs or C-SCAs. Refer to sections (Non-Hazardous) Segregated Compounding Areas (SCA) or (Hazardous) Containment Segregated Compounding Areas (C-SCA) for requirements.***

Reference	Requirement(s)
5.3.2.5 Clean room	The clean room must be physically separated from the rest of the pharmacy and from other non-controlled areas, to reduce the risk of introducing viable and non-viable contaminants into the room. It must be physically separated from contiguous areas by walls, doors and pass-throughs.
	Access to the clean room must be restricted to personnel with specific responsibilities in the clean room.
	To enable verification activities, one or more observation windows must be installed.
***NAPRA Non-Hazardous* 5.3.2.5 Clean room – Use** 	The clean room is used only for the compounding of non-hazardous sterile preparations.
***NAPRA Non-Hazardous* Table 2: Functional parameters of the compounding clean room** 	The clean room must be kept under positive pressure relative to the anteroom and adjacent areas.
	The pressure differential must be at least 5.0 Pa (ideally between 5.0 Pa and 12.5 Pa, equivalent to 0.02 to 0.05 inch water column) relative to the anteroom.
	ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions.
	There must be at least 30 or more air changes per hour (ACPH).
***NAPRA Hazardous 5.3.2.5* Clean room** 	The clean room must be physically separated from the rest of the pharmacy and from other non-controlled areas, to reduce the and the spread of hazardous drug contamination outside the room.
***NAPRA Hazardous* 5.3.2.5 Clean room – Use** 	The clean room is used only for the compounding of hazardous sterile preparations.
***NAPRA Hazardous* Table 2: Functional parameters of the clean room for the compounding of hazardous sterile preparations** 	The clean room must be kept under negative pressure relative to the anteroom.
	The pressure of the clean room must be –2.5 Pa (equivalent to 0.01-inch water column) relative to surrounding areas (pharmacy or other).
	The pressure differential between the anteroom and the clean room must be at least 2.5 Pa to maintain unidirectional airflow from the anteroom to the clean room.
	ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions.
	There must be at least 30 air changes per hour (ACPH) in the clean room.

(Non-Hazardous) Segregated Compounding Areas (SCA)

*** Note: this section applies to pharmacies that compound non-hazardous sterile preparations using a SCA. The below requirements are not exhaustive. Pharmacies operating as a SCA are still required to meet all applicable sections/sterile compounding standards within this form (e.g. policies and procedures, personnel training and assessments, aseptic compounding and verification, labelling, quality assurance, etc.).*

Reference	Requirement(s)
5.3.2.11 Signage NH	Each room/area must be identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, cytotoxicity, hazards, restricted access and dress code).
5.3.2.10 Work surfaces NH	Any material used for work surfaces must be able to withstand repeated cleaning and disinfecting and be resistant to damage from cleaning and disinfecting products.
5.3.3.2 Waste containers NH	A sufficient number of easy-to-clean waste containers of suitable size and made of materials resistant to damage from cleaning and disinfecting products must be available.
***NAPRA Non-Hazardous* 6.1.5 Beyond-use times of 12 hours or less for preparations compounded in segregated areas** NH	For compounded sterile preparations made in an LAFW that is not placed in an environment meeting the standards for ISO Class 7 air quality, or in a CAI that does not meet the requirements described in section 5.3.3.1, the following conditions must be met: • The PEC is certified every 6 months and maintains ISO Class 5 air quality or better. • Only low-risk preparations are compounded. • Only one preparation is compounded at a time. • The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination. • The sink is not directly adjacent to the PEC and is separated from the immediate area of the PEC. • The preparation area has no unsealed windows or doors leading to the exterior of the building. Furthermore, the preparation area is not in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites. • Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting. • Beyond-use time of 12 hours or less
***NAPRA Non-Hazardous* 5.3.3.1 Compounding Aseptic Isolator (CAI)** NH	The CAI may be positioned in an environment where the air particles exceed ISO Class 7 if all of the following conditions are met: • The CAI maintains an ISO Class 5 environment at all times during compounding, including when ingredients, equipment and devices are being transferred into and out of the CAI. • Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CAI shows ISO Class 5 air quality during compounding. • Particulate sampling conducted as close as possible to the doors when materials are being transferred, without obstructing the passageway, shows no more than 3520 particles (0.5 µm diameter or larger) per cubic metre of air (ISO Class 5) in the CAI.

(Hazardous) Containment Segregated Compounding Areas (C-SCA)

*** Note: this section applies to pharmacies that compound hazardous sterile preparations using a C-SCA. The below requirements are not exhaustive. Pharmacies operating as a C-SCA are still required to meet all applicable sections/sterile compounding standards within this form (e.g. policies and procedures, personnel training and assessments, aseptic compounding and verification, labelling, quality assurance, etc.).*

Reference	Requirement(s)
5.3.2.11 Signage 	Each room must be identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, cytotoxicity, hazards, restricted access and dress code).
5.3.2.10 Work surfaces 	Any material used for work surfaces must be able to withstand repeated cleaning and disinfecting and be resistant to damage from cleaning and disinfecting products.
***NAPRA Hazardous* 5.3.3.2 Hazardous waste containers** 	A sufficient number of hazardous waste containers of suitable size and made of materials resistant to damage from cleaning, disinfecting and decontamination products must be available. Waste containers must be closable, to limit the spread of vapours.
***NAPRA Hazardous* 6.1.5 Beyond-use times of 12 hours or less for preparations compounded in segregated areas** 	For compounded sterile preparations made in a BSC that is not placed in an environment meeting the standards for ISO Class 7 air quality, or in a CACI that does not meet the requirements described in section 5.3.3.1, the following conditions must be met: • The segregated area has walls to separate the room from other areas. • The C-PEC is certified every 6 months and maintains ISO Class 5 air quality or better. • The room has a minimum of 12 ACPH. • The room maintains negative pressure of at least –2.5 Pa relative to adjacent spaces. • Only low- or medium-risk preparations are compounded. • Only one preparation is compounded at a time. • The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination. • The sink is 1 metre away from the C-PEC. • The preparation area has no unsealed windows or doors leading to the exterior of the building. Furthermore, the preparation area is not in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites. • Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting. • Beyond-use time of 12 hours or less
***NAPRA Hazardous* 5.3.3.1 Compounding Aseptic Containment Isolator (CACI)** 	The CACI may be positioned in an environment where the air particles exceed ISO Class 7 if all of the following conditions are met: • The room has negative pressure (at least 2.5 Pa negative pressure relative to adjacent spaces). • The room has at least 12 ACPH. • The CACI maintains an ISO Class 5 environment (see Table 1) at all times during compounding, including when ingredients, equipment and devices are being transferred into and out of the CACI. • Particulate sampling from 15 to 30 cm upstream of the critical exposure site within the CACI used for hazardous sterile preparations shows ISO Class 5 air quality during compounding.

Reference	Requirement(s)
	• Particulate sampling conducted as close as possible to the doors when materials are being transferred, without obstructing the passageway, shows no more than 3520 particles (0.5 µm diameter or larger) per cubic metre of air (ISO Class 5) in the CACI.

(Hazardous) Storage of Hazardous Products

Reference	Requirement(s)
***NAPRA Hazardous* Table 3: Requirements for a hazardous products storage area** 	Area separate from unpacking area.
	Dedicated room. Hazardous products must be stored separately from non-hazardous products.
	Negative pressure (-2.5 Pa) relative to surrounding areas.
	At least 12 air changes per hour (ACPH).
	Presence of shelves with lips to prevent drug containers from falling off and breaking.
	Storage spaces for hazardous products and preparations identified with the proper signage to indicate the presence of hazardous products.
	Sufficient ventilation to prevent contamination from spreading to adjoining rooms.
***NAPRA Hazardous* 5.3.2.5 Area for storing hazardous products** 	Alternatively, hazardous sterile preparations and the refrigerator in which they are stored may be placed in the clean room for compounding hazardous sterile preparations. This approach ensures that the drugs are stored in a negative-pressure room with sufficient ACPH (since the clean room has at least 30 ACPH, with the air being completely exhausted to the exterior). The facility must ensure that air exhausts are placed so that they will remove particles generated within the storage area and the refrigerator and must also ensure sufficient ACPH to maintain an ISO Class 7 clean room.

Equipment

*** Note: this section is not applicable to SCAs or C-SCAs. Refer to sections (Non-Hazardous) Segregated Compounding Areas (SCA) or (Hazardous) Containment Segregated Compounding Areas (C-SCA) for requirements.***

Reference	Requirement(s)
5.3.2.11 Signage	Each room must be identified with appropriate and informative signs (e.g., pictograms depicting the need for special care, cytotoxicity, hazards, restricted access and dress code).
5.3.2.10 Work surfaces	Work surfaces and furniture must be constructed of smooth, impervious, non-friable and non-porous materials, preferably stainless steel. Any material used for work surfaces must be able to withstand repeated cleaning and disinfecting and be resistant to damage from cleaning and disinfecting products. Any breakage must be repaired and sealed at the earliest opportunity.

Reference	Requirement(s)
5.3.3.2 Other devices, instruments or accessories related to the compounding of sterile preparations	Equipment used to compound sterile preparations must be clean and disinfected with germicidal detergent, followed by a sterile disinfectant such as 70% isopropyl alcohol.
	All necessary devices, instruments and accessories must be cleaned and disinfected before being placed in a controlled area.
	Equipment must be made of materials resistant to damage from cleaning and disinfecting products.
***NAPRA Non-Hazardous* 5.3.2.10 Furniture** 	All furniture in the clean room and anteroom, as well as the floor and wall surfaces, must be designed and placed to facilitate cleaning, disinfecting.
***NAPRA Hazardous* 5.3.2.10 Furniture** 	All furniture in the clean room and anteroom, as well as the floor and wall surfaces, must be designed and placed to facilitate cleaning, disinfecting and decontamination.
5.3.2.10 Furniture	Chairs used in controlled areas must be made of smooth, non-friable, non-porous, washable materials that are resistant to damage from cleaning and disinfecting products.
5.3.2.10 Pass-through	A pass-through should be installed for transferring products into and out of the clean room. The passthrough should be sealed and made of stainless steel or a smooth, non-porous, antistatic material resistant to damage from cleaning and disinfecting products. It is recommended that the pass-through be equipped with an interlocking system that prevents both doors from being open at the same time. If an interlocking system is not available, a door-opening procedure must be implemented whereby only one door is open at a time.
5.3.3.2 Carts	If carts are used to transport materials from the “clean” area of the anteroom into the clean room, one cart must be reserved for the “dirty” area of the anteroom and must remain there. A second cart must be reserved for use in the “clean” area of the anteroom and in the clean room.
	Carts used to bring supplies into the anteroom from outside the controlled area shall not cross the demarcation line. Likewise, carts taken into the anteroom from the clean room shall not be moved beyond the clean side of the demarcation line.
	If the anteroom is shared, one cart must be reserved for the “clean but chemically contaminated” area and another for the “clean and not chemically contaminated” area.
5.3.3.2 Camera and computer equipment	Preference must be given to audiovisual and computer equipment that features “hands-free” operation and that is made of smooth, nonporous, cleanable materials with low particulate emission and resistance to damage from cleaning and disinfecting products.
	Equipment cables must be covered to facilitate cleaning.
5.3.3.2 Communication system	These devices should be used in “hands-free” mode, must be easy to clean and disinfect and must be resistant to damage from cleaning, disinfecting and decontamination products. Personal electronic devices or accessories (cell phone, iPods, earbuds) are not permitted in the anteroom or clean room.

Reference	Requirement(s)
7.3.2.3 Environmental verification: Compliance with specifications for environmental parameters of facilities and proper operation of devices and Appendix 12	Pressure must be measured continuously, and an alarm system must be in place to immediately advise personnel of non-compliance with specifications and to direct that action be taken, if necessary. Periodic verification (once a week) is done by the sterile compounding supervisor.
5.3.3.2 Incubator	The incubator must not be placed in the clean room or the anteroom.
5.3.3.2 Waste containers	A sufficient number of easy-to-clean waste containers of suitable size and made of materials resistant to damage from cleaning and disinfecting products must be available.
***NAPRA Hazardous* 5.3.3.2 Hazardous waste containers** 	A sufficient number of hazardous waste containers of suitable size and made of materials resistant to damage from cleaning, disinfecting and decontamination products must be available. Waste containers must be closable, to limit the spread of vapours.
***NAPRA Hazardous* 6.11.1 Accidental exposure** 	An appropriate eyewash station must be available.
***NAPRA Hazardous* 6.11.2 Spill kits** 	Spill kits must be available in locations where hazardous products are handled and must be present on carts used for transporting hazardous products.

Refrigerator and Freezer

Reference	Requirement(s)
5.3.3.2 Refrigerator and freezer Choice	Refrigerators and freezers used to store medications must be commercial, biomedical-grade units. Domestic refrigerators and freezers must not be used. Refrigerators and freezers used for storing medications must not be used to store food.
***NAPRA Hazardous* 5.3.3.2 Refrigerator and freezer Use and placement** 	Refrigerators and freezers designated for hazardous drugs must not be used to store other medications/solutions, etc.
	Hazardous sterile preparations and hazardous sterile drugs and the refrigerator and freezer in which they are stored may be placed in the clean room for compounding hazardous sterile preparations. An air exhaust must be placed behind the refrigerator or freezer to remove any particles generated by the unit. There must be sufficient ACPH in the clean room to maintain the ISO Class 7 air quality classification.
5.3.3.2 Temperature and temperature control	The tested storage temperature in these units must meet the following parameters: controlled refrigeration temperature: 2°C to 8°C and controlled freezing temperature: –25°C to –10°C.
	Accurate temperature probes (gauges or sensors) must be installed to indicate the actual temperature.
	A notification system must be installed in each refrigerator and freezer to alert pharmacy personnel when temperatures deviate from specifications.

Temperature Monitoring of Equipment and Controlled Areas

Reference	Requirement(s)
7.3.1.2 Temperature readings	At least once a day, compounding personnel must check the temperature log of equipment with an integrated recording device (e.g., refrigerator, freezer, incubator), to review temperatures over the previous 24 hours, and must take corrective actions in case of substantial variance with respect to specified parameters.
	When a thermometer is used as a verification instrument, the temperature must be read twice a day (at specified but different times of day; e.g., morning and night). The pharmacist or pharmacy technician must record and retain proof of calibration of the thermometer.
	Temperature readings will include the actual temperature, the minimum temperature and the maximum temperature.
	If a computerized temperature monitoring system is used, the system must offer features to record and store temperature readings at the same frequency as specified above (at a minimum). The system must also trigger an alarm if the temperature readings deviate from the acceptable range.
5.3.3.2 Incubator	When the incubator is in operation, the incubator temperature must be read and recorded in the general maintenance log at least once a day.
5.3.3.2 Temperature and temperature control	Refrigerator and freezer temperature readings must be recorded on a form stored in the general maintenance log unless the units are equipped with a continuous temperature recorder. In the latter situation, the data recorded by this device must also be verified and stored.
	Temperature probes must be maintained and calibrated at least once a year or in accordance with the manufacturer's instructions. Calibration of these instruments must be noted in the general maintenance log.
7.3.2.3 Compliance with specifications for environmental parameters of facilities and proper operation of devices	The temperature of ISO Class 7 and ISO Class 8 areas must be verified and documented at least once a day.

(Non-Hazardous) Primary Engineering Control (PEC)

Reference	Requirement(s)
***NAPRA Non-Hazardous* 5.3.3.1 PEC** NH	Primary engineering control (PEC) options for non-hazardous sterile preparations include LAFWs and CAIs. The PEC is positioned in the clean room.
	A PEC must operate 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.
	The PEC must provide a work area with unidirectional airflow and quality meeting ISO Class 5 or better under dynamic operating conditions.

Reference	Requirement(s)
	The working surface of the PEC must be resistant to damage from cleaning and disinfecting products and must be changed if it becomes damaged.
***NAPRA Non-Hazardous* 5.3.3.1 Location of PEC and other furniture** NH	The PEC and other pieces of furniture should be positioned to avoid interfering with facility ventilation systems.
	To facilitate cleaning and disinfecting activities, such as cleaning the exterior of the PEC, and to avoid interfering with the operation of the PEC, there must be sufficient clearance around the PEC (usually 0.3 m).
***NAPRA Non-Hazardous* 5.3.3.1 LAFW** NH	The LAFW must be positioned in an ISO Class 7 clean room that is adjacent to an ISO Class 8 anteroom and must not be placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
	If multiple LAFWs are used, they must be positioned to prevent interference with one another.
***NAPRA Non-Hazardous* 5.3.3.1 CAI** NH	If a CAI is in use, the recovery time recommended by the manufacturer (i.e., the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started) must be observed when transferring products from the clean room to the manipulation area.
***NAPRA Non-Hazardous* 5.3.3.1 Compounding Aseptic Isolator (CAI)** NH	The CAI must be positioned in an ISO Class 7 clean room adjacent to an ISO Class 8 anteroom.

(Hazardous) Containment Primary Engineering Control (C-PEC)

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.3.1 (C-PEC)** H	Hazardous sterile preparations must be compounded inside a C-PEC. Examples of C-PECs for hazardous sterile preparations include Class II or Class III BSCs and CACIs.
	Oncology adjunctive therapies can also be prepared in these devices if they are being compounded for the same patient as the hazardous sterile preparation. These adjunctive therapies must be handled and labeled to require hazardous drug precautions.
	The C-PEC must be externally ventilated.
	A C-PEC must operate continuously, 24 hours a day. If the C-PEC has been turned off, it must be allowed to run for at least 30 minutes, or as recommended by the manufacturer, before decontamination, cleaning and disinfection and then compounding of hazardous sterile preparations are undertaken.
	The C-PEC must provide a work area with unidirectional airflow and air quality meeting ISO Class 5 or better under dynamic operating conditions.
	The working surface of the C-PEC must be resistant to damage from cleaning, disinfecting, deactivating and decontamination products and must be changed if it becomes damaged.

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.2.9 Functional parameter control systems** H	BSCs and CACIs must be connected to a notification system to alert personnel to any unscheduled interruption, or any alert related to the operation of the device outside compounding periods.
***NAPRA Hazardous* 5.3.3.1 Location of C-PEC and other furniture** H	To facilitate cleaning and disinfecting activities, such as cleaning the exterior of the C-PEC, and to avoid interfering with the operation of the C-PEC, there must be sufficient clearance around the C-PEC (usually 0.3 m).
	The C-PEC and other pieces of furniture should be positioned to avoid interfering with facility ventilation systems.
***NAPRA Hazardous* 5.3.3.1 Biological safety cabinet (BSC)** H	The BSC must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom.
	The BSC must not be placed near doors or other sources of drafts that might adversely affect unidirectional airflow.
	If multiple BSCs are used, they must be positioned to prevent interference with one another.
***NAPRA Hazardous* 5.3.3.1 Compounding Aseptic Containment Isolator (CACI)** H	If a CACI is in use, the recovery time recommended by the manufacturer (i.e., the waiting time required to achieve ISO Class 5 air quality after materials have been transferred, before aseptic processing is started) must be observed when transferring products from the clean room to the manipulation area.
	The CACI must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom.
	Compounding personnel working in a CACI must comply with the garbing procedure for compounding of hazardous sterile preparations, both to maintain air quality and to protect themselves from spills.

(Non-Hazardous) Personal Protective Equipment and Garbing

Reference	Requirement(s)
***NAPRA Non-Hazardous* 5.3.3.3 Personal protective equipment (PPE) and clothing** NH	Compounding personnel and anyone else who accesses controlled areas must wear appropriate protective clothing.
***NAPRA Non-Hazardous* Table 5: PPE for the compounding of non-hazardous sterile preparations** NH	PPE to be worn for the compounding of non-hazardous sterile preparations and when accessing facilities for the compounding of non-hazardous sterile preparations includes the following: • pair of shoe covers or dedicated shoes • hair cover • beard cover (if applicable) • surgical mask • non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) • pair of non-powdered sterile gloves, which must cover the cuffs of the non-shedding gown

Reference	Requirement(s)
***NAPRA Non-Hazardous* 6.6.5 Aseptic technique for compounding sterile preparations – General** NH	The frequency and circumstances of glove changes must be defined in a procedure.
***NAPRA Non-Hazardous* 6.6.2.2 Garbing** NH	Compounding personnel must don and remove garb in the sequence described in the policies and procedures. The selected sequence must be documented and reviewed regularly.

(Hazardous) Personal Protective Equipment and Garbing

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.3.3 Personal protective equipment (PPE) and clothing** H	PPE adapted and approved for the compounding of hazardous sterile preparations must be worn during such compounding activities.
***NAPRA Hazardous* 5.3.3.3 Uniform** H	Compounding personnel shall wear clean room scrubs, not street clothes. Use of clean room scrubs reduces the risk of contaminating the environment through clothing.
***NAPRA Hazardous* 5.3.3.3 Shoe covers** H	Two pairs of disposable shoe covers are required.
	The shoe covers must be changed after each removal or in the event of contamination, spill or breakage.
	Shoe covers worn in hazardous drug compounding areas are not to be worn outside the controlled area.
***NAPRA Hazardous* 5.3.3.3 Beard cover** H	If the compounder has facial hair, a disposable beard cover must be worn while compounding hazardous sterile preparations.
	The beard cover must be changed at the earliest of the following: after 3.5 hours of continuous work, after each removal or if contamination occurs or is suspected.
***NAPRA Hazardous* 5.3.3.3 Hair cover** H	A disposable hair cover must be worn during the compounding of hazardous sterile preparations. It must be changed after each removal or if it becomes contaminated.
***NAPRA Hazardous* 5.3.3.3 Mask** H	N95 or N100 (NIOSH approved) is worn for the compounding of hazardous sterile preparations.
	Any mask (including N95 or N100 masks and chemical cartridge respirators) must first be fit-tested.
	The mask must be changed at the earliest of the following: after 3.5 hours of continuous compounding work, after each removal or if contamination has occurred or is suspected.
***NAPRA Hazardous* 5.3.3.3 Gown**	The gown must have been tested by the manufacturer for resistance to permeability by hazardous drugs.

Reference	Requirement(s)
	It must close in the back (i.e., no open front), and it must have long sleeves with fitted cuffs at the wrists.
	The gown must be discarded and replaced at the earliest of the manufacturer's time limit for permeation of the gown or after 2–3 hours of continuous compounding work or after each removal or after a contamination has occurred or is suspected.
***NAPRA Hazardous* 5.3.3.3 Gloves** 	For the following activities, personnel must wear two pairs of gloves meeting the ASTM International standard D-6978-05: unpacking; cleaning and disinfecting the clean room; disinfecting the C-PEC; compounding of hazardous preparations (including isolators); managing a spill; disposing of hazardous products.
	All compounding personnel must wear two pairs of gloves. The first (inner) pair of gloves goes under the sleeves of the gown, while the second (outer) pair must be pulled up over the gown cuffs. The outer gloves must be sterile.
***NAPRA Hazardous* 5.3.3.3 Glove changes** 	Both pairs of gloves must be discarded and replaced at the earliest of the manufacturer's limit for permeation of the gloves, every 30 minutes or immediately if a tear, puncture, or contamination has occurred or is suspected.
***NAPRA Hazardous* 5.3.3.3 Chemical Cartridge Respirator** 	A chemical cartridge respirator with a pre-filter must be worn in the presence of vapours, gas, and particles (e.g., dust) or if there has been a spill.
***NAPRA Hazardous* 5.3.3.3 Goggles and face shield or full face-piece respirator** 	Goggles and a face shield or full face-piece respirator must be worn when working at or above eye level, when deactivating, decontaminating and cleaning underneath the work surface of a C-PEC, when cleaning up a spill, when there is risk of splashes to the face and eyes and when unpacking suspected damaged drugs.
***NAPRA Hazardous* 6.6.2.2 Garbing** 	When the compounding of hazardous sterile preparations is complete, personnel must remove the PPE following an established technique and sequence, to minimize the risk of chemical contamination, as set out in a detailed procedure developed by the facility.
	Personnel must dispose of soiled PPE in a container for cytotoxic waste and must then wash their hands before exiting the compounding area and performing any other activity.
***NAPRA Hazardous* 6.8.1.2 Garbing of personnel for unpacking** 	For unpacking **intact** hazardous products that have been received from the supplier sealed in impervious plastic, two pairs of ASTM International–approved gloves are required.
	For unpacking **potentially damaged** hazardous products, the following garb is required: • two pairs of ASTM International–approved gloves • gown approved for the compounding of hazardous sterile preparations • hair, face, beard and shoe covers • eye protection (goggles) and a face shield or full face-piece respirator • chemical cartridge respirator.

Cleaning and Disinfecting

Reference	Requirement(s)
5.3.4.1 Cleaning and disinfecting in areas reserved for the compounding of sterile preparations: General	Cleaning and disinfecting (housekeeping) in the controlled area must be performed to ensure the cleanliness required for the quality and integrity of final sterile preparations.
	Cleaning and disinfecting procedures must be strictly adhered to in the clean room and the anteroom.
	Only trained and qualified cleaning and disinfecting personnel may be allowed to clean controlled areas.
***NAPRA Non-Hazardous* 6.6.4 Cleaning and disinfecting the PEC** NH	Only compounding personnel who have successfully achieved the competencies required for sterile compounding may clean and disinfect ISO Class 5 environments.
***NAPRA Non-Hazardous* 5.3.4.2 *NAPRA Hazardous* 5.3.4.3 Disinfectant**	The sterile compounding supervisor must select an appropriate disinfecting agent for controlled areas, considering mainly its effectiveness and compatibility with materials used for facilities and equipment.
	Use of a germicidal disinfectant detergent is required to disinfect all surfaces in a clean room and anteroom.
	The daily use of a germicidal disinfectant should be augmented with weekly (or monthly) use of a sporicidal agent.
***NAPRA Non-Hazardous* 5.3.4.3 *NAPRA Hazardous* 5.3.4.4 Equipment used for cleaning and disinfection and its storage**	To avoid cross-contamination and to protect cleaning and disinfecting personnel, equipment must be specifically designated for cleaning areas used for the compounding of sterile preparations.
	Non-shedding equipment must be used for cleaning controlled areas. 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. If reusable accessories are used, one set of accessories must be dedicated to cleaning ISO Class 5 areas and a separate set dedicated to cleaning ISO Class 7 and 8 areas.
	Cleaning equipment and supplies (mop handle, outside of bottles, etc.) must be disinfected before each entry into a controlled area.
	A cabinet located in the anteroom or nearby must be provided for storing equipment (mop handle, etc.), refills (mop heads, towels) and cleaning products used for cleaning and disinfecting.
***NAPRA Non-Hazardous* 5.3.4.4 *NAPRA Hazardous* 5.3.4.5 Garbing of cleaning and disinfecting personnel (housekeeping personnel)**	Cleaning and disinfecting personnel must comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties.
***NAPRA Non-Hazardous* 5.3.4.4 Garbing of cleaning and disinfecting personnel (housekeeping personnel)** NH	Housekeeping personnel must don gloves before starting work.

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.4.5 Garbing of cleaning and disinfecting personnel (housekeeping personnel)** 	Housekeeping personnel must don two pairs of ASTM International–approved gloves before starting work. The outer gloves must be sterile.
5.3.3.2 Waste containers	The waste containers must be emptied and cleaned at least once a day, at a time when no compounding is occurring.
***NAPRA Hazardous* 5.3.3.2 Hazardous waste containers** 	The waste shall be removed once a day, at a time when no compounding is occurring. Waste containers must be identified with appropriate hazardous materials symbols (e.g., pictogram indicating cytotoxicity).
***NAPRA Non-Hazardous* 5.3.4.5** ***NAPRA Hazardous* 5.3.4.6 Cleaning frequency**	Daily cleaning, decontamination and disinfecting are required for the following surfaces and areas: • PEC/C-PEC • counters • carts • floors • surfaces that are touched frequently (e.g., doorknobs, switches, chairs)
	Monthly cleaning and disinfecting are required for the following surfaces and areas: • walls • ceiling • shelves • outer surfaces of the PEC/C-PEC
6.6.4 Cleaning and disinfecting the PEC/C-PEC	Personnel must follow the cleaning and disinfecting method described in the pharmacy's procedures and record cleaning and disinfecting activities in the general maintenance log.
	Sterile water shall be used for diluting concentrated disinfectant solutions used inside any ISO Class 5 device.

(Hazardous) Decontamination, Deactivation, and Disinfection

Reference	Requirement(s)
***NAPRA Hazardous* 5.3.4.2 Surface decontamination, deactivation and disinfection** 	When hazardous sterile preparations are compounded, cleaning of the premises and equipment must also eliminate chemical contamination from the hazardous products used. Methods used include decontamination, deactivation and disinfection.
***NAPRA Hazardous* 6.6.4 Surface decontamination, deactivation and disinfection of the C-PEC** 	Only compounding personnel who have successfully achieved the competencies required for sterile compounding are allowed to decontaminate, deactivate and disinfect the C-PEC.

Reference	Requirement(s)
***NAPRA Hazardous* 6.6.4.2 Decontamination of the C-PEC** 	For daily activities such as disinfecting the inside of a C-PEC, a surface decontamination step using an appropriate agent must precede the usual disinfection step with sterile 70% isopropyl alcohol.
***NAPRA Hazardous* Table 8 Minimum frequency of surface decontamination, deactivation and disinfection of the inside BSC or CACI** 	Disinfection of the work surface in BSC or CACI is done before start of compounding.
	Decontamination and disinfection of the work surface in BSC or CACI is done: • On each preparation change, upon removal from BSC or CACI • At the start or end of each shift • When surface contamination is suspected • If there has been noncompliance with aseptic techniques
	Decontamination and disinfection of all surfaces inside BSC or CACI is done: • At start of workday • At start of workday if BSC or CACI has not been used for one or more days • When there has been a spill • Before and after certification • After service interruption (ex power outage) • If the C-PEC is moved
	Decontamination, deactivation and disinfection of all surfaces inside BSC or CACI and subfloor of BSC or CACI is done weekly, at the end of a workday or as recommended by manufacturer.
***NAPRA Hazardous* 5.3.3.2 Other devices, instruments or accessories related to the compounding of sterile preparations** 	Devices, instruments and accessories to be used in controlled areas should not be removed without good reason. If they must be removed, they must be decontaminated.
***NAPRA Hazardous* 6.6.4 Surface decontamination, deactivation and disinfection of the C-PEC** 	Decontamination, deactivation and disinfection tasks performed must be recorded in the general maintenance log.

Conduct of Personnel

Reference	Requirement(s)
6.5.1 Conditions that may affect preparation quality	Personnel afflicted with uncontrolled weeping skin condition, burns to the skin, including sunburns, cold sores (active herpes simplex viral infection), conjunctivitis (viral or bacterial), active respiratory infection with coughing, sneezing or runny nose, fresh piercings or other fresh wounds shall be excluded from sterile compounding activities and sterile compounding areas until the condition has been remedied.
6.5.2 Conduct before entering the anteroom	Before entering the anteroom, personnel must: • remove personal outer garments (e.g., coat, hat, jacket, scarf, sweater, vest, boots and outdoor shoes); • remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or

Reference	Requirement(s)
	accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room); • remove all cosmetics, including makeup, false eyelashes, perfume, hair products such as hairspray, henna tattoos and paper tattoos, as these products can generate particles that are possible sources of contamination; • tie up long hair; • remove nail polish and other nail applications (nail extensions and other synthetic nail-lengthening products are prohibited); • ensure that natural nails are kept short and trimmed (0.6 cm); • ensure that skin of hands and forearms is undamaged; • change into dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs); • wear pants that fully cover the legs; • wear closed shoes and socks; • wash hands.
6.5.3 Conduct in controlled areas (clean room and anteroom)	In controlled areas: • Food items, drinks, chewing gum, candy and cigarettes (or other smoking products) are prohibited. • All access doors to controlled areas must be kept closed. • Access to the controlled areas is restricted to personnel with specific responsibilities in the controlled areas. • All personnel in the controlled area must follow specified hand hygiene and garbing procedures. • Only essential conversations are allowed, to minimize the risk of particulate contamination.

Compounding Personnel Responsibilities

Reference	Requirement(s)
5.1.1.3 Compounding personnel – Responsibilities	The compounding pharmacist or pharmacy technician must • perform or supervise compounding activities; • ensure compliance with policies and procedures related to the compounding of sterile preparations; • enforce or ensure compliance with required rules relating to asepsis, hygiene, cleanliness and safety; • ensure that all records related to ongoing activities are completed and initialled; • ensure that all data required for monitoring and reproducing the preparation are recorded; • ensure that the equipment, instruments and space used are properly cleaned and maintained; • ensure application of and compliance with existing compounding procedures; • ensure that there is a compounding procedure/worksheet for each preparation produced; • ensure the accuracy of calculations and measurements; • ensure that appropriate equipment and instruments are used for each preparation to be produced; • follow the compounding process defined in the compounding protocol; • perform verification during the various stages of compounding and verify the final preparation;

Reference	Requirement(s)
	• ensure that all required verification and quality control measures are performed to ensure the quality and sterility of each preparation; • ensure that preparations are packaged and labelled in accordance with provincial/territorial requirements and that a BUD is included on the label; • ensure that the final preparation is properly stored until delivery to the patient or to the pharmacist who ordered it.

Aseptic Compounding of Sterile Preparations

Reference	Requirement(s)
6.6.1 General	Before the compounding of sterile preparations begins, the pharmacist or pharmacy technician must ensure that calculations are accurate and that the appropriate drugs, equipment and devices have been selected. The pharmacist or pharmacy technician must also ensure that compounding personnel follow the protocol for compounding the sterile preparation and must validate the preparations log.
6.8 Storage	Products that have been stored must be inspected before use for evidence of deterioration.
***NAPRA Hazardous* 6.8.1 Receipt of hazardous products** 	Products used for preparations must be unpacked outside of controlled areas (clean room and anteroom), to limit the introduction of dust and particles into the controlled areas.
6.6.3 Introducing products and equipment into the clean room	Before any product is introduced into the anteroom, it must be removed from its cardboard shipping box. Cardboard has been found to harbour mould spores, so the product must then be wiped with a sporicidal agent.
	Where packaging allows, compounding equipment and products must be disinfected with sterile 70% isopropyl alcohol just before being introduced into the clean room or PEC/the C-PEC.
	Non-shedding wipes or swabs must be used for disinfection. The wipes or swabs must be changed regularly during disinfection of products and equipment.
6.6.3 Introducing products and equipment into the clean room	For introduction of compounding equipment and products into the clean room, the items must be placed in a plastic or stainless steel bin to help prevent errors (such as mixing up preparations for different patients or mixing two different batches). The bin is then placed in the pass-through for transfer to the clean room. Bins used for this purpose must be disinfected before use.
	If there is no pass-through, the equipment and products are transferred from the "dirty" cart or bin to the "clean" cart or bin at the demarcation line in the anteroom and are then introduced into the clean room. The equipment and products are disinfected while being transferred to the clean cart or bin.
6.6.2 Hand and forearm hygiene and garbing	Hand and forearm hygiene is required for anyone entering the clean room.
	Hand and forearm hygiene is required for sterile compounding, regardless of the type of PEC/C-PEC that is used.
6.6.2.2 Garbing	PPE must be worn during the compounding of sterile preparations, regardless of the type of PEC/C-PEC that is used.

Reference	Requirement(s)
***NAPRA Hazardous* 6.6.3 Introducing products and equipment into the clean room** 	Disinfection of equipment and products is performed by wiping (not spraying) with sterile 70% isopropyl alcohol.
6.6.5 Aseptic technique for compounding sterile preparations – General	All equipment with surfaces that can be disinfected must be disinfected with sterile 70% isopropyl alcohol before being introduced into the PEC/C-PEC.
	Compounding personnel must use first air and meticulous aseptic technique when preparing compounded sterile preparations. Compounding must occur in the direct compounding area of the PEC/C-PEC, such that critical sites are exposed to first air.
6.6.1 General	Exposure of critical sites must be limited to a PEC/C-PEC that maintains ISO Class 5 air quality requirements.
6.6.5 Aseptic technique for compounding sterile preparations – General	Each preparation must be completed from start to finish before compounding of another preparation is begun.
	Gloved hands must be disinfected with sterile 70% isopropyl alcohol before re-introduction into the PEC/C-PEC or after gloves have come into contact with a microbiologically contaminated surface.
6.3 Compounded sterile preparation log	A compounded sterile preparation log must be completed during the compounding process.
***NAPRA Hazardous* 6.6.5.2 Aspects of compounding hazardous preparations** 	• When diluting powder or withdrawing liquids, use a ventilated system equipped with a 0.22-µm hydrophobic filter. • When withdrawing a hazardous solution, comply with the maximum fill limit of the syringe, i.e., 75% (3/4) of total syringe capacity. • When dispensing a hazardous preparation in a syringe, use a protective Luer-Lok safety tip system. • Before removing a container holding a final hazardous compounded sterile preparation from the C-PEC, follow the surface decontamination procedure on all surfaces of the container. • All final hazardous compounded sterile preparations must be marked "cytotoxic".

Verification of Sterile Preparations

Reference	Requirement(s)
6.6.6.1 Role of personnel in verification	The sterile compounding supervisor must perform (*or ensure*) the following activities: • all compounded sterile preparations comply with compounding protocols; • verify the identity of the ingredients (drug and diluent); • verify the volume of the ingredients (drug and diluent); regularly verify the quality of the manipulations. ** *(It is expected that the Sterile Compounding Supervisor (SCS) develops policies and procedures for their workplace that ensure these appropriate verification steps, but not necessarily that the SCS performs the verification themselves.)* **

Reference	Requirement(s)
	When compounding a preparation, compounding personnel must undertake the following activities: • perform a visual inspection of each unit for evidence of particulates, to verify the clarity, colour and volume of the solution, to check the container for possible leaks and to verify the integrity of the container; • verify the information on the label; • place final compounded sterile preparations that require storage at 2°C to 8°C in the refrigerator pending verification and delivery to patients or the patient care unit.
6.6.6.2 Process for verification	Verification may be performed in one of three ways: • direct observation during compounding; • viewing of the identity and quantity of ingredients through an observation window located close to the PEC/C-PEC; • remote observation using a digital camera connected to a monitor.
6.6.6.3 Verification by image capture or live camera	Verification may be conducted by capturing images of the critical site (in the PEC/C-PEC) with a camera connected to a monitor. Such verification must be performed before the compounded sterile preparation is delivered to the patient.
Appendix 8 Examples of Sterile Preparations that Must be Verified at Each Stage of Compounding	Ophthalmic drops, diluted cassettes, and preparations made using a volumetric pump must be verified at each stage of compounding.
***NAPRA Non-Hazardous* 6.6.6.5** ***NAPRA Hazardous* 6.6.6.4 Second verification**	Each preparation must be inspected by a person other than the individual who performed the aseptic compounding. This person must inspect each unit for evidence of particulates, verify the clarity, colour and volume of the solution, check the container for possible leaks and verify its integrity.
	Like the compounder, the verifier must sign the preparation log.

Labelling

Reference	Requirement(s)
6.6.7.1 Labelling of Final Compounded Sterile Preparations	Compounding personnel must label the following items: • final compounded sterile preparations; • each unit of a compounded sterile preparation for an individual patient, along with required auxiliary labels; • each unit of sterile preparations compounded in batches (with, at a minimum, drug name, concentration, route of administration, batch number and BUD); • each package containing final preparation units, along with auxiliary labels indicating required storage conditions and special precautions.
	The compounding pharmacist or pharmacy technician must similarly label sterile preparations that have been compounded at the request of another pharmacy, where permitted by provincial/territorial legislation. At the pharmacy where the compounded sterile preparations will be dispensed to the patient, another label must be added containing all information required by the respective provincial/territorial regulatory authority; a supplementary document must be prepared, if required. Both labels must be retained on the preparations.

Reference	Requirement(s)
6.6.7.2 Label	The label must contain the following information, at a minimum: • pharmacy identification (name, address and telephone number of the compounder's or dispenser's pharmacy); • drug identification (active ingredients, source, concentration, form, route of administration, volume, solute, amount prepared); • overfill volume when overfilling has occurred; • special precautions (e.g., if product is an irritant/if product is cytotoxic); • storage method; • date when the sterile preparation was compounded; • BUD; • preparation batch number.

Transport and Delivery of Compounded Sterile Preparations

Reference	Requirement(s)
6.9 Transport and delivery of compounded sterile preparations	For community pharmacies and health care facility pharmacies making deliveries outside the facility, the delivery container should be lockable or sealed.
	The pharmacist or pharmacy technician must dispose of any unused compounded sterile preparations returned from a patient's home.
	In health care facilities, unused preparations returned from the patient care unit to the pharmacy may be reused if it can be shown that they have been properly stored (at the correct temperature, with protection from light, etc.) and there is no evidence of tampering.
	The transport and delivery procedures must include any precautions to be taken by the delivery person, especially during delivery (e.g., personal delivery of the compounded sterile preparation, rather than delegation to another person) and during return of medications, waste, and sharp or pointed items.
	Where compounding is undertaken by another pharmacy, as permitted by provincial/territorial legislation, the compounding personnel must ensure that the preparation is transported to the dispensing pharmacy under conditions that maintain stability of the preparation. The receiving pharmacy must then ensure that transport conditions are maintained until delivery to the patient.
***NAPRA Hazardous* 6.9 Transport and delivery of compounded sterile preparations** 	All personnel involved in transporting hazardous compounded sterile preparations must be trained in the procedures for such transport and for spills or accidental exposure.
	Hazardous compounded sterile preparations must be transported in rigid containers marked "Cytotoxic" and designed to minimize the risk of cracking or failure of the preparation containers.
	The sterile compounding supervisor must also ensure that the private carrier knows the procedures to be followed in the event of a spill, that a spill kit is available and that transport personnel have received appropriate training.